Assessment Findings Associated with Partial Thickness Rotator Cuff Tears:

A Secondary Analysis

by

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Abstract

Background: Shoulder pain is a common problem treated by physicians and physical therapists. A large number of these patients have injury to the rotator cuff. There is a range of severity in rotator cuff disease, which likely includes a high proportion of partial thickness tears (PTT). This condition is difficult to diagnose since current methods to identify PTT (imaging and physical assessment special tests) are inadequate. Other items from physical assessment may help with the patho-anatomical diagnosis of PTT, but there is also growing support for diagnostic approaches which emphasize movement as the basis for classification of shoulder conditions. The objective of this study was to determine if clinical presentation factors that focus on demographics, injury history, physical assessment and patient reported outcomes were associated with a surgical diagnosis of PTT in a group of patients all previously diagnosed with full thickness tear (FTT) using imaging.

Methods: A secondary analysis was performed using pre-operative baseline data from two randomized controlled trials of 452 adult patients awaiting rotator cuff repair surgery. All subjects were previously diagnosed with imaging as having a FTT. Nineteen factors were assessed for association with an outcome of PTT or FTT (which was diagnosed at the time of surgery.) Factors were selected for analysis based on previous identification in the literature as having association with PTT or FTT, and were limited to those items collected in both primary studies. Logistic regression was used to test independent associations of each factor with the

outcome. Items with univariate association of $p<0.20$ were entered into multivariate logistic regression analyses. Several multivariate models were purposefully built, ensuring no collinearity between the variables. Confounding was controlled for by noting change in the regression output as variables were maintained or removed from the models. Several purposeful steps were performed in various combinations to arrive at a final reduced model that identified the key factors associated with PTT (significance level $p<0.05$).

Results: Comparison of the data in the two primary studies showed a small number of statistical differences in the variables, but none with clinical significance. This allowed for combining the two data sets for secondary analysis. Of the 452 subjects, 32 (7.1%) had PTT. In the total group, 294 (65%) subjects were male and of the PTT subjects, 23 (71.9%) were male. A majority of participants (n=303; 67%) reported an atraumatic onset to shoulder symptoms. In multivariate analyses, the Constant Power score, which assesses abduction strength, was the sole factor statistically associated with PTT (Odds Ratio 1.067, 95% CI 1.017, 1.120, p= 0.008). A traumatic mechanism of injury showed a trend toward significance in analysis, but was not statistically significant in the final multivariate model (p= 0.067). Other factors from the assessment: age, pain at rest, pain with activity, active range of motion (flexion, abduction, scaption, eternal rotation at 0° abduction, external rotation at 90°abduction, internal rotation at 90°abduction), Western Ontario Rotator Cuff Index scores (total and dimensions), and SF-36 Physical Component Summary and Mental Component Summary scores, did not show association with PTT ($p>0.520$).

Conclusion: The findings of this study indicate that a higher Constant Power score is associated with having a PTT in a group of patients previously diagnosed with imaging as having a FTT. Mechanism of injury (traumatic onset) showed a trend toward association with PTT. Other findings from patient assessment which were evaluated did not help distinguish this diagnosis. Clinicians could consider adding a structured evaluation of abduction strength, like the Constant Power score to a physical examination of suspected rotator cuff patients.

A major limitation in this study was related to the sample of PTT subjects: all were high-degree PTT so the sample was not representative of all PTT patients. To improve the body of information provided by this study, similar research should be undertaken with a broader spectrum of PTT subjects.

Perhaps our findings are not solely affected by the selection of subjects. There is a growing collection of studies that show an inconsistent relationship between tissue pathology and impairments. The identification of only a small number of clinical assessment factors associated with PTT in this study may suggest using a different assessment approach that is less focused on patho-anatomy in future research studies.

Preface

This thesis is an original work by Anne Edwards. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, Project Name "Factors that predict Partial Thickness Rotator Cuff Tears: a secondary analysis", No. Pro00049469, 7/7/2014.

The data utilized for this secondary analysis was obtained from two other research projects which also obtained research ethics approval from the University of Alberta Research Ethics Board:

1) Project name: "Early Mobilization following Arthroscopic Rotator Cuff Repair: a Randomized Control Trial" No. Pro00014046 Date: 6/28/2010
   Principal Investigator: David Sheps
2) Project name: "Early Mobilization following Mini-open Rotator Cuff Repair: a Randomized Control Trial" No. Pro00001096 Date: 5/1/2003
   Principal Investigator: Robert Balyk

The entirety of the thesis including the literature review in chapter 2, the summary of the primary studies in chapter 3, the methods description and data analysis in chapter 4, the discussion in chapter 6 and the conclusion in chapter 7 are the original work of Anne Edwards. No part of this thesis has previously been published.

Dedication

For my husband Scott, who has been my biggest source of validation, and who constantly encourages me to trust myself.

Thank you.

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1.0 INTRODUCTION

In the human body, the shoulder allows more widespread motion than any other joint.[1]It facilitates a remarkable range of tasks involving strength, speed and precision, placing the hand in space or bringing objects back to the body. The shoulder requires a complex coordination of active and passive structures to maximize its potential flexibility but maintain stability. [1] The shoulder's significant role in activities from self-care to high level sport means sub-optimal function and pain in this area can greatly impact a person's daily life.

Unfortunately, shoulder pain is a very common musculoskeletal complaint. In the general population at a given time, 6.9 to 26 percent of adults experience shoulder pain, and up to 66 percent will experience pain in their lifetime.[2] Because of the significant impact on activities of daily living (ADL), work, and leisure activity, shoulder pain is the third most common orthopedic problem treated by physicians, and a very common condition treated by physical therapists.[2,3] Within the broad complaint of shoulder pain, rotator cuff disease (RCD) is the most common condition seen by physicians[4] RCD can cause extensive disruption of physical activity, but also affects mental health and social participation.[5]

RCD consists of tendinopathy of one or more of the muscles of the rotator cuff, partial-thickness tears (PTT), or full-thickness tears (FTT) of the rotator cuff tendons.[4] To date, much of the RCD research has focused on tendinopathy and FTT.[6] Up to 30% of soft tissue disorders of the shoulder have been attributed to rotator cuff tendinitis[7] and one population study from a village in Japan noted the prevalence of FTT as 22.1%.[8] PTT tears are, however, a common source of pain and disability,[9] and prevalence of PTT increases with age.[10,11] Cadaveric studies have reported an incidence of 13-32%, [12] but actual frequency of PTT is not known, since they are inadequately defined.[9,13]

Diagnosis of RCD generally involves physical examination and often imaging (usually diagnostic ultrasound [US] or magnetic resonance imaging [MRI]), with occasional confirmation of diagnosis during surgery. MRI and US are purported to have an acceptable degree of validity.[3] Physical examination, which includes various "special tests" to identify RCD, is also widely used by physicians and physical therapists since it can be used at any stage in the patient's care and in any setting.

Despite access to these tools, accurate quantification of the damage to an injured rotator cuff is notoriously difficult. PTT is especially troublesome to diagnose, even though it is more common than FTT.[11, 14] Surgery is the gold standard for diagnosis, but it is clearly impractical to use for every patient with shoulder pain. MRI and US are considered reference standards;[3] however

there is doubt regarding the accuracy of these tests in identifying PTT.[11, 15] US accuracy is highly operator dependent [16] and obtaining an MRI can involve significant wait-time and/or expense.[16, 17] Special physical tests for the rotator cuff, although easy to apply and inexpensive, [3] generally have high sensitivity but low specificity. [18, 19]

Most research into diagnosis of RCD concludes that no single test (physical or imaging) is accurate on its own.[20] Further, as all tests have been shown to have limitations in discriminating between FTT and PTT, identification of other patient information which is associated with PTT may lead to earlier screening for the pathology, or earlier intervention for asymptomatic individuals. Age, pain level, and traumatic injury are variables which have been investigated with regard to their links with FTT and PTT.[21] Further investigation of some of these factors, alone or in combination with other clinical assessment findings and patient reported outcome measures, may facilitate identification of which patients have PTT. Using an assessment framework that considers demographics (e.g. age, sex), injury/work characteristics, physical assessment (e.g. pain, range of movement, strength) and patient reported outcome measures may assist in differential diagnosis of patients with PTT.

Accurate diagnosis of PTT may have important implications for research and patient care. The natural history of rotator cuff tears is not fully understood. It is known that PTT often progress over several years,[10] and it is also possible to have asymptomatic tears.[8] Reliable identification

of PTT may allow better research on why some are painful and affect function and why some do not. Further research may also identify whether a patho-anatomical diagnosis of PTT is useful for physical therapists when treating patients with shoulder complaints or whether a more comprehensive assessment approach that assists in directing patient care is more clinically useful.

This project was an exploratory secondary analysis of data from patients with known PTT and FTT. The study goal was to explore factors within a standard clinical assessment framework that included demographics, injury/work characteristics, physical assessment and patient reported outcomes that may assist in more accurate non-surgical diagnosis of patients with PTT. We hypothesized that these assessment factors would be associated with a diagnosis of PTT (confirmed by surgery) in a group of adult patients previously diagnosed with FTT using imaging.

The data used in this analysis were from two randomized controlled trials (RCT) that included prospective collection of demographics, injury characteristics, physical assessment findings, and patient reported outcomes in subjects diagnosed with FTT using imaging. All subjects proceeded to surgery, which allowed confirmation of the degree of rotator cuff tear. The majority of subjects did in fact have FTT, but some subjects in the original studies were found to

have PTT at the time of surgery. The finding of some PTT diagnoses in these RCT allowed examination of possible pre-operative determinants for a differentiation between FTT and PTT.

The overall aim of this secondary analysis of these data was to determine if demographic features (age, sex, mechanism of injury), clinical assessment findings (pain scores, active range of motion, strength) and patient reported outcome measures (Western Ontario Rotator Cuff Index [WORC] and SF-36 scores) were able to detect patients with PTT.

2.0 LITERATURE REVIEW

The shoulder is a complex, multi-joint structure in the human body. It plays a significant role in activities of self-care, work and leisure. Dysfunction and pain in this region can greatly impact a person's daily life.[22] Effective management of shoulder pain and disability involves accurate identification of the problem.

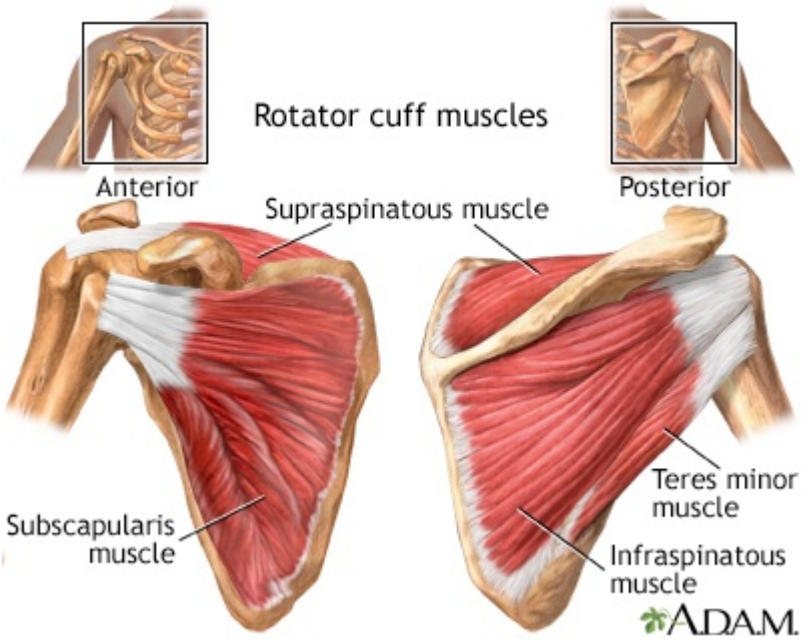
The Shoulder: Rotator Cuff Anatomy

The shoulder joint complex includes the glenohumeral joint, acromioclavicular joint, sternoclavicular joints and the articulation between the scapula and the thorax.[23] Each joint is reinforced by ligamentous and musculotendinous structures. All four articulations are important for proper function of the upper extremity, but the glenohumeral joint provides most of the mobility in this area.[23]

The "ball-and-socket" glenohumeral joint is formed by the articulation of the rounded head of the humerus and the shallow glenoid fossa on the scapula.[24] This structure allows a large range of movement in three degrees of freedom along the transverse, sagittal and coronal planes.[23] To control the relative instability of the glenohumeral joint, motion is limited by muscular, capsular and ligamentous structures. Four muscles and their tendons mobilize and stabilize the glenohumeral joint of the shoulder complex: supraspinatus, infraspinatus, teres minor and subscapularis. [24] All four muscles originate on the scapular body and insert onto the

tuberosities of the humeral head. (Figure 1) Their tendons blend at the insertion point to form a common tendon, known as the rotator cuff.[25]

Figure 1: Rotator Cuff Muscles[26]



The supraspinatus muscle passes laterally from the supraspinatus fossa and superior surface of the spine of the scapula, through the subacromial space to insert on the superior facet and superior half of the middle facet of the greater tuberosity.[27] Supraspinatus generates its peak force at 30° abduction and is capable of significant moment production throughout the range of motion.[28]

The infraspinatus originates from the inferior surface of the spine of the scapula and the infraspinatus fossa of the scapula. It passes laterally to attach to the middle facet on the greater tuberosity and covers part of the supraspinatus tendon.[27] Infraspinatus externally rotates the arm and is a strong depressor of the humeral head in the glenoid fossa.[14]

Below the infraspinatus, the teres minor muscle attaches proximally to the lateral edge of the scapular body and distally to the inferior facet of the greater tuberosity of the humerus.[24] Along with infraspinatus, teres minor is an external rotator for the arm.

The only muscle to attach to the lesser tuberosity of the humerus is the subscapularis. It is also the lone muscle originating from the anterior surface of the scapular body.[24] Subscapularis performs internal rotation at the glenohumeral joint.

