

School of Physiotherapy and Exercise Science

**Shoulder Pain: Current Surgical Trends and Criteria,
and Exploration of Psychological and Other Factors
Associated with Outcome After Surgery**

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**This thesis is presented for the Degree of
Doctor of Philosophy
of
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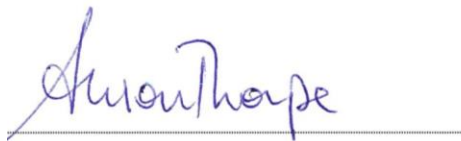
Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgement has been made.

This thesis contains no material that has been accepted for the award of any other degree or diploma in any university.

Human Ethics

The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council Statement on Ethical Conduct in Human Research (2007) – updated in March 2014. The proposed research study received human research ethics approval from the Curtin University Human Research Ethics Committee, Approval Number HR 178/2013; Bethesda Hospital Medical Advisory Committee; and Sir Charles Gairdner Hospital Human Research Ethics Committee, Approval Number 2013-202.

A handwritten signature in blue ink that reads "Alison Thorpe". The signature is written in a cursive style and is positioned above a horizontal line.

Alison May Thorpe

July 2018

Statement of Originality

This thesis is presented for the degree of Doctor of Philosophy at Curtin University Western Australia. Studies were undertaken between January 2013 and May 2018, through the School of Physiotherapy and Exercise Science at Curtin University, in association with Bethesda Hospital, Sir Charles Gairdner Hospital and Osborne Park Hospital, Western Australia.

This research project was developed in association with my supervisors who have been involved in editing both this thesis and all associated publications. All material presented in this thesis is original.

Abstract

Background and research questions

Shoulder pain disorders are commonly seen in clinical practice with one in four individuals reporting an episode of shoulder pain at some stage during their life. Shoulder pain can become persistent and disabling. Current literature does not provide robust clinical guidelines for the best management of shoulder pain.

Shoulder surgery has dramatically increased in popularity over recent decades, with rising trends evident in many countries. It is likely that Australia follows the same global trends, however shoulder surgery trends in Australia have not been reported. There is also a lack of robust criteria to inform the decision for shoulder surgery, with surgeons in the USA and UK lacking agreement regarding surgical indications. It is likely that Australian surgeons also have disparate opinions, however surgical indications in Australia have not been reported. Efficacy for some shoulder surgical procedures has also been questioned.

Added to this complexity is current evidence underpinning a biopsychosocial approach to musculoskeletal pain. Shoulder surgery targets the structural aspects of shoulder pain. Other factors, such as health comorbidities, social, lifestyle, psychological factors and patient expectations have more recently been considered important factors in a biopsychosocial understanding of shoulder pain. These factors may also be associated with surgical outcomes. Outcome after shoulder surgery has been measured by a range of different metrics across shoulder studies. There is a lack of consistency across studies for their use and which measures provide the most contemporary aspect of patient-centred care.

Therefore, the aims of this thesis are:

1. To investigate the trends and associated costs over time of shoulder surgery for rotator cuff disease undertaken in Western Australia during the 13-year period 2001-2013;
2. To survey Western Australian shoulder surgeons for opinions regarding indications for shoulder surgery, clinical tests commonly used to aid surgical decision-making, intra-operative findings predictive of outcome and what constitutes a successful surgical outcome;

3. To explore the existence of clusters with different profiles of psychological measures in patients undergoing shoulder surgery and test if membership of psychological clusters is associated with pain and disability outcomes up to one year after surgery;
4. To investigate the association between three different aspects of patient-centred outcome one year after shoulder surgery, and also the association of these outcomes with psychological factors and other factors previously identified as being associated with outcomes after shoulder surgery.

Study 1: Rising trends in surgery for rotator cuff disease in Western Australia

The following research questions were addressed in Study 1:

- i. Are shoulder surgery trends for rotator cuff disease in Western Australia similar to previous reports of rising surgical trends worldwide?
- ii. Are surgical trends similar across hospital setting, gender and age?
- iii. What are the increases in health care costs as a result of rising surgical trends?

Methods: Numbers and costs for surgical procedures for rotator cuff disease performed in WA were extracted from the WA Department of Health database for the 13-year period, 2001–2013.

Results: Rising surgical trends were demonstrated with arthroscopic subacromial decompression (ASAD) and arthroscopic reconstruction showing large proportional increases of 108.7 and 68.4%, respectively. Increasing trends were mostly linear across hospital setting, gender and age. The rise in consumer price index-adjusted costs for ASAD in private and public hospitals was 273.7 and 320.8%, respectively, and for arthroscopic reconstruction 220.2 and 472.5%, respectively.

Conclusions: The substantial increase in arthroscopic surgery rates for rotator cuff disease and associated costs in WA over the period 2001–2013 is in spite of evidence that surgical outcomes are no different to exercise interventions. Conservative treatments should be recommended as an initial treatment choice, to arrest escalating health care costs.

Study 2: Rotator cuff disease: opinion regarding surgical criteria and likely outcome

The following research questions were addressed in Study 2:

- i. What are Western Australian shoulder surgeons' opinions regarding: indications for shoulder surgery for rotator cuff disease; utility of physical examination tests; tests commonly used to aid decision-making for surgery; findings at surgery that are predictive of outcome and what constitutes a successful outcome of surgery?