The area where the rotator cuff tendons insert on the humeral head is known as the “rotator cuff footprint”.[6] (Figure 2) Blending with the coracohumeral ligament, the glenohumeral ligaments, joint capsule and the rotator cuff cable, the rotator cuff tendons surround the humeral head.[6]

Figure 2: Rotator Cuff Footprint[29]

Biomechanics of the Rotator Cuff

The rotator cuff provides movement and dynamic stability for using the arm.[14] The common rotator cuff tendon attachment provides excellent stability and rotation of the humeral head in various positions.[14]

Providing stability for the glenohumeral joint is a main function of the rotator cuff. The combined contraction of the subscapularis from the front of the scapula and infraspinatus and teres minor from the back, compress the humeral head into the glenoid fossa.[25] In the mid-ranges of movement, other capsular and ligamentous structures are lax, so the rotator cuff muscles act as primary restraints.[30] Contraction of the infraspinatus in particular, also serves to prevent upward migration of the humeral head in the glenoid fossa.[25]

The four rotator cuff muscles initiate gross movement at the glenohumeral joint in the primary directions of abduction, internal rotation and external rotation.[23] Many different movements of the upper limb can also be produced depending on the position of the humerus.[14] For example, when the humerus is placed in external and internal rotation, the subscapularis and infraspinatus also contribute to abduction.[25] Since all rotator cuff muscles originate on the scapula, scapular position and movement play a vital role in arm function by providing a stable base for muscle activation.[1]

Pathology and Classification of Rotator Cuff Disease

Shoulder pain is the most common musculoskeletal complaint of the limbs treated by physical therapists, and the third most common musculoskeletal complaint for patients visiting their physician.[31] Up to 40% of patients presenting with shoulder pain have rotator cuff disease (RCD).[31]

Pathology of the rotator cuff includes a spectrum of injury from tendonitis through various degrees of PTT, to FTT of the tendons. In 1934, Codman, who pioneered much of the anatomical and surgical work on RCD, described four different lesions of the supraspinatus tendon including complete or FTT, and what he described as a "condition of great clinical importance": PTT or "rim rents ".[32] Neer's work on shoulder injury from 1983 has also been extensively referenced with regard to classification of subacromial impingement lesions of the

rotator cuff tendons. Neer's stage 1 refers to edema and hemorrhage of the tendons, generally affecting young people aged 25 years and younger.[33] When inflammation occurs repeatedly, fibrosis and tendinosis occur: Neer's Stage 2.[33] He described this lesion as less common, occurring in people 25-40 years of age. In Stage 3, further wear has occurred for patients over 40 years old, and partial or complete tears of the rotator cuff result.[33] This classification has a limitation in that it does not distinguish between PTT and FTT.[10]

More recently, Ellman expanded labelling of RCD to include specifics about PTT. Most rotator cuff tendons are approximately 10-12 millimeters (mm) thick, so PTT are graded by depth. Grade 1 is noted as less than three mm deep, 2: three to six mm deep, and 3: greater than six mm deep.[10] He also included information on location of the tear, identifying bursal surface, articular surface, or interstitial tears.[10] Another detailed description of tearing comes from Fukuda. He labeled RCD as Grade 1: subacromial bursitis or tendonitis (a "pre-tear"), Grade 2: PTT tear (involving at least one quarter thickness of the supraspinatus tendon), and Grade 3: FTT.[21] Fukuda also followed the example of Ellman and distinguished the location of PTT to bursal-side tears, intra-tendinous tears and joint-sided tears.[21]

A third classification of rotator cuff tears comes from Snyder, based on tear location and severity: articular and bursal for PTT, named 'A' and 'B', and 'C' for complete tears.[34] Degree of damage for PTT is labeled from zero (normal tendon) to four (very severe PTT).[34] It should be

noted that all the aforementioned classifications are only possible with visualization of the damaged tissue during surgery or in cadaveric dissection.

The supraspinatus tendon is the most common starting location of rotator cuff tears[32] because this site is subject to significant loading, even at rest.[25] If a load exceeds the tissue's strength, fibres fail and tear. Tears increase the strain on remaining fibres and are predisposed to worsening when loads are concentrated at the margin of the tear.[25] Due to the blending of the rotator cuff tendons, tears of the supraspinatus can extend to the infraspinatus tendon,[18, 25] but rarely involve subscapularis.[9]

Causes of RCD are generally classified as intrinsic and extrinsic. A common intrinsic cause is weakening of the rotator cuff tendons due to metabolic and vascular changes, usually related to aging.[6, 13, 35] Intra-tendinous lesions developing from shear stress are also classified as intrinsic causes.[6, 13] Extrinsic causes may be related to shoulder anatomy and biomechanics in the form of subacromial impingement, shoulder instability or internal impingement.[6, 36] A single acute trauma or repetitive micro-trauma could also be an extrinsic source of RCD.[36]

Prevalence of Rotator Cuff Tears

Rotator cuff tears can be present at any stage of adulthood. According to one population survey, as many as 20% of people over 20 years old have rotator cuff tears.[37] Prevalence may be 25% in those over 50 years, although a significant proportion is asymptomatic.[37] Symptomatic RCD is estimated at 2.8% in those over age 30, and 15% in adults over age 70.[4] Tears tend to progress over time becoming larger, more painful or involving more muscles,[10] so with an aging population the incidence of symptomatic RCD can be expected to grow.[25]

The majority of research on RCD has focused on pre-tear and FTT likely because they are easier to diagnose.[6, 11] PTT are, however, increasingly recognized as a source of impairment.[13, 38,] Incidence of PTT is not fully known. Codman estimated them to be twice as common as FTT.[23] Cadaveric studies have consistently shown that PTT are more common than FTT[9] and that 13%-32% of shoulders contain PTT.[12] Magnetic resonance imaging (MRI) and ultrasound (US) in one study identified PTT in 8% of symptomatic shoulder subjects, and 16% in asymptomatic subjects aged 45-55.[39] A study using arthroscopic surgery noted two-thirds of their patients, who were over the age of 35, undergoing surgery for supraspinatus tendinopathy had some degree of PTT.[36] It is generally acknowledged in the literature that differentiating PTT from other shoulder disorders remains difficult.[11, 20, 40]

Current Methods for Diagnosing PTT

The importance of accurate identification of PTT can be seen in clinical care and research arenas. Effective management of patients with PTT can limit disability for an individual[21] and the burden on healthcare systems.[3] Targeted research on known PTT subjects can advance information on natural history of the disease, identify causal factors and develop treatment strategies. To have success in both the clinical and research domains requires correct diagnosis of the problem as a starting point.

Currently, diagnosis of RCD generally involves physical examination (including rotator cuff-specific special tests) and often imaging (usually diagnostic US or MRI), with occasional confirmation of diagnosis during surgery, if surgery is indicated.

1) The Gold Standard for Diagnosis

Surgical inspection is the most accurate way to diagnose RCD.[15, 38] Visualization and probing of the bursal and articular surfaces and the footprint of the cuff allows direct assessment of the quality of the tissue.[38] Measurement of the size and depth of a tear can be accomplished for PTT,[38] however routine diagnosis of PTT with surgery is unlikely due to costs, time constraints and ethical considerations.

2) Diagnosis with Imaging

As technology has advanced, diagnostic imaging using MRI and US has become an integral part of RCD diagnosis. This has resulted in greater recognition of PTT.[6] MRI has high sensitivity (89%) and specificity (93%) for diagnosing FTT, as noted in a systematic review of 29 studies.[41] Sensitivity for PTT identification is much lower (44%), with high specificity (90%).[41] These results must be evaluated cautiously. In general, the studies used in the review did not include enough information to judge whether an appropriate selection of patients was included.[41] Although MRI is deemed acceptable for ruling in PTT, cost and wait times for testing are additional impediments to using this approach to diagnose PTT. [22]

The same systematic review evaluated 38 studies related to diagnosis with US. It showed US is also accurate for diagnosing FTT but only fair for evaluating PTT.[41] (Table 1) The mean age of participants in the studies was 51 years, and three studies included on average younger participants.[41] Unfortunately, most studies in the review also did not provide sufficient information on which to judge the spectrum of included patients.[41]

Table 1: Sensitivity and Specificity of Imaging [41]

Test (Lesion)	Sensitivity (pooled)	Specificity (pooled)
MRI: (FTT)	0.89	0.93
MRI: (PTT)	0.44	0.90
US: (FTT)	0.87	0.96
US: (PTT)	0.67	0.90

3) Diagnosis with Physical Examination Special Tests

Accurate nonsurgical diagnosis of all grades of rotator cuff tear using clinical assessment has been elusive. Since Codman`s original description of RCD, many special physical examination tests have been developed to identify these lesions, such as Neer's, Empty can, and Hawkins' tests.[3] (Table 2). Unfortunately, all have limited usefulness. Several systematic reviews have been conducted in the last seven years evaluating many common tests for diagnosis of RCD.[3, 4, 41-44] Generally all tests are adequate at ruling out rotator cuff lesions, but less accurate for ruling them in. A Cochrane review in 2013 found no strong physical examination tests for diagnosis of FTT of supraspinatus, infraspinatus or the posterior-superior rotator cuff in general.[3] To identify any lesion of the infraspinatus, resisted external rotation had very high specificity (95%), and high sensitivity (94%).[3] The Empty Can test, which involves resisted abduction at 90°in full internal rotation, was useful for ruling out any disease of supraspinatus (sensitivities 0.94 and 0.96), but no tests were specific.[3] No studies identified a special test which was diagnostic for PTT.

Table 2: Sensitivity and Specificity of Rotator Cuff Special Tests [3]

Test	Sensitivity	Specificity
Neer's	0.89	0.32
Hawkin's	0.92	0.20
Jobe	0.84	0.58
Empty Can	0.89	0.50

Part of the difficulty in diagnosing PTT, is that its clinical presentation is non-specific compared to cuff tendonitis or FTT.[11, 13] Although physical examination is easily and inexpensively performed by trained health care professionals, analyses have failed to identify any one test or combination of tests which can reliably distinguish PTT from other shoulder pathology. [20]

For physical therapy, the patho-anatomical approach to diagnosis of shoulder complaints, exemplified by imaging and special tests, is regarded by many as inappropriate.[45-47] Ludewig et al. outline limitations to this model: 1) patho-anatomical diagnoses may not adequately direct physical therapy interventions, 2) a given diagnosis may not actually describe the true underlying pathology, or include coexisting pathologies, 3) patho-anatomical diagnoses are not consistently used among healthcare practitioners, 4) physical therapy scope of practice does not include all of the tools needed to formulate some diagnostic labels (eg. use of imaging or surgery), and 5) the clinical special tests currently used for diagnosis in physical therapy have poor specificity.[46] Alternative models have been proposed based around movement disorders.[45, 46, 48]

Movement systems diagnoses have advantages for physical therapy: 1) diagnoses are consistent with physical therapy training and are within the scope of the profession, 2) they maintain communication with other healthcare professionals by using accepted biomechanical and kinesiological terminology, and 3) allow increased focus on patient function.[46] This fits with both the American Physical Therapy Association's and Canadian Physiotherapy Association's emphasis on movement as the primary area of intervention in physical therapy practice. Use of movement impairment based language highlights patient function, as outlined the International Classification of Functioning, Disability and Health (ICF) framework developed by the World Health Organization (WHO).[49]

Sahrmann has advocated for movement-based shoulder diagnoses with a rationale that identifying a symptomatic tissue, if possible, is only one step. To completely describe a musculoskeletal condition, patient symptoms, structural findings on imaging and movement observations need to be included.[50] Similarly, the Staged Approach for Rehabilitation of Shoulder Disorders (STAR-Shoulder) uses several "levels" of evaluation to arrive at a diagnosis. Level 1 or "screening" includes patient history, basic physical examination, and evaluation of red or yellow flags. Level 2 arrives at a "pathoanatomical diagnosis" using specific physical examination, according to traditional diagnostic methods. Level 3 is a "rehabilitation classification" which includes assessment of tissue irritability and impairments to guide the intensity and specific choice of treatment.[47] Both models require systematic research for validation.[45, 47]

Assessment Framework for Determining Factors Associated with PTT

Despite the limitations of the pathoanatomical model for diagnosing shoulder complaints in physical therapy, it is still widely used in the medical profession, and is a recommended component of the movement-based diagnostic symptoms. When examining the shoulder, healthcare professionals consider several factors in addition to special tests and imaging results. These include ***demographics*** (e.g. age, sex), ***injury and work characteristics*** (e.g. mechanism of injury, onset of symptoms, occupation, sports/ leisure involvement), ***clinical assessment*** (e.g. pain, Range of Motion, strength, special tests,) and ***patient-reported outcomes*** (e.g. disease-specific and general health status outcome measures).

Some of these other clinical factors have been shown to contribute to an accurate diagnosis of rotator cuff tear.[1] Mechanism of injury, degree and type of pain, stiffness and weakness [3, 4, 11, 12] are commonly associated with RCD and have been investigated for association with PTT.[9, 11]

When considering the lack of specificity of special tests, the cost and poor accuracy of imaging and low practicality of routine diagnosis with surgery, other findings from the subjective and physical examination and patient history may provide information to assist PTT diagnosis. In undertaking this secondary analysis, additional factors were considered within a structured assessment framework as elucidated above as demographics, work/injury characteristics, clinical assessment and patient reported outcomes.

Demographics

1) **Age**

Of all factors related to RCD, age has the most consensus regarding its relationship to rotator cuff tearing.[6, 38, 51, 52] The prevalence of both PTT and FTT increases markedly after 50 years of age.[53] Tearing is however, not limited to older adults; PTT are also reported in younger overhead-throwing athletes.[54, 55] Other young populations have also presented with PTT, such as active-duty military personnel.[56] One surgeon postulated that PTT presented more often in this type of population than in an older, more sedentary group.[56] Unfortunately this statement has not been experimentally validated.

2) **Sex**

Several studies on prevalence of RCD have commented on sex comparisons.[8, 57] Yamamoto et al. included sex in an analysis of rotator cuff tears diagnosed with US in symptomatic and asymptomatic subjects. For presence of FTT, comparing men to women, an odds ratio of 0.95 (95% CI 0.70, 1.28) was reported.[57] This study did not specifically look at PTT; rather PTT subjects were included in a "no tear" group. In a study of RCD prevalence in a village in Japan, Minagawa et al. reported no significant difference between males and females for FTT. Because US was used for diagnosis, PTT were included in the no-tear group due to the lack of sensitivity of US in diagnosing PTT.[8]

Summary of Demographics

Age appears to be a potential factor associated with RCD, and in particular PTT. The sex of a subject is commonly recorded in the demographic information, but in several studies reviewed here, connections between sex and RCD diagnosis are not reported.[20, 36, 51] An assumption is made from these studies that sex has no influence on diagnosis of RCD.

Injury Characteristics

1) **Mechanism of Injury**

Mechanism of injury is often documented in studies for RCD, but is not well defined. Authors refer to the intrinsic (generally age related) and extrinsic factors which are believed to cause injury to the cuff tendons.[36, 38] Extrinsic causes include subacromial impingement, internal impingement, micro-instability, repetitive microtrauma, and acute events.[38, 40] Any mention of a traumatic mechanism seems to refer to these extrinsic elements. In some cases, it refers to repetitive impingement, in others to a documented injury beginning after a fall, blunt trauma, heavy lifting or heavy exercise.[36, 40]

Post et al. noted that RCD patients often attempted to make a correlation between symptoms onset and a specific incident.[35] Fukuda noted 65% of patients with FTT recalled a defined incident causing shoulder symptoms, whereas those with PTT and tendonitis recalled injury less often: 46.7% and 36.7%.[21] Yamamoto studied symptomatic and asymptomatic subjects in Japan

and found that in subjects under the age of 49 years, FTT were more strongly associated with dominant arm and a history of trauma.[57] This study, which diagnosed RCD using US, included suspected PTT in a "no tear" group, and did not specifically comment on PTT subjects. Rudziki et al. found that overhead-throwing athletes with PTT generally do not have a discrete event causing the injury.[13]

2) **Occupation**

Yamamoto et al. also questioned subjects about the heaviness of their work.[57] Patients reported subjectively whether their work was light, intermediate or heavy. No definition was given for these categories, and no distinction was made regarding overhead work. Significant differences were noted in proportions between FTT and the "no tear" group (which included PTT): FTT group- light 7.4%, intermediate 55.8%, heavy 36.8%; no tear group- light 22.4%, intermediate 53.0 %, heavy 24.6%. However, the reported odds ratio for heaviness of labor for an outcome of FTT was 1.2 (95% CI 0.96-1.53).[57]

Repetitive tasks at work and their effect on the upper limb was evaluated by Roquelaure et al.[58] This study's findings showed presence of RCD in workers at a prevalence rate of 29% for those highly exposed to repetitive work, and 16% in those weakly exposed.[58]

Summary of Injury Characteristics

Both mechanism of injury and occupation have been investigated for their association with RCD generally, and have the potential to be associated with PTT.

Physical Assessment

1) **Pain**

Pain is a strong motivator for patients to seek medical care, and pain is the most common symptom of FTT or PTT.[37, 55, 56] It has been noted that PTT may be more painful than FTT,[59, 60] however the mechanism for pain in RCD is not well- established.[22]

Many studies highlight night pain and pain with overhead activities as important items to note in assessment of RCD, although these findings are not specific for PTT or even specific to RCD.[38,59] In a study by Uchiyama et al., all PTT subjects had pain with movements, 73.7% had night pain and 63.2% had pain at rest.[40]

The Visual Analog Scale (VAS) has been widely used as a measurement of pain, and is considered a valid, robust, sensitive and reproducible method of expressing pain severity.[53, 61] One version of the VAS is a 10 cm long horizontal line which is anchored with the terms “No

pain at all" on the left and "As bad as it can be" on the right.[62] A score is obtained by measuring the distance from the left anchor to a line drawn by the patient indicating his or her level of pain.[62] Test-retest reliability for VAS for pain has been reported as high: ICC=0.71-0.99.[63] There is no "gold standard" for measurement of pain, but VAS shows convergent validity or 0.30 to 0.95 when correlated with other pain measures.[3] For patients with RCD, a 1.4 centimeter improvement on the scale is considered a minimally important difference.[64]

2) Strength

Muscle strength measurements are commonly used in the orthopedic diagnostic process to assess musculotendinous integrity. These tests rely on the assumption that function of a certain muscle can be isolated, and lead to accurate assessment of tissue patency and/ or neuromuscular function. Anatomical and biomechanical studies have been used to identify the positions which emphasize rotator cuff activity.[18] The extent to which weakness is affected by rotator cuff tear size is not well understood.[51] Millican et al. found supraspinatus strength testing and strength measurements for external rotation to be significantly lower in patients diagnosed arthroscopically with FTT compared to those with PTT.[20] Uchiyama et al. found weakness in abduction and external rotation in PTT subjects when compared to the unaffected side,[40] but Xiao et al. claimed there is usually no decreased strength in PTT due to the remaining fibres of the cuff.[11]

Manual muscle tests are the most widely used method to clinically evaluate strength, but they are recognized as being subjective and examiner-dependent.[65] An ordinal grade is assigned to the muscle group which relies on the examiner's decision for comparing the test result with what he or she considers normal for that patient's demographic characteristics.[65] Criticisms of this technique include poor interrater reliability and an inability to detect small differences in strength.[65]

A hand held dynamometer is a quantitative, objective method for assessment of muscular strength. It is a reliable tool from an interrater and intra-rater perspective, for measurement of shoulder strength.[65] Compared to the assumed "known standard" of Cybex dynamometry, hand held dynamometry has meaningful correlation, suggesting clinical validity.[13] An acceptable level of intra-rater reliability is also noted (.83 to .94).[66]

Another common strength test for shoulder dysfunction is found in the Constant Murley Score (CMS): the Constant Power score. This is more accurately described as a "strength" test, rather than a "power" test, since it measures force at the end of a lever arm, and not the rate of work.[67] A protocol for testing is outlined by the developer: the arm is actively lifted to 90° abduction in the scapular plane with the elbow in extension and wrist pronated. Resistance is applied at the dorsal wrist and measured with a dynamometer to a maximum of 25 lbs. If a subject is unable to reach 90° abduction, a score of zero is given.[67]

The exact technique for testing Constant Power was not described for many years, despite its frequent use.[67, 68] A lack of reproducibility for the maneuver coupled with manual muscle testing for the assessment of strength caused considerable concern regarding the test's reliability.[67, 69] Johansson et al. found, however, when performed using a digital or mechanical dynamometer, as described by Bankes et al. in 1998,[70] that the test demonstrated acceptable intra-observer and inter-observer reliability.[68]

3) Active Range of Motion (AROM)

AROM involves voluntary movement of the arm at the shoulder against gravity, with no additional resistance provided against the movement. It assesses several components involved in movement: a patient's willingness to move, joint range, and muscle power.[71] With biomechanical testing, muscles are known to be primary or secondary contributors to certain movements. Supraspinatus and infraspinatus, the muscles most often implicated in PTT, are assessed with abduction and external rotation respectively.[71]

Some authors have documented decreased active and/ or passive ROM with rotator cuff tears,[35, 72, 73] but not all have described the degree of tears (ie FTT or PTT) in their subjects adequately.[35] Hawkins found no correlation between tear size and AROM.[62]

The universal full-circle goniometer is a versatile and widely used instrument to measure range of motion of the peripheral joints. Reliability of goniometry is dependent on method of application, so standardized methods of testing are adopted.[72] The main sources of error in goniometric measurements are positioning of the patient and positioning of the instrument (i.e.: the variability in locating anatomic landmarks used to align the goniometer). Intra-rater reliability is generally agreed to exceed inter-rater reliability.[72, 74] For the shoulder, the same evaluator can accomplish an intra-class correlation coefficient (ICC) of .76 to .94 but between different evaluators, reliability is less acceptable: .36 to .91, depending on the movement.[74]

Summary of Physical Assessment Findings

All of the physical assessment findings listed here are commonly used by clinicians to determine current status of patients and to direct their patient care. As with other variables they have been investigated in greater depth in FTT, but there appears to be potential for all of these factors to have an association with PTT.

Patient-Reported Outcome Measures

RCD has high incidence rates and active members of society are often afflicted.[75] In Canada, RCD is the second most common reason for claims being registered with Workers' Compensation Boards, which suggests significant loss of productivity.[76] One-dimensional

measurements such as strength and AROM, may fail to capture the full impact of RCD. Most treatments for musculoskeletal complaints are designed to improve quality of life, so directly measuring this outcome is required to evaluate efficacy.[77]

The functional disability of RCD affects mental and social aspects of a patient's life, not simply the physical aspect.[78, 79] Clinicians may not be aware of potential emotional impact caused by RCD.[78] The primary clinical symptoms of RCD are pain (including pain at rest and nocturnal pain), motion loss, and weakness.[9, 12, 37, 51] These symptoms can lead to disruption of ADL, work and leisure, with poor quality of life experience comparable to diabetes, myocardial infarction, congestive heart failure or depression.[5]

Health Related Quality of Life (HRQL) outcomes may differ between rotator cuff pathologies, and may be useful for differentiation. In RCD patients, condition-specific outcome measures, joint specific outcome measures and generic health questionnaires should be studied for maximum reliability.[75, 80]

1) The Western Ontario Rotator Cuff Index (WORC)

The WORC is a self-report instrument used to assess HRQL, specifically in people with rotator cuff disease.[75, 81] The WORC was developed using a rigorous stepwise process.[82] Both patients and healthcare practitioners provided items they considered important to people with RCD. It

consists of 21 visual analog scale items organised into 5 subscales or domains: physical symptoms, sports/ recreation, work, lifestyle, and emotions.

The physical symptoms section includes six questions about pain, weakness and stiffness in the shoulder which, as noted previously, are common to RCD patients. This section also measures other symptoms such as "clicking, grinding and crunching."[82] The sports and recreation section asks four questions about specific movements such as throwing, push-ups and strenuous exercises, as well as physical contact.[82] Work capacity around or outside the house is evaluated with four questions and includes items asking about overhead use and lifting.[82] The lifestyle section has four questions that address sleep disturbance, self-care and physical play with family and friends.[82] Finally, emotions are documented in the last section, including three questions around frustration, depression and worry. [82]

Each item in WORC has a possible score from 0–100. A total score is summated and can range from 0–2100, with a higher score representing lower quality of life.[81] The authors advise using the total score for primary outcomes in clinical trials, but also recommend reporting individual domain scores.[82]

In evaluating the psychometric properties of the WORC, de Witte et al. evaluated patients aged 18-75 with FTT and PTT from two studies and found an effect size of 0.96 with a standardized

response mean of 0.91, indicating good responsiveness.[75] WORC has also been shown to have high internal consistency (Cronbach α= -0.95) and high test-retest reliability (ICC= 0.89).[42] Construct validity ranges from 0.56 to 0.73,[42, 83] which is moderate to good. These findings support the use of the WORC as a condition-specific self-reported outcome measure in RCD patients.

2) **Medical Outcomes Study Short Form 36 (MOS SF-36, or SF-36**)

The SF-36 is a generic health measure which has become one of the most internationally used measures of health in medical, epidemiological and social research.[84] The SF-36 was designed to measure overall HRQL, that is, not specific to a disease of condition.

The SF-36 assesses items in eight separate domains of life quality: physical functioning (10 items), role limitations due to physical health (4 items), role limitations due to emotional problems (3 items), pain (2 items), general health perceptions (5 items), vitality (4 items), social functioning (2 items), emotional well-being (5 items), and changes in health (1 item).[85] Each domain is scored from 0 to 100, representing a percentage of a total possible score. Items in each of the eight domains are averaged together to obtain eight scale scores.

The eight domains can also be totaled into two summary measures: mental component summary (MCS) and physical component summary (PCS).[86] The summaries allow better precision, fewer floor and ceiling effects, and allow simpler analysis when used as outcomes in clinical trials.[86] The PCS and MCS are scored in three steps: 1) Each scale is standardized using a z-score transformation, and means and standard deviations from the general population.[85] 2) An aggregate score is computed using the physical factor score and mental factor score coefficients from the general population.[85] 3) The component score is transformed to norm-based scoring.[85]

Brazier et al. found considerable evidence for internal consistency of the SF-36 (Cronbach's $\alpha >$ .85).[87] They also noted excellent test-retest reliability and substantial evidence for construct validity.[87]

Although the SF-36 allows comparison across diverse health conditions, its generic health focus may limit its utility for comparisons within a specific health condition. In particular, its emphasis on lower body activities and locomotion may limit utility for upper extremity conditions. However, in a study of 67 working-age subjects with various rotator cuff tears (supraspinatus tendon only, supraspinatus and infraspinatus tendons, infraspinatus tendon only, biceps tendon), Piitulainen et al. found a moderate relationship between functional disability and the PCS as well as the MCS, indicating that disability in this population has effects

on both the physical and mental quality of life.[5] Thus, despite including no shoulder-specific questions, Piitulainen recommends using the SF-36 for assessing RCD, in conjunction with a shoulder-specific disability measure.[5]

Summary of Patient Reported Outcome Measures

Patient Reported Outcome Measures have been used less frequently in assisting with diagnosis of PTT. However, these could be potentially useful additions to a clinician's toolkit.

Summary

It has been acknowledged that no single test can diagnose RCD, and it is clear the same is true for differentiating between FTT and PTT. Current literature is limited in regards to how standard clinical assessment may assist in identifying patients with PTT. Given the likely high, but unidentified prevalence of PTT, additional information is needed to aid diagnosis of this common problem.

Using an assessment framework that considers different elements of patient presentation that are commonly assessed by clinicians: demographics, injury characteristics, physical assessment and patient-reported outcome measures, may provide a more complete picture. Current literature has emphasized the physical exam (special tests, strength, AROM), but examining

each of these additional assessment elements may identify other factors which can contribute to a cost-effective, non-invasive discrimination between PTT and FTT. This work contributes to the literature by providing information on whether components of a standard clinical assessment can define the diagnosis of PTT.

3.0 DESCRIPTION OF PRIMARY STUDIES

This secondary analysis was possible through the pooling of data obtained from two RCTs that utilized the gold standard of RCD diagnosis - surgery. Both studies sought to include only FTT subjects, but at time of surgery some subjects were identified as having PTT and were excluded from the primary study. However, all subjects had undergone preoperative assessment so that subjects with PTT and FTT could be compared based on demographic, injury, and physical assessment characteristics as well as patient reported outcomes.

Both primary studies were single blind, RCT evaluating functional outcomes following shoulder surgery. One study used a mini-open rotator cuff repair (MORCR), the other an arthroscopic technique and following surgery both studies randomized patients to intervention groups treated with either early mobilization or standard care.

The first study utilized a MORCR surgical technique. Its primary objective was to determine if the early initiation of AROM was associated with improved shoulder movement at six and 12 weeks. Secondary objectives were: 1) to assess if early initiation of AROM was associated with improved pain at six and 12 weeks, 2) to assess whether early initiation of AROM had detrimental effects on abduction strength at six months and 3) to evaluate whether any differences presented between the two intervention groups with regard to ROM, pain, or HRQL in the first six months post-operatively.

Subjects for the first study were recruited from a "Canadian metropolitan centre" between 2003 and 2011 using convenience sampling. Patients who consented to involvement in the study (n=204) underwent a MORCR. Inclusion criteria were patients who were over 18 years of age, had attempted non-operative treatment (i.e. physical therapy consisting of progressive ROM, strengthening, and postural exercises), and had a FTT of the supraspinatus and/or infraspinatus, as confirmed by appropriate diagnostic imaging (MRI, Arthrogram, US). Those excluded from the study had a FTT of the subscapularis and/or teres minor**,** had PTT of the rotator cuff, had undergone previous rotator cuff surgery to the affected shoulder, had chronic dislocation, inflammation, or degenerative glenohumeral arthropathy, or did not speak, read or understand English.

Prior to surgery, demographic and injury characteristic information was collected through questionnaires and data related to pain and HRQL were assessed using standardized outcome measures. Subjects were also evaluated for strength and AROM by one of two experienced Physical Therapists. These data provided the information used in this secondary analysis.

After surgery, subjects were randomized to a reference group of standard rehabilitation, six weeks in a sling, or the experimental group which allowed sling removal and use of the surgical arm for ADL as early as pain allowed.

The second study was also a single-blind RCT with 248 subjects. Three primary objectives were stated: to determine if the experimental group showed 1) improved shoulder ROM at six weeks and three months post-operatively, 2) improved disease-specific HRQL at six weeks and three months post-operatively, and 3) any post-operative adverse events/ rotator cuff healing at one year post-operatively. A secondary objective was to assess ROM, HRQL, adverse events and rotator cuff healing based on tear size and demographic factors.

Participants were identified using convenience sampling at pre-operative clinics in the Greater Edmonton area between 2011 and 2015. As in the previous study, to be included subjects were over 18 years of age, had attempted non-operative treatment (i.e. physical therapy consisting of progressive ROM, strengthening, and postural exercises), and had a FTT of the supraspinatus and/or infraspinatus, as confirmed by appropriate diagnostic imaging (MRI, Arthrogram, US). Those excluded from the second study also had a FTT of the subscapularis and/or teres minor, had undergone previous rotator cuff surgery to the affected shoulder, had chronic dislocation, inflammation, or degenerative glenohumeral arthropathy, or did not speak, read or understand English. Additional exclusion criteria for the second study were: 1) patient had major joint trauma, infection, or avascular necrosis, 2) patient had evidence of significant cuff arthropathy (superior glenohumeral translation and/or acromial erosion, as diagnosed by diagnostic imaging), 3) patient had a psychiatric illness, cognitive impairment, or other health condition (i.e. visual impairment) which precludes informed consent or renders the patient unable to complete study questionnaires, 4) patient had a major medical illness where life expectancy is

less than 2 years, 5) patient had no fixed address or means of contact, 6) surgeon or patient had decided to cancel surgery, 7) surgeon concluded that an arthroscopic repair is not appropriate at time of surgery (based on rotator cuff tear characteristics or concomitant shoulder pathology), 8) patient was unwilling to complete necessary follow-ups.

Data were obtained prior to surgery using the same demographic questionnaires, similar physical assessment of strength and ROM conducted by a qualified Physical Therapist and the same HRQL questionnaires as the previous trial, allowing an opportunity to consolidate the data from both studies.

Following arthroscopic surgery, a member of the operating room staff retrieved a pre-assigned envelope containing information regarding the patient's group assignment. The subject was placed in either an early mobilization group (patient self-weaned from the sling post-surgery as soon a pain and comfort allowed) or a standard care group (patient used the sling for six weeks post-surgery).

For the two primary studies, the following data potentially associated with PTT were collected in an identical manner:

- **Age:** a continuous variable measured in years.

- **Sex:** a dichotomous variable male or female
- **Mechanism of injury**: a dichotomous variable, “atraumatic”: patient has no recollection of specific incident causing injury or “traumatic”: patient identifies a specific incident causing injury.
- **Pain at rest**: a continuous variable measured using a visual analogue scale (VAS). This scale was a 10 cm long horizontal line anchored with the terms “no pain at all” on the left and “pain as bad as it can be” on the right.
- **Pain with activity**: a continuous variable, measured using a VAS as for “pain at rest”.
- **AROM shoulder flexion**: a continuous variable, measured in degrees with the patient standing.
- **AROM shoulder abduction**: a continuous variable, measured in degrees with the patient standing.
- **AROM shoulder external rotation at 0° abduction**: a continuous variable, measured in degrees with the patient standing.
- **AROM shoulder external rotation at 90° abduction**: a continuous variable, measured in degrees with the patient supine.
- **AROM shoulder internal rotation at 90° abduction**: a continuous variable, measured in degrees with the patient supine.
- **AROM shoulder scaption**: a continuous variable, measured in degrees with the patient standing.
- **Constant Power score**: a continuous variable, measuring strength in pounds.
- **WORC Total Score:** a continuous variable, out of 2100

- **WORC Physical Symptoms Score**: a continuous variable, out of 600
- **WORC Sports and Recreation Score**: a continuous variable, out of 400
- **WORC Work Score**: a continuous variable, out of 400
- **WORC Lifestyle Score**: a continuous variable, out of 400
- **WORC Emotions Score**: a continuous variable, out of 400
- **SF-36 Physical Component Summary Score (PCS)**: a continuous variable from a self-report survey.
- **SF-36 Mental Component Summary Score (MCS)**: a continuous variable from a self-report survey.

The data available (or not available) from the primary studies shaped the direction of the secondary analysis. Some relevant items from the pre-operative data could not be used because they were not collected consistently between the two studies. Occupation was identified as a potential associated factor in PTT but Study 1 recorded occupation information in terms of sedentary, light, medium, heavy, and very heavy, whereas Study 2 classified occupation based on repetitive activity and amount of arm elevation required. Strength testing was significantly different between the studies. The Constant Power score was the only measure of strength included in Study 1 while Study 2 included measurement of isometric shoulder flexion, abduction, internal rotation, and external rotation using a dynamometer.

The subjects included in the studies were already diagnosed as having FTT, so some commonly used assessment items for diagnosis of RCD were not collected pre-operatively, namely the physical examination special tests: Neer's, Empty Can, Hawkin's and Jobe's.

4.0 METHODS

This study was a secondary analysis of prospectively collected preoperative data from two RCT involving patients who underwent surgery for rotator cuff repair. It was a hypothesis generating investigation, so a large number of explanatory variables were evaluated. The research question this study sought to answer was: Does a standard clinical assessment framework assist in identifying patient characteristics associated with PTT?

Objective

The objective was to determine if clinical presentation factors that focused on demographics, injury history, physical assessment and patient reported outcomes was associated with a surgical diagnosis of PTT in a group of patients all previously diagnosed with FTT using imaging.

Specifically, the following factors were considered as factors associated with PTT:

- ***Demographics*** that included age

- ***Injury characteristics*** that included mechanism of injury

- ***Physical Assessment*** that included Constant Power score, AROM of the shoulder (flexion, abduction, external rotation at 0° abduction, external rotation at 90°abduction, internal rotation at 90°abduction, scaption), pain at rest, pain with activity

- ***Patient reported outcome measures*** that included the WORC (total score and dimension scores), and SF-36 summary scores (MCS and PCS).

Hypotheses

Main Hypothesis: Demographic, injury characteristic, physical examination and patient-reported outcome factors of clinical presentation will be associated with PTT (identified at time of surgery) in a group of adult patients who were all previously diagnosed with FTT using MRI or US.

The following specific *a priori* hypotheses were developed based on previous published literature and the researcher's clinical experience:

a) **Age:** subjects with PTT will be younger than FTT subjects
b) **Mechanism of Injury**: subjects with PTT will have no specific trauma related to their shoulder condition while those with FTT will have a traumatic onset
c) **Pain level**: subjects with PTT will have higher pain scores than FTT subjects
d) **AROM**: subjects with PTT will have greater AROM in all movements than FTT subjects
e) **Constant Power score**: subjects with PTT will have better strength than FTT subjects
f) **WORC**: (low score indicates better function)
    a. **Total score**: subjects with PTT will have lower scores than FTT subjects

b. **Physical Symptoms score**: subjects with PTT will have lower scores than FTT subjects

c. **Sports and Recreation score**: subjects with PTT will have lower scores than FTT subjects

d. **Work score**: subjects with PTT will have lower scores than FTT subjects

e. **Lifestyle score**: subjects with PTT will have no difference in scores from FTT subjects

f. **Emotions score:** subjects with PTT will have no difference in scores from FTT subjects

g) SF-36: (higher score indicates a more favorable health state)

a. **Physical Component Summary scale:** subjects with PTT will have higher scores than FTT subjects

b. **Mental Component Summary scale:** subjects with PTT will have no difference in scores from FTT subjects

Study Design

This historical cohort study is a secondary analysis of pre-operative data from two RCT.

Ethical Considerations

Ethics approval for this secondary analysis was obtained from the University of Alberta Human Research Ethics Board. Data used in this project were de-identified, so confidentiality was ensured. As all information was obtained from an existing collection of data, there was no risk to the original subjects. The original studies from which the data were obtained, also received ethics approval.

Data Management

Sampling

Subjects for this secondary analysis were obtained via convenience sampling from the two primary trials. All subjects from the two studies who completed the preoperative evaluation and proceeded to surgery were included in this secondary analysis.

Power Calculation

Sample size was limited to the number of subjects available from the primary studies. Of the 452 total subjects, 32 subjects (Study 1 n=15, Study 2 n=17) had the outcome of interest: PTT. To calculate if this sample size was adequate for the desired power of 0.80, a squared population multiple correlation of 0.50 was used at an α-level of 0.05 and β-level at 0.20. The

number of predictors which could be accommodated by the sample size was between 2 and 3.[88] (Table 3)

Table 3: Sample size Determination

Number of predictors		
1-β= 0.80		
p^2= 0.50, α= 0.05	2	3
n	20	36

According to guidelines described by Stevens, in multiple regression 10 to 15 subjects per predictor is considered adequate.[89] In this calculation, the squared population multiple correlation was estimated at 0.50, based on recommendations by Stevens.[89] Power represents the probability of avoiding a false negative result,[90] or 1-β, and was set at 0.80, according to convention.[90] To complete the calculation, the probability of making a false-positive conclusion is also taken into account, with an α set at 0.05. This level is conventionally most frequently used.[90]

Data Collection

Information collected during the primary studies was stored electronically, password protected and in the possession of the Investigators of the primary studies. Access to the de-identified data for secondary analysis was made available via permission and provision of those Investigators.

The Variables

Outcome (Dependent) Variable

The outcome in this analysis was a dichotomous variable, based on degree of tear established at the time of surgery, PTT or FTT (reference variable),

Explanatory (Independent) Variables

Nineteen variables that fit within the pre-specified assessment framework were extracted from the questionnaires, physical assessment and outcome measures used in the preoperative phase of the primary studies. Items selected were limited to those collected in both primary studies and identified as possible explanatory variables. Age, mechanism of injury, physical assessment findings (AROM, strength) have been studied in RCD, so will be included in this secondary analysis. Patient reported outcome measures have not previously been used to differentiate between RCD diagnoses but may potentially be useful. The variables chosen for analysis were:

1) **Age:** a continuous variable measured in years.

2) **Mechanism of injury**: a dichotomous variable, “atraumatic” (reference variable): patient has no recollection of specific incident causing injury or “traumatic”: patient identifies a specific incident causing injury.

3) **Pain at rest**: a continuous variable measured using a visual analogue scale (VAS). This scale was a 10 cm long horizontal line anchored with the terms “no pain at all” on the left and “pain as bad as it can be” on the right.
4) **Pain with activity**: a continuous variable, measured using a VAS as for “pain at rest”.
5) **AROM shoulder flexion**: a continuous variable, measured in degrees using a universal full circle goniometer with the patient standing.
6) **AROM shoulder abduction**: a continuous variable, measured in degrees using a universal full circle goniometer with the patient standing.
7) **AROM shoulder external rotation at 0° abduction**: a continuous variable, measured in degrees using a universal full circle goniometer with the patient standing.
8) **AROM shoulder external rotation at 90° abduction**: a continuous variable, measured in degrees using a universal full circle goniometer with the patient supine.
9) **AROM shoulder internal rotation at 90° abduction**: a continuous variable, measured in degrees using a universal full circle goniometer with the patient supine.
10) **AROM shoulder scaption**: a continuous variable, measured in degrees using a universal full circle goniometer with the patient standing.
11) **Constant Power score**: a continuous variable, strength in pounds. The arm is actively lifted to 90° abduction in the scapular plane with the elbow in extension and wrist pronated. Resistance is applied at the dorsal wrist and measured with a dynamometer.

12) **Western Ontario Rotator Cuff Index (WORC) Total Score:** a continuous variable from a patient self-report questionnaire where an aggregate score out of 2100 is calculated.
13) **WORC Physical Symptoms Score**: a continuous variable, out of 600
14) **WORC Sports and Recreation Score**: a continuous variable, out of 400
15) **WORC Work Score**: a continuous variable, out of 400
16) **WORC Lifestyle Score**: a continuous variable, out of 400
17) **WORC Emotions Score**: a continuous variable, out of 400
18) **SF-36 Physical Component Summary Score (PCS)**: a continuous variable from a self-report survey
19) **SF-36 Mental Component Summary Score (MCS)**: a continuous variable from a self-report survey

To control for any possible biases in the data between the two primary studies, a variable "Study" was also created. This was a dichotomous variable indicating a subject was included in "Study 1" or "Study 2" of the primary studies.

Statistical Analysis

The data were analysed by the Principal Investigator using STATA 13 and STATA 14 statistical software (StataCorp, College Station, Texas, USA).

Study Comparisons

Prior to undertaking the primary analyses, statistical comparisons were initially performed to determine if any systematic differences existed between the two primary studies. This was done to justify treating the two groups of data as one large dataset. Bivariate statistics were used to compare two study groups. Proportions and Chi squared tests were used to compare the dichotomous variables PTT, sex and mechanism of injury. To assess potential mean differences in continuous variables, t-tests were performed for age, pain at rest, pain with activity, Constant Power score, AROM measurements, WORC total and individual WORC dimension scores and MCS and PCS portions of the SF-36. To provide evidence of group differences, a threshold of $p< 0.05$ was used to determine statistical significance; however clinical importance was also considered as this was a large data set and it was possible that group differences of $p< 0.05$ would not be clinically important.

Descriptive Statistics

Descriptive statistics were then generated to describe the overall study population using the trial data as a single cohort. PTT and FTT groups were described separately, and also combined

for total group information. Frequencies of sex and mechanism of injury were calculated and compared using chi square tests. Means and standard deviations were reported for the continuous explanatory variables: age, pain at rest, pain with activity, AROM variables, Constant Power score, WORC total and dimension scores, PCS and MCS with group comparisons made using independent t-tests.

Logistic Regression

Logistic regression was used for the primary data analysis. Logistic regression is used to model the odds of a binary outcome. Clinical and epidemiological studies often look at binary outcomes, and logistic regression is the most widely used model in these applications.[73] When compared to analysis of binary outcomes using contingency tables, regression allows comparison of a large number variables and allows analysis of both categorical and continuous variables.[73] The logistic model also allows for describing a smooth change in risk for the range of a predictor variable.[73] Since this study looked at a binary outcome of PTT or FTT, and included both categorical and continuous explanatory variables, logistic regression was an appropriate choice as an analytic approach.

Results of logistic regression are reported as odds ratios: a ratio of the odds that an outcome occurs, over the odds that the outcome does not occur. In addition, 95% confidence intervals allow assessment of statistical significance and precision of the reported results.

Univariate Analysis

Univariate analysis was initially performed to test the independent association between each variable and the outcome. This step was used to identify potential variables that should be considered in multivariate analysis. Variables were selected based on clinical or statistical significance.

If a variable was independently associated with the outcome, it might continue to be associated once other variables are taken into account. However, if there was no association between the outcome and the individual variable, it is unlikely that the variable is associated with the outcome and thus, could be excluded from the multivariate analysis.

The independent associations between each pre-selected covariate (age, sex, mechanism of injury, pain at rest, pain with activity, AROM flexion, AROM abduction, AROM external rotation at 0° abduction, AROM external rotation at 90° abduction, AROM internal rotation at 90° abduction, AROM scaption, Constant Power score, WORC total and dimension scores, SF-36 PCS and MCS) and the outcome PTT were tested with logistic regression.

Odds Ratios with 95% confidence intervals and standard error were calculated. Variables with a p-value of < 0.2 in the univariate models were advanced to multivariate analysis to ensure that potentially useful variables are not omitted from the multivariate analysis.

Multivariate analysis

Multiple regression analysis identifies the association between an outcome and a given explanatory variable, accounting for any influence from other explanatory variables.[73] When faced with a large number of potential explanatory variables, decisions must be made about which covariates to include in analysis. The goal is to minimize the number of covariates included to produce a model which best describes the data, has numerical stability and has generalizability in its results.[91]

Collinearity

Although testing for collinearity is typically done after the multivariate model has been developed, our choice of variables warranted assessing for collinearity prior to multivariate model building. Collinearity occurs when two variables in a multivariate model are highly related. This can result in unstable results and an inefficient model.

It was anticipated that the WORC total score and the WORC dimension scores would be highly correlated so building of the purposeful selection model was preceded by checking collinearity among WORC variables using Pearson's R-squared. If collinearity was found, then it would be inappropriate to build a single model that contained multiple WORC scores. Instead, multiple multivariate models would be required to test each of the WORC dimension scores and the WORC total score separately with the other selected co-variates. In addition, collinearity was checked among the WORC scores and Constant Power score and AROM abduction as there was potential for these variables to also be associated with each other as well as the WORC Physical Symptoms score. Collinearity was defined as a correlation > 0.5.

Purposeful Selection and Model Building

Purposeful selection was selected as the method for building the multivariate model. Purposeful selection is a process of building a model in which the investigator controls each step.[110] Variables which have high face validity or clinical significance can be included, as well as those which are statistically significant.[91] In keeping with the exploratory nature of this study, for multivariate analysis covariates with established relationships in RCD as well as those identified as plausible by the investigator's clinical experience were included. Variables from the univariate analysis were chosen with a liberal selection threshold ($p<0.20$) and analysed with multiple logistic regression. The variable "Study" was also included to control for potential influence from combining data from the two primary studies.

After evaluating the p-values in the first model iteration, selective entry was used to develop the model. Variables with p-values under a significance level of 0.20 in the initial models were maintained. The confounding effect of variables that were removed at each step of the model building was assessed by noting the change in the regression output of other variables that stayed in the model. A change of 15% or more in any of the point estimates of the variables retained in the model would suggest confounding. The non-significant variable would then be returned to the model to control for confounding despite its non-significance. Further purposeful steps were performed in various combinations to arrive at a final reduced model that identified the key factors associated with PTT (i.e. those with a level of significance of $p<0.05$).

Testing Model Stability

Once the final model was developed, backward stepwise regression was conducted post-analysis to confirm stability of the multivariate model. In the backward stepwise selection procedure, a regression equation was fitted with all explanatory variables. Variables presenting with a p-value > 0.05 were discarded from the model. The item with the greatest p-value was dropped first, and the data was refit with the remaining variables. This process was repeated automatically in STATA 14 until all variables in the model had a p-value less than 0.05. Odds ratios, standard error, 95% confidence intervals and p-values were calculated for all variables.

Forward stepwise regression was also performed. A simple logistic regression was run automatically in STATA 14 for the outcome variable PTT against all explanatory variables. Variables with a significance of $p < 0.05$ were considered for entry into the model. The explanatory variable with the greatest statistical significance was selected, and subsequent variables were added based on degree of significance. All possible models were fitted until none of the remaining variables had significance level of $p < 0.05$.

Models produced by backward and forward selection were compared to the original purposeful selection model. Agreement among the three models with respect to included variables and the magnitude of their Odds Ratio p-values were used to determine the stability of the final model.

Goodness of Fit

Goodness of fit indicates how effectively the model which has been built describes the data. Pearson's Chi-squared was calculated to determine goodness of fit. A p-value of > 0.05 was used to indicate no significant difference between the data and the model.

5.0 RESULTS

Primary Study Comparisons

Of the 452 subjects, 204 were from Study 1 and 248 from Study 2. Males accounted for 61.8% (n= 126) and 67.7% (n= 168) of subjects in Study 1 and 2 respectively. Mean age in the first study was 55.2 (SD 9.5) years, and in the second was 56.0 (SD 9.8) years. The percentage of subjects with PTT was 7.4% (n= 15) in Study 1 and 6.9% (n= 17) in Study 2. In both studies, the majority of subjects had an atraumatic mechanism of injury: Study 1 63.7% (n= 130), Study 2 69.8% (n=173). (Table 4)

On comparison, data from the primary studies showed few differences between the two studies participants. Sex (p=0.185), mechanism of injury (p=0.198), degree of tear (p=0.837), age (p=0.395), pain with activity (p= 0.510), AROM abduction (p=0.344), AROM scaption (p=0.609), AROM external rotation at 90° (p=0.892), AROM internal rotation at 90° (p=0.149)and all WORC scores (p>0.600)showed no statistically significant differences between the two primary studies. (Table 4)

For the remaining variables with p-values < 0.05, very few clinically important differences were noted between the primary studies. For the Constant Power score, the mean difference between the two studies was 1.86 pounds. Both external rotation at 0° and flexion AROM were statistically different between groups, with measurements showing a mean difference of less

than 10°: 3.26° for external rotation at 0° and 8.40° for flexion AROM. For the SF-36 component parts, PCS and MCS, differences in the mean scores were 11.71 points and 10.04 points respectively, which approached clinical importance. One variable, Pain at Rest, showed a significant p-value (p= 0.002) and a clinically significant difference in the means (11.79 points), i.e. greater than 20%. (Table 4)

Descriptive Statistics

Since the differences between the primary studies subjects were relatively small and likely not clinically relevant, the two groups were combined into a single cohort. Of the total cohort of 452 subjects, 92.9% (n=420) had a FTT rotator cuff tear. Thirty-two subjects (7.1%) had PTT. In the total cohort 65% were male (n=294), 35% were female (n=158). FTT subjects had a similar gender distribution to the total group (64.5% male n=271, 35.5% female n=149) but the PTT tear group had a higher proportion of males: 71.9% (n=23; females 28.1%, n=9). The mean age of the total group was 55.6 years (SD 9.673) with a distribution of 25 to 86 years old. (Table 5 & Figure 3: Distribution of Age)

Sixty-seven percent (n=303) of participants reported an atraumatic onset to shoulder symptoms. Pain was rated higher with activity than at rest. No statistical differences were seen in the means for AROM (p>0.05). (Table 5)

Logistic Regression

Univariate Analysis

Binary logistic regression identified variables associated with the outcome of PTT; of the 19 variables tested, only two were statistically significant at $p< 0.05$: Mechanism of Injury ($p=0.037$) and Constant Power score ($p= 0.009$). (Table 6)

Using a threshold of $p<0.20$, the criterion for inclusion in multivariate analysis, AROM abduction ($p=0.159$), WORC total score ($p=0.122$), WORC Physical Symptoms score ($p=0.067$), WORC Sports and Recreation score ($p=0.183$) and WORC Work score ($p=0.090$) were also potentially associated with PTT and were carried forward for possible entry into the multivariate analysis. (Table 6)

Multivariate Analysis

Collinearity

As anticipated, WORC total score was highly collinear with all WORC dimension scores. At an evaluation level of $r> 0.5$, there was also collinearity between dimensions of the WORC. To ensure independent associations between all variables, only one WORC score was entered into any model. Constant Power and AROM abduction did not have a strong relationship with each

other or the WORC scores and could be considered together in models with the individual WORC elements. (Table 7)

Model Building

In the initial step of model building, the four multivariate regression models that were considered included Study, Mechanism of Injury, Constant Power score, AROM abduction and one of the WORC scores: Model 1 - WORC total, Model 2 - WORC Physical Symptoms, Model 3 - WORC Sports and Recreation, Model 4 - WORC Work.

In all four models, Mechanism of Injury and Constant Power were the most significant variables associated with PTT (Mechanism of Injury range $p \leq 0.072$; Constant Power score range $p \leq 0.072$). Of the WORC items, only Physical Symptoms had a p-value less than 0.20 when tested with the other four variables. (Table 8)

In the second purposeful step, Mechanism of Injury, Constant Power and WORC Physical Symptoms were entered into a single regression model. Mechanism of Injury and Constant Power remained significant at $p < 0.10$ and were retained for the next step. (Table 9)

In the next regression step, Mechanism of Injury and Constant Power retained significance at $p< 0.10$, but only Constant Power was significant at $p<0.05$. Thus the final purposeful selection model found one variable, Constant Power, to be significantly associated with PTT. (Table 10)

Confounding was assessed specifically with regard to the nonsignificant variable Age, and the two most significant variables Mechanism of Injury and Constant Power score. The literature reports findings which suggest younger age may be associated with a traumatic onset.[36,57] In this dataset, adjusting for age did not significantly change the odds ratio for a traumatic Mechanism of Injury (OR 2.220, 95% CI 1.08, 4.59) compared to the initial univariate analysis (OR 2.174, 95% CI 1.06, 4.44). The literature also reports decreases in strength related to aging.[67] For these data, adjusting for Age, the Constant Power score's relationship to PTT was relatively unaffected.

Model Testing

Backward and forward stepwise regression, with a removal and entry levels set at $p< 0.05$, produced identical results to the purposeful selection model. Constant Power score was the only variable in the models significantly associated with PTT although, as with the purposeful selection model, Mechanism of injury trended towards significance at $p<0.10$. (Appendix 2) In the reduced model the Constant Power score was significant with an Odds Ratio (OR) of 1.067 and 95% confidence interval (CI) of 1.017, 1.120 ($p=0.008$).

Goodness of Fit

Testing Pearson's Chi squared goodness of fit for the final model resulted in a non-significant p-value (p=0.1326). This suggests the model fits the data reasonably well. (Appendix 3)

Table 4: Comparison of Primary Studies Participants

Variables	**Study 1**	**Study 2**	**p-value**	**Total n = 452**
Demographics				
Sex n (%) *Reference Variable: Male*	Male: 126 (61.8%) Female: 78 (38.2%)	Male: 168 (67.7%) Female: 80 (32.2%)	0.185 [a]	Male: 294 (65.0%) Female: 158 (35.0%)
Age mean (SD)	55.18 (9.49)	56.0 (9.75)	0.3944 [b]	55.61 (9.36)
Injury Characteristics				
Degree of Tear n (%) *Reference Variable: FTT*	FTT: 189 (92.6%) PTT: 15 (7.4%)	FTT: 231 (93.1%) PTT: 17 (6.9%)	0.837 [a]	FTT: 420 (92.9%) PTT: 32 (7.1%)
Mechanism of Injury n (%) *Reference Variable: Atraumatic*	Atraumatic: 130 (63.7%) Traumatic: 73 (35.8%)	Atraumatic: 173 (69.8%) Traumatic: 75 (30.2%)	0.198 [a]	Atraumatic: 303 (67.0%) Traumatic: 148 (32.7%)
Pain at Rest mean (SD*)*	42.95 (27.86*)*	31.16 (34.81)	0.0002 [b]	36.12 (32.57)
Pain with Activity mean(SD)	57.87 (27.11)	60.54 (49.35)	0.5104 [b]	59.42 (41.46)
Objective Findings				
AROM Flexion mean (SD)	*120.28 (32.26)*	*128.68 (33.53)*	*0.0073 [b]*	124.88 (33.19)
AROM Abduction mean(SD)	115.80 (41.80)	119.44 (39.41)	0.3436 [b]	117.79 (40.51)
AROM ER @ 0° abd[*] mean (SD)	***48.03 (15.82)***	***44.77 (17.23)***	***0.038***	46.25 (16.67)
AROM ER @ 90° abd[^] mean (SD)	59.61 (36.79)	59.16 (34.30)	0.8922 [b]	59.36 (35.41)
AROM IR @90°abd[+] mean (SD)	28.46 (19.85)	31.08 (18.58)	0.1491 [b]	29.90 (19.19)
AROM Scaption mean (SD)	122.44 (34.85)	124.11 (34.28)	0.6090 [b]	123.36 (34.51)
Constant Power mean (SD)	***8.60 (7.16)***	***6.74 (6.55)***	***0.0044 [b]***	7.59 (6.89)
Health Related Quality of Life measures				
WORC Total Score mean (SD)	1248.67 (374.15)	1248.52 (379.86)	0.9967 [b]	1248.56 (376.86)
WORC Physical Symptoms Score mean (SD)	329.51 (114.83)	324.11(115.92)	0.6212 [b]	326.55(115.33)

WORC Sports and Recreation Score mean (SD)	278.23(77.23)	279.03(77.76)	0.9131 [b]	278.67(77.44)
WORC Work Score mean (SD)	270.93(82.53)	272.65(82.42)	0.8260 [b]	271.87(82.42)
WORC Lifestyle Score mean (SD)	226.80(94.36)	223.49(94.20)	0.7105 [b]	224.99(94.19)
WORC Emotions Score mean(SD)	143.19(75.79)	146.76(71.06)	0.6069 [b]	145.15(73.18)
SF-36 PCS mean (SD)	***37.23 (10.85)***	***48.94 (7.89)***	***<0.0001 [b]***	43.66 (11.01)
SF-36 MCS mean (SD)	***53.68 (10.55)***	***43.64 (5.34)***	***<0.0001 [b]***	48.17 (9.52)

[a] Pearson's Chi^2 [b] Independent Two-sample t-test with equal variances

Table 5: Comparison of Subjects with PTT and FTT

Variables	PTT N= 32 (7.1%)	FTT N= 420 (92.9%)	p-value	Total n = 452
DEMOGRAPHICS				
Sex n (%) *Reference Variable: Male*	*Male*: 23 (71.9%) Female: 9 (28.1%)	*Male*: 271 (64.5%) Female: 149 (35.5%)	0.401[a]	Male: 294 (65.0%) Female: 158 (35.0%)
Age mean (SD)	53.90 (9.65)	55.74 (9.63)	0.298[b]	55.61 (9.63)
INJURY CHARACTERISTICS				
Mechanism of Injury n (%) Reference Variable: Atraumatic	***Atraumatic:16 (50.0%) Traumatic: 16(50.0%)***	***Atraumatic: 287 (68.3%) Traumatic:132(31.4%)***	***0.032[a]***	***Atraumatic: 303 (67.0%) Traumatic: 148 (32.7%)***
Pain at Rest mean (SD)	33.50 (23.95)	35.35 (26.59)	0.708[b]	35.21 (26.39)
Pain with Activity mean(SD)	60.08 (26.06)	57.72 (25.91)	0.628 [b]	57.89 (26.06)
OBJECTIVE FINDINGS				
AROM Flexion mean (SD)	127.25 (31.06)	124.70 (33.38)	0.676 [b]	124.88 (33.19)
AROM Abduction mean(SD)	***127.53 (38.80)***	***117.05 (40.58)***	***0.159 [b]***	***117.79 (40.51)***
AROM ER 0° abd* mean (SD)	49.22 (17.91)	46.02 (16.57)	0.296 [b]	46.25 (16.67)
AROM ER 90°abd^mean(SD)	57.94 (36.98)	59.47 (35.33)	0.813 [b]	59.36 (35.41)
AROM IR 90°abd+mean (SD)	31.91 (20.31)	29.74 (19.12)	0.539 [b]	29.90 (19.19)
AROM Scaption mean (SD)	128.41 (32.06)	122.97 (34.69)	0.391 [b]	123.36 (34.51)
Constant Power mean (SD)	***10.92 (8.91)***	***7.35 (6.67)***	***0.006 [b]***	***7.58 (6.88)***
Health Related Quality of Life measures				
WORC Total mean(SD)	***1147.59 (444.67)***	***1256.32 (370.65)***	***0.116 [b]***	***1248.58 (376.86)***
WORC Physical Symptoms mean (SD)	***290.16 (122.04)***	***329.33 (114.48)***	***0.064 [b]***	***326.55 (115.33)***
WORC Sports and Recreation mean (SD)	***260.68 (89.30)***	***280.05 (76.40)***	***0.173 [b]***	***278.67 (77.44)***
WORC Work mean(SD)	***247.34 (99.87)***	***273.74 (80.73)***	***0.081 [b]***	***271.87 (82.39)***

WORC Lifestyle	mean (SD)	210.67 (101.71)	226.08 (93.30)	0.373 [b]	224.99 (94.19)
WORC Emotions	mean(SD)	138.73 (79.53)	145.64 (72.75)	0.608 [b]	145.15 (73.18)
SF-36 MCS	mean (SD)	48.37 (8.33)	49.15 (9.62)	0.898 [b]	48.17 (9.52)
SF-36 PCS	mean (SD)	44.86 (9.33)	43.56 (11.13)	0.520 [b]	43.66 (11.01)

[a] Pearson's Chi^2

[b] Independent Two-sample t-test with equal variances

[*] External Rotation at 0°abduction

[^] External Rotation at 90°abduction

[+] Internal Rotation at 90° abduction

SD: Standard Deviation

WORC: Western Ontario Rotator Cuff Index

MCS: Mental Summary Score

PCS: Physical Summary Score

AROM: Active Range of Motion

PTT: Partial Thickness Tear

FTT: Full Thickness Tear

Figure 3: Distribution of Age (in years)

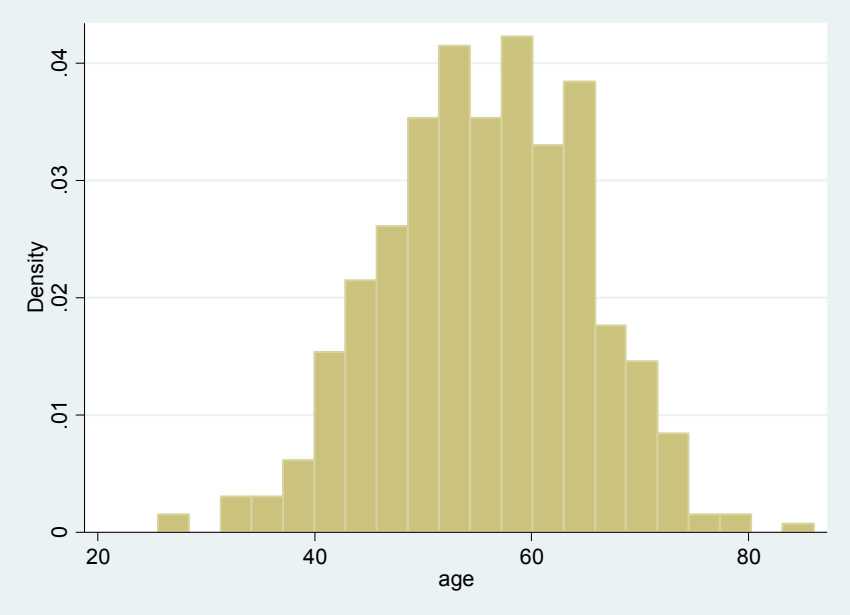


Table 6: Univariate Analysis for Outcome of PTT

Variable	Odds Ratio (95% CI)	SE	p-value [a]
Demographics			
Age	0.981 (0.947, 1.017)	0.018	0.304
Sex	0.712 (0.321, 1.578)	0.289	0.392
Injury Characteristics			
Mechanism of Injury	***2.174 (1.055, 4.480)***	***0.802***	***0.037***
Pain at Rest	0.997 (0.983, 1.011)	0.007	0.706
`Pain with Activity	1.003 (0.989, 1.018)	0.007	0.625
Objective Findings			
AROM Flexion	1.002 (0.991, 1.014)	0.006	0.673
AROM Abduction	***1.007 (0.997, 1.016)***	***0.005***	***0.161***
AROM Ext Rot 0°	1.012 (0.990, 1.035)	0.012	0.289
AROM Ext Rot 90°	0.999 (0.989, 1.009)	0.005	0.813
AROM Int Rot 90°	1.006 (0.987, 1.025)	0.010	0.537
AROM Scaption	1.005 (0.994, 1.016)	0.006	0.289
Constant Power	***1.068 (1.018, 1.120)***	***0.026***	***0.009***
Health Related Quality of Life Measures			
WORC Total Score	***1.015(0.996, 1.035)***	***0.010***	***0.122***
WORC Physical Symptoms Score	***0.997 (0.993, 1.000)***	***0.001***	***0.067***
WORC Sports and Recreation Score	***0.997 (0.993, 1.001)***	***0.184***	***0.183***
WORC Work Score	***0.996 (0.993, 1.000)***	***0.090***	***0.090***
WORC Lifestyle Score	0.998 (0.995, 1.002)	0.375	0.375
WORC Emotions Score	0.999 (0.994, 1.004)	0.607	0.607
SF-36 MCS Score	1.002 (0.965, 1.041)	0.019	0.900
SF-36 PCS Score	1.012 (0.976, 1.049)	0.019	0.503

[a] Logistic regression

Table 7: Testing for Collinearity of Explanatory Variables

	Constant Power Score	AROM Abduction	WORC Total Score	WORC Physical Symptoms Score	WORC Sports and Recreation Score	WORC Work Score
Constant Power Score	1.000	_____	_____	_____	_____	_____
AROM Abduction	0.427	1.000	_____	_____		_____
WORC Total Score	-0.347	-0.372	1.000	_____	_____	_____
WORC Physical Symptoms Score	-0.287	-0.264	0.877	1.00	_____	_____
WORC Sports and Recreation Score	-0.277	-0.287	0.848	0.665	1.00	_____
WORC Work Score	-0.367	-0.383	0.878	0.685	0.745	1.00

Table 8: Multiple Regression Models: Step 1

Variable	Odds Ratio (95% CI)	Standard Error	p-value
Model 1			
Study	1.248 (0.580, 2.686)	0.488	0.571
Mechanism of Injury	2.055 (0.963, 4.384)	0.794	0.062
Constant Power Score	1.056 (0.998, 1.116)	0.030	0.057
AROM Abduction	1.000(0.989, 1.012)	0.006	0.974
WORC Total Score	1.000 (1.000, 1.000)	0.001	0.448
Model 2			
Study	1.245 (0.576, 2.688)	0.489	0.577
Mechanism of Injury	2.159 (1.004, 4.640)	0.843	0.049
Constant Power Score	1.052 (0.996, 1.112)	0.030	0.072
AROM Abduction	1.000 (0.989, 1.011)	0.006	0.989
WORC Physical Symptoms Score	0.998 (0.994, 1.001)	0.002	0.165
Model 3			
Study	1.246 (0.580, 2.678)	0.486	0.573
Mechanism of Injury	2.003 (0.941, 4.263)	0.772	0.072
Constant Power Score	1.060 (1.003, 1.120)	0.030	0.038
AROM Abduction	1.001 (0.990, 1.012)	0.006	0.869
WORC Sports and Recreation Score	0.999 (0.994, 1.004)	0.003	0.710
Model 4			
Study	1.241 (0.577, 2.670)	0.485	0.581
Mechanism of Injury	2.025 (0.951, 4.312)	0.781	0.067
Constant Power Score	1.056 (0.998, 1.116)	0.030	0.059
AROM Abduction	1.000 (0.989, 1.012)	0.006	0.967
WORC Work Score	0.998 (0.993, 1.003)	0.002	0.445

Table 9: Multiple Regression Model: Step 2

Variable	Odds Ratio (95% CI)	Standard Error	p-value
Mechanism of injury	2.151 (1.003, 4.610)	0.837	0.049
Constant Power Score	1.050 (0.998, 1.105)	0.027	0.060
WORC Physical Symptoms Score	0.998 (0.994, 1.001)	0.002	0.156

Table 10: Multiple Regression Model- Step 3

Variable	Odds Ratio (95% CI)	Standard Error	p-value
Mechanism of Injury	2.019 (0.951, 4.288)	0.776	0.067
Constant Power Score	1.064 (1.014, 1.117)	0.026	0.011

6.0 DISCUSSION

A large amount of clinical data can be easily and non-invasively collected prior to rotator cuff repair surgery. Demographic information and history of a problem are routinely collected in patient charts. Physical assessment of strength and ROM are quick and easy to administer, as are HRQL outcome measures and pain scores. For this secondary analysis, the two primary RCTs offered a large sample size and a large number of potential explanatory variables that could be explored for associations with PTT.

Main Findings

This endeavor was exploratory in nature, so it was anticipated many variables would be non-significant in univariate models. Analysis supported this expectation: of the 19 variables assessed, only two (Mechanism of Injury and Constant Power score) were statistically significant at $p<0.05$ and only five (AROM abduction, WORC Total score, WORC Physical Symptoms score, WORC Sports and Recreation score, WORC Work score) were significant at $p<0.20$.

No single area of the outlined assessment framework (demographics, injury characteristics, physical assessment, patient reported outcome measures) presented as dominant in identifying PTT. Combining areas of this framework also did not help with differentiating between FTT and PTT, although repeating this work in a larger and more varied group of PTT subjects may be

warranted. The PTT patients involved in this study were assumed to all have FTT based on their history, clinical assessment findings, lack of response to treatment and imaging findings, but were found to have PTT at time of surgery. Those with PTT therefore likely had high grade PTT (although degree of tear was not quantified in the primary studies), which mimicked FTT. Thus, this sample was very likely not representative of the full spectrum of PTT.

Perhaps our findings then lead to the question of whether the true patho-anatomical diagnosis matters in this population of subjects. Surgery was offered to these patients not based solely on their FTT imaging diagnosis, but also because they experienced persistent pain and/or disability following three months of conservative medical treatment. The factors selected for exploration in this study are commonly utilized in clinical assessment; however, it is possible that the assessment framework should be more comprehensive and include other factors that assist in directing patient care rather than focusing on a patho-anatomical diagnosis.

In this cohort, abduction strength, as measured by the Constant Power score, showed a significant univariate association (p=0.007), and aligned with the expectation of increased strength being associated with PTT. The odds of having a PTT increased by 6.8% with a one-pound increase in Constant Power score (OR 1.068, 95% CI 1.02, 1.12). This corresponds to a secondary finding reported by Millican et al. that abduction strength can distinguish PTT from FTT.[20]

Other studies using strength measures for diagnosis of RCD had different goals and different measurement techniques. Millican et al. sought to use strength, measured with a dynamometer, to differentiate various rotator cuff tears from other shoulder diagnoses.[20] Murrell et al. also differentially diagnosed rotator cuff tears among other shoulder conditions using supraspinatus and external rotation weakness, but assessed strength with manual muscle testing and did not distinguish between PTT and FTT.[92] McCabe et al. found that strength at 10°abduction, measured with a dynamometer, could diagnose large or massive FTT.[51] None of these findings can be compared to the results of this study. The outcomes being tested were different, and strength testing positions and techniques were different.

Although techniques and outcomes differed in the details, the fundamental finding in the afore-mentioned studies and the current study is the same: that strength has a relationship with rotator cuff integrity. More rigorous study, which includes designing studies with similar objectives, and standardization of the way strength testing is performed and measured, would clarify results and increase the usefulness of strength as a diagnostic tool.

The Mechanism of Injury variable was also significant at the univariate stage of evaluation. It was hypothesized that those subjects with partial tears would have no “traumatic” incident.

The analysis however showed a positive association, with PTT subjects more than twice as likely to recall a specific injury (OR 2.174, 95% CI 1.06, 4.48).

This is contrary to the results of Fukuda, who reported increasing incidence of trauma for patients with FTT.[21] He did, however note that trauma was related differently to the subtypes of partial tears: bursal sided tears were very infrequently traumatic (8%), intratendinous tears were very frequently traumatic (92.3%).[21] Uchiyama et al. also found a high incidence of trauma in subjects with intratendinous PTT. Yamamoto et al. used diagnostic ultrasound to associate a history of trauma with FTT, but did not investigate PTT.[57] Some authors conversely noted that younger patients with PTT often experienced a traumatic mechanism[36, 57] In this analysis, adjusting for age did not significantly change the odds ratio for Mechanism of Injury.

This variable may not be accurate as it relies on the patient's memory and the patient's evaluation of the significance of an event involving the shoulder. Different studies may also have varying definitions for a "traumatic mechanism", so could include repetitive microtrauma or a single incident of trauma.

Rotator cuff tears are also seen as an age-related phenomenon.[36] Severity of tears is also linked with age[20, 36] due to loss of vascularity of the cuff.[27] A progression of tears has also been noted in patients over the age of 60.[37] In this analysis, age showed no association with degree of tear.

Pain is an important symptom for RCD patients, but its significance in discriminating severity of pathology is not clear. Pain can be present with little or no tendon damage[11] or tears can be asymptomatic.[8] Xiao noted no difference in pain for degree of PTT,[11] and Minegawa et al. postulated that pain had more to do with the location of the tear, rather than the degree.[8] One qualitative study reported on patients with FTT who were "shocked" at how painful their shoulders were,[78] yet others claim PTT to be more painful than FTT.[9] Several authors highlight night pain as significant [9, 11] and overhead activity as particularly painful.[11]

We found no difference between groups for either Pain at Rest or Pain with Activity. Several factors may have influenced this outcome. First, the PTT subjects had tears that were diagnosed at FTT on imaging, which may have presented as FTT in many ways, including pain level. Second, the way pain was measured may have differed between studies. This analysis used the descriptions "pain at rest" and "pain with activity" but did not specify night pain or pain with particular activities, such as overhead work. Finally, pain is difficult to measure. VAS are used frequently because they are sensitive to change, but are also known to have lower reliability.[77]

Both AROM and strength rely on a mechanical force generated by contraction of the rotator cuff. The hypotheses for these items linked greater rotator cuff integrity (PTT) to higher scores. In this analysis, all active movements for both groups were limited but there was no difference

between PTT and FTT subjects, including AROM abduction. This is in contrast to the outcome for Constant Power score, which is a strength test for abduction.

This may be explained by the small to moderate amount of work required to move a limb through its range of motion. The relatively low load of AROM may not have been sufficient to test the limits of the rotator cuff tissues, thereby showing no differentiation between PTT and FTT groups. For some subjects, movement may also have been limited by pain.[78] Given that PTT and FTT groups showed similar pain scores, both may have also had AROM scores reduced by pain. It has also been suggested that composite movements (reach behind the head, reach behind the back), rather than single plane AROM, should be measured in shoulder conditions because they are more functional.[67] Evaluation of these active movements to assess function of the rotator cuff may identify differences in PTT and FTT.

In its development, the WORC was administered to patients with the full spectrum of RCD, from tendinitis to FTT.[82] It was not designed to differentiate these patients from each other and there is no literature which supports this application, but it was speculated that a spectrum of responses may manifest in the test results based on the spectrum of the disease.

Neither the WORC dimension scores nor the total score showed a significant association with PTT in univariate analysis, contrary to the hypotheses. The Physical Symptoms dimension

included items related to pain, weakness, and stiffness- items which were similar to variables assessed in this study. Since pain and AROM as variables were not different between the groups in this study, it should not be surprising the same subjects would show no difference on this dimension.

Perhaps the discriminatory potential of the dimensions and the total score are obscured in this study by the severity of the PTT in this study group. More range may register between patients with milder forms of RCD, such as tendonitis, and FTT. It is possible that when trying to detect PTT, the dimension scores may be more useful than the overall WORC score as the functional differences between PTT and FTT may be quite subtle.

As a global health assessment instrument, the SF-36 summary scores were not useful in discriminating between PTT and FTT. The SF-36 is likely too broad to measure the changes in quality of life caused by such a specific diagnosis as degree of rotator cuff tear. Closer inspection of the questions in the SF-36 may explain its limitation. In a section about daily activity, five of ten questions relate exclusively to walking. The other five involve the upper extremity and lower extremity. There are also no questions about sleep, which is a primary problem area for patients with RCD. A different generic heath measure which collects information about sleep and overhead activity may be more useful.

Although the lack of differential findings in this analysis was influenced by the particular PTT cohort, perhaps the results are not solely affected by the selection of subjects. Assessment factors may simply not provide the information we are looking for to diagnose RCD. There is a growing collection of studies that show an inconsistent relationship between tissue pathology and impairments at the shoulder.[93, 94] Using a pathoanatomical diagnosis suggests that patients with the same tissue pathology are similar, that they can be treated in the same way and have the same prognosis.[47] The prevalence of asymptomatic PTT and FTT[8, 37, 52, 57] is a clear sign that this is not the case for RCD.

If degree of tearing is shown to correlate poorly with pain, movement, most strength measurements and function, perhaps it should not heavily influence clinical diagnosis or decision-making in rehabilitation. Alternative diagnostic categorization, not based on medical models of tissue disruption, may be more useful for physical therapists.

Diagnostic labels are intended to direct treatment and inform prognosis. When the appropriate treatment involves surgical repair of a torn tissue, the extent and location of a rotator cuff tear is certainly relevant, but when best practice for RCD shows movement away from surgical repair, the patho-anatomical diagnosis becomes less directive for patient care. Several authors have advocated for a movement based approach to diagnosis of shoulder conditions.[45, 46, 48]

Diagnostic labels related to conservative treatment like physical therapy, then should reflect the physical therapy goals of increasing function.[46]

The Staged Approach for Rehabilitation Classification for shoulder disorders (STAR-Shoulder) is an expanded classification system that includes the patho-anatomical diagnosis, but also a rehabilitation classification based on tissue irritability and identified impairments.[47] This proposed model still requires evaluation, refinement and validation,[47] but has high face validity in the context of physical therapy. Traditional assessment of shoulder conditions generally attempts to identify a tissue at fault (special tests for patho-anatomical diagnosis), extent of tissue irritability (mechanism of injury, pain measures, willingness to move-AROM), and identifies impairments (AROM and strength measures, HRQL measures). Synthesizing these findings as described by the STAR- Shoulder framework may offer better direction for treatment. The assessment factors identified in this study may be helpful in developing standardized operational definitions for such an impairment-based classification. Thus, future research may need to also be directed at the impact of these more comprehensive assessments rather than focusing on the standard clinical assessment framework that we evaluated.

Strengths of the Study

This secondary analysis was an opportunity to utilize the gold standard of RCD diagnosis, surgery, to identify PTT versus FTT. Access to surgical diagnosis would have been unlikely for a project of this scope as a primary analysis, given the cost and time associated with surgery. Secondary analysis of data had some additional advantages. A significant one was convenience, because the data were already collected.[95] The original studies collected pre-operative data in a standardized fashion over many years, which would have been impossible for the scope of the current project. The large total sample population provided by the primary studies also allowed exploration of several factors that could be associated with PTT.

Limitations of the Study

As previously indicated, the most significant limitation in this study was the narrow range of PTT patients available for analysis. All were likely high grade PTT as they were diagnosed as FTT using imaging techniques. Findings and conclusions from this analysis may not necessarily apply to less extreme PTT. Results from this study may, therefore have limited generalizability.

Further, despite a large cohort for the study, the number of subjects with PTT was small, which opened the possibility for an under-powered study. If more subjects with PTT had been included, it is possible that the variables trending towards significance may have attained statistical significance.

There are also some limitations associated with the study design. Because this was a secondary analysis, data were not collected with the intent to answer the current question, so some potentially useful information was not available. Demographic information regarding occupation and other activities which stress the shoulder could not be used because they were collected differently between the primary studies. Data on standard clinical tests for RCD such as Neer' test and Empty Can test were not collected, and therefore were unavailable for analysis. Evaluation of rotator cuff strength was not comprehensive in both studies; the primary studies shared only Constant Power as a strength test. AROM was limited to single plane movements, when "functional" multi-planar movement such as reaching behind the back or behind the head may be more apt to show deficits.[18]These variables all potentially could have added information to the study.

This study may also be affected by limitations of the primary studies. Both primary studies employed convenience sampling, which is fast, inexpensive, easy and subjects are readily available, but is vulnerable to selection bias. They also collected subjects at surgical clinics many years apart so there may have been some secular trends in patient referrals that we were unable to control. Variations in the healthcare system over time could have influenced the sample of people presenting to the clinics, such as changes in surgical referral criteria or availability of surgeons/surgical space. The surgeries performed in the primary studies were also different, which may have further affected participant selection.

Finally, since the current researcher did not participate in any aspect of the primary studies, it was difficult to confirm the quality of the procedures,[95] although all research associates who participated in the primary studies were experienced and underwent training sessions to standardize assessment procedures.

Summary

The secondary analysis of these data allowed an exploratory investigation of many variables which were postulated to have a relationship with PTT. Two variables were significant in univariate analysis: Mechanism of Injury and Constant Power score. In multivariate analysis, only Constant Power Score was statistically significant for association with PTT. No one area of the assessment framework outlined in this study (demographics, injury characteristics, physical assessment, HRQL measures) was useful for improved identification of PTT. Although this study was adequately powered for the single explanatory variable from the analysis, the small sample of available PTT subjects, who were likely not representative of the PTT patient population, was a significant limitation in this endeavor. However, the finding of few assessment factors associated with PTT may also point to using a different assessment approach that is less focused on pathoanatomy in future research studies.

7.0 RECOMMENDATIONS/ CONCLUSION

PTT is a common problem that is poorly understood. Improved management of this complaint may be assisted with more accurate diagnosis. Current physical examination and diagnostic imaging tools are inadequate for the task. Extensive previous investigation has shown that no one test, physical or imaging, can diagnose RCD. Even when using a standard clinical assessment framework typically used in clinical settings, few factors were associated with PTT.

Recommendations

The overarching limitation of this study was the small number of, and narrow range of PTT subjects available for inclusion. To develop the findings from this analysis, further studies of subjects with a broader array of RCD could further elucidate associations with PTT. Any of the variables identified in this study as significant at $p < 0.20$ would be of particular interest: AROM abduction, WORC total and WORC dimension scores. The disease-specific WORC in particular, may show more discrimination with a broader spectrum of RCD. The WORC total score and WORC Physical Symptoms score in particular are good candidates for further study. Additional strength testing for the rotator cuff, especially external rotation, combined with broader and better-defined PTT outcome groups could also offer interesting information.

Abduction strength, in the form of the Constant Power score, was the only factor in this study significantly associated with PTT, but maximal rotator cuff strength is related to scapular

function.[96] An evaluation of strength in different degrees of RCD, controlling for scapular stability may offer additional insights.

To effectively use the results of the Constant Power score in clinical practice, it is necessary to establish normal values for comparison to patient assessment findings. Constant developed a formula for a "relative Constant score"[97] which compares a patient's score to an age and gender matched score from a normal population. Yian et al. also reported normative age and sex-specific Constant Power values from a large population sample.[98] There is a suggestion that more shoulder treatment centres could develop population-specific norms for this measure to provide more meaningful interpretation of results.[67, 98] Further study would then be required to quantify the difference in strength for different degrees of PTT.

Another research variation to consider is testing abduction strength in different positions. The palm-down, internally rotated position of the Constant Power score is an impingement position and risks pain influencing the test. A less painful position may provide a clearer assessment of true strength. The Full Can test, as described by Kelly et al., assesses strength in 90° abduction in the scapular plane and 45° external rotation.[99] Muscle activity for the supraspinatus is reported to be similar in the Full Can and Empty Can test (a standard special test for RCD), but the Full Can test is less pain provocative.[99] Itoi used the Full Can test to identify FTT, and found it to be equivalent to Empty Can for accuracy in that application.[37] Evaluation of the Full Can

test and repeating the work of McCabe et al. with testing abduction at 10° [51] in various PTT subjects are other research options.

Clinicians should consider adding a structured evaluation of abduction strength, such as the Constant Power score, to a physical examination of suspected rotator cuff injured patients. Use of a hand-held dynamometer or a standardized testing protocol like the Constant strength assessment is recommended over manual muscle testing for quantification of results. To allow interpretation, findings should be compared with reference scores from a similar population sample.

Conversely, AROM, pain, and the outcome measures WORC and SF-36 should not be relied upon for diagnosis in suspected RCD. They may be used to document a patient's clinical picture and measure change with treatment, but have no association with diagnosis of PTT.

Patients should be instructed that pain in the shoulder or a memorable injury do not show a defined connection to severity of rotator cuff injury. Additionally, findings on imaging or any other single finding is not wholly diagnostic in this condition, so the utility of diagnostic imaging may also need to be reconsidered. If tissue status does not necessarily determine symptoms (and therefore treatment) perhaps the expense can be spared. Patients also may be unnecessarily concerned about an incidental finding.

Conclusion

As front-line healthcare providers, physicians and physical therapists encounter many people with RCD and therefore with PTT. Improved management of shoulder patients requires more information on natural history of RCD and clarification of the range of presentation possible with PTT. To date, the tools we have for diagnosis are inadequate.

Some factors identified in this study may warrant further evaluation with regard to their association with PTT: Constant Power score and other abduction strength measurements, a broader range of rotator cuff strength measurements, injury characteristics such as mechanism of injury, and the WORC total score and physical symptoms domain score. Further study of this condition may aid in better non-invasive diagnosis, which can lead to more targeted treatment for PTT. Further research may also find that an accurate non-surgical diagnosis of PTT is not possible. It may, however, be the case that a patho-anatomical diagnosis is not necessary for appropriate treatment of these patients. A rehabilitation-focused diagnosis may provide better information for therapists. Regardless of the outcome, further study can only enhance development of best treatment practices which ultimately lead to improved outcomes for all patients with rotator cuff tears.

8.0 ADDITIONAL INFORMATION

No costs were incurred while performing this study.

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APPENDICES

Appendix 1: **Patient information for Primary Studies**

-Range of Motion tracking sheet

-CMS tracking sheet

-Demographics information sheet

-Pain Questionnaire

-SF-36 tracking sheet

-WORC tracking sheet

Arthroscopic Sling Study
Range of Motion (Pre-op)

Site # — Screening # Initials (F&L)

Interval: ☐ Pre-op

☐ Not completed

Standing AROM—Left Side

1. **Forward flexion**

   Description: In standing; with elbow straight and leading with the thumb up.

   Active ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

2. **Scaption**

   Description: In standing; with the elbow straight and leading with the thumb up, elevate the arm in the scapular plane (30° anterior to coronal plane)

   Active ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

3. **External rotation (0° abduction)**

   Description: In standing; with elbows bent 90° and maintained at the sides of the torso and thumb pointing up.
   Note: Perform AROM bilaterally to avoid trunk rotation and express scapular retraction

   Active ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

4. **Abduction**

   Description:

   Active ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

Supine AROM/PROM—Left Side

1. **Forward flexion**

   Description: In supine; with elbow straight and leading with the thumb

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

2. **Abduction**

   Description: In supine; with the elbow straight and leading with the thumb (palm up) maintaining humerus parallel to the bed (coronal plane)

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

3. **External rotation (0° abduction)**

   Description: In supine; with the elbow bent 90° and supported on a folded towel to maintain humerus in midline of the trunk in 0° abduction

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

4. **External rotation (90° abduction)**

   Description: In supine with the elbow bent 90° and the shoulder abducted 90°, support the humerus on a folded towel to maintain humerus parallel to the bed

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

5. **Internal rotation (90° abduction)**

   Description: In supine; with the elbow bent 90° and the shoulder abducted 90°, support the humerus on a folded towel to maintain humerus parallel to bed

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

6. **Horizontal adduction**

   Description: In supine; with the shoulder flexed 90° and the elbow bent 90°

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

Arthroscopic Sling Study
Range of Motion (Pre-op)

Site # — Screening # Initials (F&L)

Interval: ☐ Pre-op

☐ Not completed

Standing AROM—Right Side

1. **Forward flexion**

   Description: In standing; with elbow straight and leading with the thumb up.

   Active ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

2. **Scaption**

   Description: In standing; with the elbow straight and leading with the thumb up, elevate the arm in the scapular plane (30° anterior to coronal plane)

   Active ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

3. **External rotation (0° abduction)**

   Description: In standing; with elbows bent 90° and maintained at the sides of the torso and thumb pointing up.
   Note: Perform AROM bilaterally to avoid trunk rotation and express scapular retraction

   Active ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

4. **Abduction**

   Description:

   Active ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

Supine AROM/PROM—Right Side

1. **Forward flexion**

   Description: In supine; with elbow straight and leading with the thumb

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

2. **Abduction**

   Description: In supine; with the elbow straight and leading with the thumb (palm up) maintaining humerus parallel to the bed (coronal plane)

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

3. **External rotation (0° abduction)**

   Description: In supine; with the elbow bent 90° and supported on a folded towel to maintain humerus in midline of the trunk in 0° abduction

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

4. **External rotation (90° abduction)**

   Description: In supine with the elbow bent 90° and the shoulder abducted 90°, support the humerus on a folded towel to maintain humerus parallel to the bed

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

5. **Internal rotation (90° abduction)**

   Description: In supine; with the elbow bent 90° and the shoulder abducted 90°, support the humerus on a folded towel to maintain humerus parallel to bed

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

6. **Horizontal adduction**

   Description: In supine; with the shoulder flexed 90° and the elbow bent 90°

   Active ☐☐☐.☐ degrees
   Passive ☐☐☐.☐ degrees
   Unable ☐ Not tested ☐

☐ Not completed

3. Range of Motion (ROM)

A. Forward Elevation (degrees) *(Check one only)*

0☐ 0-30
2☐ 31-60
4☐ 61-90
6☐ 91-120
8☐ 121-150
10☐ 151-180

B. Lateral Elevation (degrees) *(Check one only)*

0☐ 0-30
2☐ 31-60
4☐ 61-90
6☐ 91-120
8☐ 121-150
10☐ 151-180

C. External Rotation (hand must not touch the head or neck) *(Check all that appy)*

2☐ Hand behind head with elbow held forward
2☐ Hand behind head with elbow held back
2☐ Hand on top of head with elbow held forward
2☐ Hand on top of head with elbow held back
2☐ Full elevation from on top of the head
0☐ Unable to perform any part of 6

D. Internal Rotation: Thumb to… *(Check highest level of internal rotation)*

0☐ …lateral thigh
2☐ …buttock
4☐ …lumbosacral junction
6☐ …waist (L3)
8☐ …T12
10☐ …interscapular region (T7)

4. Power: # of pounds of pull *(1 point per pound)*

Operative side: ☐☐☐.☐☐
(to a maximum of 25 pounds)

Non-operative side: ☐☐☐.☐☐
(to a maximum of 25 pounds)

Arthroscopic Sling Study
Demographics

Site # ☐ — Screening # ☐☐☐ Initials (F&L) ☐☐

1. Date of birth: _____ / _____ / _____
   dd mmm yyyy
2. Operative shoulder: ☐ Left ☐ Right
3. Do you have symptoms in your other shoulder? ☐ Yes ☐ No
4. Dominant hand: ☐ Left ☐ Right
5. Gender: ☐ Male ☐ Female
6. Height: _____ ☐ cm ☐ inches
7. Weight: _____ ☐ kg ☐ pounds
8. Occupation: _____

   Occupation classification: *(check most severe option)*

   - ☐ Repetitive activity above shoulder level
   - ☐ Repetitive activity at shoulder level
   - ☐ Repetitive activity at waist level
   - ☐ Desk job (typing or writing)
   - ☐ No repetitive activity required
   - ☐ No shoulder activity required
   - ☐ Not applicable (unemployed or retired)
   - ☐ Other, please specify: _____

9. Type of employment: *(check all that apply)*

   - ☐ Full-time
   - ☐ Part-time
   - ☐ Self-employed
   - ☐ Volunteer
   - ☐ Retired
   - ☐ Student
   - ☐ Unemployed
   - ☐ Other, please specify: _____

10. Have you had to reduce your hours of work because of your shoulder problems? ☐Yes ☐No ☐ N/A

11. Have you had to modify your duties at work because of your shoulder problem? ☐Yes ☐No ☐ N/A

12. Check this box if you are off work for reasons **unrelated** to your shoulder problem. ☐

If you checked the box, please describe the reason:_____

13. Date of injury: _____ / _____ / _____
dd mmm yyyy

☐ Not applicable/gradual onset; please specify duration of symptoms in years: _____

14. Activity at injury:

☐ Activities of daily living

☐ Traffic

☐ Work

☐ Sport, please specify: _____

☐ No specific injury recalled

15. What previous treatment have you had on your shoulder? *(Check all that apply)*

☐ Painkillers (e.g., Tylenol)

☐ Anti-inflammatories (e.g., Advil, Naproxen)

☐ Corticosteroid injection

☐ Non-steroid injection (e.g., Synvisc)

☐ Physical therapy

☐ Surgery, please specify: _____

☐ Other, please specify: _____

16. Are you currently claiming or receiving third-party compensation related to your shoulder condition?
(Check all that apply)

Yes	No	
☐	☐	Short-term disability, weekly indemnity, sickness and accident, or company sick leave
☐	☐	Long-term disability or long-term income protection (LTIP)
☐	☐	Canada Pension Plan (CPP) disability
☐	☐	Employment Insurance (EI) sick leave
☐	☐	Automobile insurance
☐	☐	Workplace Safety and Insurance Board (WSIB) or worker's compensation
☐	☐	Litigation

Arthroscopic Sling Study
Pain Questionnaire

Site # ☐ — Screening # ☐☐☐ Initials (F&L) ☐☐

Interval: ☐ Pre-op ☐ 6-week ☐ 3-month ☐ 6-month ☐ 12-month ☐ 24-month

☐ Not completed

*Mark an X on the line in the place that best describes your pain on average **in the past week**.*

1. At Rest

No pain at all |——————————————————————| As bad as it can be ☐☐.☐

2. At Night

No pain at all |——————————————————————| As bad as it can be ☐☐.☐

3. With Activity

No pain at all |——————————————————————| As bad as it can be ☐☐.☐

Arthroscopic Sling Study
SF-36

Site # ___ — Screening # ___ ___ ___ Initials (F&L) ___ ___

Interval: ☐ Pre-op ☐ 6-week ☐ 3-month ☐ 6-month ☐ 12-month ☐ 24-month

☐ Not completed

This next section asks for your views about your health. This information will help tell us how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(Check one)*

   1☐ Excellent
   2☐ Very good
   3☐ Good
   4☐ Fair
   5☐ Poor

2. Compared to one year ago, how would you rate your health in general now? *(Check one)*

   1☐ Much better now than one year ago
   2☐ Somewhat better now than one year ago
   3☐ About the same as one year ago
   4☐ Somewhat worse now than one year ago
   5☐ Much worse now than one year ago

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Check one box on each line	**Yes, Limited A Lot**	**Yes, Limited A Little**	**No, Not Limited At All**
3.	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
4.	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
5.	Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
6.	Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3
7.	Climbing **one** flight of stairs	☐ 1	☐ 2	☐ 3
8.	Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
9.	Walking **more than a mile/kilometer**	☐ 1	☐ 2	☐ 3
10.	Walking **several blocks**	☐ 1	☐ 2	☐ 3
11.	Walking **one block**	☐ 1	☐ 2	☐ 3
12.	Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

☐ Not completed

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Check one box on each line	**YES**	**NO**
13.	Cut down on the **amount of time** you spent on work or other activities	☐ 1	☐ 2
14.	**Accomplished less** than you would like	☐ 1	☐ 2
15.	Were limited in the kind of work or other activities	☐ 1	☐ 2
16.	Had **difficulty** performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Check one box on each line	**YES**	**NO**
17.	Cut down the amount of time you spent on work or other activities	☐ 1	☐ 2
18.	Accomplished less than you would like	☐ 1	☐ 2
19.	Didn't do work or other activities as carefully as usual	☐ 1	☐ 2

20. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(Check one)*

1☐ Not at all
2☐ Slightly
3☐ Moderately
4☐ Quite a bit
5☐ Extremely

21. How much bodily pain have you had during the past 4 weeks? *(Check one)*

1☐ None
2☐ Very mild
3☐ Mild
4☐ Moderate
5☐ Severe
6☐ Very severe

22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? **(circle one)**

1☐ Not at all
2☐ A little bit
3☐ Moderately
4☐ Quite a bit
5☐ Extremely

Arthroscopic Sling Study
SF-36

Site # ☐ — Screening # ☐☐☐ Initials (F&L) ☐☐

Interval: ☐ Pre-op ☐ 6-week ☐ 3-month ☐ 6-month ☐ 12-month ☐ 24-month

☐ Not completed

The next questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	Check one box on each line	**All of the Time**	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
23.	…did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
24.	…have you been a very nervous person?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
25.	…have you felt so down in that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
26.	…have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
27.	…did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
28.	…have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
29.	…did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
30.	…have you been a happy person?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
31.	…did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

32. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends, relatives, etc.? *(Check one)*

1☐ All the time
2☐ Most of the time
3☐ Some of the time
4☐ A little of the time
5☐ None of the time

How TRUE or FALSE is each of the following statements for you?

	Check one box on each line	**Definitely True**	**Mostly True**	**Don't Know**	**Mostly False**	**Definitely False**
33.	I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34.	I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35.	I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36.	My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Arthroscopic Sling Study
WORC

Site # ☐ — Screening # ☐☐☐ Initials (F&L) ☐☐

Interval: ☐ Pre-op ☐ 6-week ☐ 3-month ☐ 6-month ☐ 12-month ☐ 24-month

☐ Not completed

Section A: Physical Symptoms

The following questions concern the physical symptoms you have experienced due to your shoulder problem. In all cases, please enter the amount of the symptom you have experienced in the last week. Please mark your answers with a slash " / ".

Please refer to page 6 for more detailed instructions and explanations of each question.

1. How much sharp pain do you experience in your shoulder?

no pain — 0 ——— 100 — extreme pain ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

2. How much constant, nagging pain do you experience in your shoulder?

no pain — 0 ——— 100 — extreme pain ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

3. How much weakness do you experience in your shoulder?

no weakness — 0 ——— 100 — extreme weakness ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

4. How much stiffness or lack of range of motion do you experience in your shoulder?

no stiffness — 0 ——— 100 — extreme stiffness ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

5. How much are you bothered by clicking, grinding, or crunching in your shoulder?

none — 0 ——— 100 — extreme ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

6. How much discomfort do you experience in the muscles of your neck because of your shoulder?

no discomfort — 0 ——— 100 — extreme discomfort ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

☐ Not completed

Section B: Sports/Recreation

The following section concerns how your shoulder problem has affected your sports or recreational activities in the past week. For each question, please mark your answers with a slash " / ".

7. How much has your shoulder affected your fitness level?

not affected — 0 ——— 100 — extremely affected

(PUT A SLASH " / " ON THE SCALE)

☐☐☐.☐☐ (for office use only)

8. How much has your shoulder affected your ability to throw hard or far?

not affected — 0 ——— 100 — extremely affected

(PUT A SLASH " / " ON THE SCALE)

☐☐☐.☐☐ (for office use only)

9. How much difficulty do you have with someone or something coming in contact with your affected shoulder?

no fear — 0 ——— 100 — extremely fearful

(PUT A SLASH " / " ON THE SCALE)

☐☐☐.☐☐ (for office use only)

10. How much difficulty do you experience doing push-ups or other strenuous shoulder exercises because of your shoulder?

no difficulty — 0 ——— 100 — extreme difficulty

(PUT A SLASH " / " ON THE SCALE)

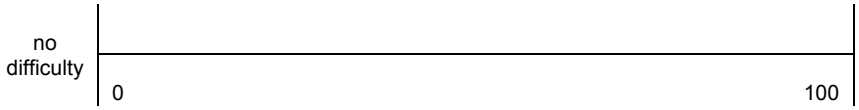
☐☐☐.☐☐ (for office use only)

☐ Not completed

Section C: Work

The following section concerns the amount that your shoulder problem has affected your work around or outside of the home. Please indicate the appropriate amount for the past week with a " / ".

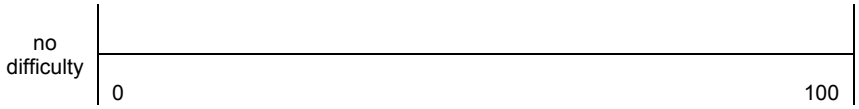
11. How much difficulty do you experience in daily activities about the house or yard?



(PUT A SLASH " / " ON THE SCALE)

☐☐☐.☐☐ (for office use only)

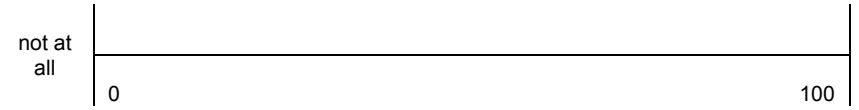
12. How much difficulty do you experience working above your head?



(PUT A SLASH " / " ON THE SCALE)

☐☐☐.☐☐ (for office use only)

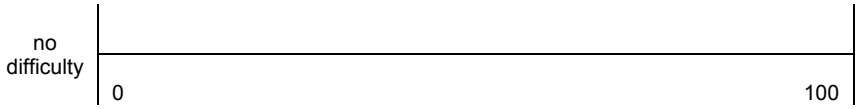
13. How much do you use your uninvolved arm to compensate for your injured one?



(PUT A SLASH " / " ON THE SCALE)

☐☐☐.☐☐ (for office use only)

14. How much difficulty do you experience lifting heavy objects at or below shoulder level?



(PUT A SLASH " / " ON THE SCALE)

☐☐☐.☐☐ (for office use only)

☐ Not completed

Section D: Lifestyle

The following section concerns the amount that your shoulder has affected or changed your lifestyle. Please indicate the appropriate amount for the past week with a " / ".

15. How much difficulty do you have sleeping because of your shoulder?

no difficulty | 0 ——— 100 | extreme difficulty ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

16. How much difficulty have you experienced with styling your hair because of your shoulder?

no difficulty | 0 ——— 100 | extreme difficulty ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

17. How much difficulty do you have "roughhouse or horsing around" with family or friends?

no difficulty | 0 ——— 100 | extreme difficulty ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

18. How much difficulty do you have dressing or undressing?

no difficulty | 0 ——— 100 | extreme difficulty ☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

☐ Not completed

Section E: Emotions

The following questions relate to how you have felt in the past week with regard to your shoulder problem? Please indicate your answers with a slash " / ".

19. How much frustration do you feel because of your shoulder?

no frustration — 0 ——— 100 — extreme frustration

☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

20. How "down in the dumps" or depressed do you feel because of your shoulder?

none — 0 ——— 100 — extreme

☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

21. How worried or concerned are you about the effect of your shoulder on your occupation?

no concern — 0 ——— 100 — extremely concerned

☐☐☐.☐☐ (for office use only)

(PUT A SLASH " / " ON THE SCALE)

An Explanation of the Meaning of the Questions in the Western Ontario Rotator Cuff Index (WORC)

Section A: Physical Symptoms

Question 1: Refers to pain in your shoulder that is quick and sudden or that you might refer to as a catching type of pain.

Question 2: Refers to the dull background ache that always seems to be there as opposed to the sharp pain that is referred to in question 1.

Question 3: Refers to a lack of strength to carry out a movement.

Question 4: Refers to the feeling of the joint not wanting to move. This is often experienced in the morning upon rising, after exercise, or after a period of inactivity. It could also refer to not having full movement of your shoulder in all or any direction(s).

Question 5: Refers to any of these sounds or feeling that you experience in your shoulder with any type of movement.

Question 6: Refers to the amount of tension, pain, or spasm that you experience in the muscles of your neck that seems to be caused by your shoulder problem.

Section B: Sports/Recreation

Question 7: Refers to the fitness level you maintained before your shoulder became a problem. Include a decrease in muscle tone or strength level, cardiovascular fitness, or strength.

Question 8: Refers to any overhead activity requiring you to use some force in exertion. If you do not throw a ball, please consider any other activity such as spiking in volleyball, throwing a stick to your dog, swimming the front crawl, serving in tennis, etc.

Question 9: Please consider whenever you have been afraid or wary of someone or something hitting or coming into contact with your affected shoulder such as in a sport, a crowded room, an elevator, or someone slapping your shoulder in a greeting.

Question 10: Refers to any exercise requiring you to put force on your shoulder such as push-ups, bench press, etc.

Section C: Work

Question 11: Refer to activities such as raking, shoveling, vacuuming, dusting, weeding, hoeing, and washing windows or floors, etc.

Question 12: Refers to any activity requiring you to raise your arms above shoulder level, e.g., putting dishing in a cupboard, reaching for an object, painting a ceiling or painting above shoulder level, etc.

☐ Not completed

Question 13: Refers to if you now use your other arm for any activity or work where you would ordinarily have done it with the arm on the problematic side. If your other shoulder is also symptomatic from rotator cuff disease or some other disease, then consider how you would answer the question if that shoulder was normal.

Question 14: This does not refer to lifting above your head but to lifting any heavy objects below shoulder level, e.g., a bag of groceries, case of pop, suitcase, equipment at work, books, etc.

Section D: Lifestyle

Question 15: Refers to having to change your sleeping positions, waking up during the night, trouble getting to sleep, or waking up feeling unrested.

Question 16: Refers to anything that you would do to your hair such as combing, brushing, or washing that requires you to reach up with your problematic arm.

Question 17: Refers to any type of rough or vigorous play activity that you would normally engage in with your family or friends.

Question 18: Refers to reaching behind to do up or undo a zipper or button(s), do up or undo a bra, pulling on or removing a sweater or top over your head, or tucking in a shirt or top.

Section E: Emotions

Question 19: Refers to the frustration you feel because of your inability to do things you used to do or that you want to do but can't.

Question 20: Down-in-the-dumps or depressed is self-explanatory.

Question 21: Refers to worrying about your shoulder getting worse instead of better or staying the same and being concerned about what effect that will have on your occupation or work (consider work inside or outside the home).

Appendix 2: Backward and Forward Stepwise Regression Model (Stata Output)

```
. stepwise,pr(.05):logistic PTT study mech_inj Constant abd physical_symptoms
                      begin with full model
p = 0.9893 >= 0.0500  removing abd
p = 0.5769 >= 0.0500  removing study
p = 0.1548 >= 0.0500  removing physical_symptoms_score
p = 0.0692 >= 0.0500  removing mech_inj

Logistic regression                               Number of obs     =        444
                                                  LR chi2(1)        =       6.75
                                                  Prob > chi2       =     0.0094
Log likelihood = -106.42592                       Pseudo R2         =     0.0307
```

PTT	Odds Ratio	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Constant_power	1.067395	.0260743	2.67	0.008	1.017495	1.119743
_cons	.0401831	.0128948	-10.02	0.000	.0214236	.0753695

```
. stepwise,pe(.05):logistic PTT study mech_inj Constant abd physical_symptoms
                      begin with empty model
p = 0.0076 <  0.0500  adding  Constant_power

Logistic regression                               Number of obs     =        444
                                                  LR chi2(1)        =       6.75
                                                  Prob > chi2       =     0.0094
Log likelihood = -106.42592                       Pseudo R2         =     0.0307
```

PTT	Odds Ratio	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Constant_power	1.067395	.0260743	2.67	0.008	1.017495	1.119743
_cons	.0401831	.0128948	-10.02	0.000	.0214236	.0753695

Appendix 3

Goodness of Fit Stata Output

Logistic model for PTT, goodness-of -fit test

Number of observations= 444
Number of covariate patterns= 20
Pearson's chi^2 = 24.73
Prob > chi^2= 0.1326