Methods: An anonymous rotator cuff survey, previously reported by the American Academy of Orthopaedic Surgeons, was emailed to all surgeons listed with the Australian Orthopaedic Association in Western Australia. Surgeons who treated patients for rotator cuff disease during the previous 12 months were invited to complete the rotator cuff survey and five additional questions were included to capture the above criteria of interest.

Results: Within a close community of surgeons based in Western Australia (n = 23) considerable heterogeneity exists in surgical decision-making criteria. A successful surgical outcome was considered to include reduced pain levels, restoration of movement and function and gains in muscle strength.

Conclusions: Research is required to inform robust clinical practice guidelines for rotator cuff surgery. Identification of prognostic factors for successful surgical outcome is imperative.

Study 3: Are psychological factors associated with shoulder scores after rotator cuff surgery?

The following research questions were addressed in Study 3

- i. Are there identifiable clusters (based on psychological functioning measures) in patients undergoing shoulder surgery?
- ii. Is poorer psychological functioning associated with worse outcome (American Shoulder and Elbow Surgeons [ASES] score) up to one year after shoulder surgery?

Methods: A prospective cohort study investigated patients undergoing shoulder surgery for rotator cuff related shoulder pain or rotator cuff tear by one of six surgeons between January 2014 and July 2015. Inclusion criteria were patients scheduled for surgery for rotator cuff repair with or without subacromial decompression and

arthroscopic subacromial decompression only. One hundred twenty-four patients who underwent shoulder surgery (46 of 124 [37%] female; median age, 54 years [21 to 79 years]) completed four psychological measures before surgery: Depression, Anxiety and Stress Scale; Pain Catastrophizing Scale; Pain Self-Efficacy Questionnaire; and Tampa Scale for Kinesiophobia. The existence of clusters of people with different profiles of affective and cognitive factors was investigated using latent class analysis, which grouped people according their pattern of scores on the four psychological measures. Resultant clusters were profiled on potential confounding variables. The ASES score was measured before surgery and 3 and 12 months after surgery. Linear mixed models assessed the association between psychological cluster membership before surgery and trajectories of ASES score over time adjusting for potential confounding variables.

Results: Two clusters were identified: one cluster (84 of 124 [68%]) had lower scores indicating better psychological functioning and a second cluster (40 of 124 [32%]) had higher scores indicating poorer psychological functioning. Accounting for all variables, the cluster with poorer psychological functioning was found to be independently associated with worse ASES score at all timepoints (regression coefficient for ASES: before surgery -9 [95% confidence interval {CI}, -16 to -2], $p = 0.011$); 3 months after surgery -15 [95% confidence interval {CI}, -23. to -8], $p < 0.001$); and 12 months after surgery -9 [95% confidence interval {CI}, -17 to -1], $p = 0.023$). However, both clusters showed improvement in ASES score from before to 12 months after surgery, and there was no difference in the amount of improvement between clusters (regression coefficient for change in ASES: cluster with poorer psychological function 31 [95% confidence interval {CI}, 26 to 36], $p < 0.001$); cluster with better psychological function 31 [95% confidence interval {CI}, 23 to 39], $p < 0.001$). In addition, membership of the cluster with poorer psychological functioning was associated with smoking ($p=0.050$), an active workers compensation claim ($p<0.001$), higher levels of pain and disability ($p<0.001$), less confidence that surgery would improve symptoms ($p=0.002$).

Conclusions: Patients who scored poorly on a range of psychological measures before shoulder surgery displayed worse ASES scores at 3 and 12 months after surgery. Screening of psychological factors before surgery is recommended to identify patients with poor psychological function. However, further research is needed to determine the optimal management for patients with poorer psychological function to improve pain and disability levels before and after surgery.

Study 4: Different aspects of patient-centred outcome after shoulder surgery are similarly associated with psychological status before surgery

The following research questions were addressed in Study 4

- i. What is the association between three different aspects of patient-centred outcome (patient-reported pain and disability change, global rating of change, satisfaction)?
- ii. Are psychological factors, and other factors previously associated with outcomes, similarly associated with each of the three measures of patient-centred outcome?

Methods: One hundred and fifty three patients scheduled for shoulder surgery completed a survey measuring factors from multiple dimensions (psychological, demographic, health, lifestyle, social, pain and disability) before surgery. Aspects of patient-centred outcome measured at 12 months after surgery were: change in pain and disability (using; American Shoulder and Elbow Surgeons score, Disabilities of the Arm, Shoulder and Hand, Shoulder Pain and Disability Index); global rating of change; and patient satisfaction. Correlations between the three aspects of patient-centred outcome were assessed, and multivariate regression analysis was used to determine and compare associations of each factor measured before surgery with the three aspects of outcome.

Results: All three aspects of patient-centred outcome were moderately to strongly associated with each other (pain and disability change and global rating of change $r=0.63$, $p<0.001$; pain and disability change and satisfaction $r=0.71$, $p<0.001$; satisfaction and global rating of change $r=0.81$, $p<0.001$). After adjustment for potential confounding factors, depression, anxiety and stress symptomatology, pain self-efficacy, confidence that surgery would relieve symptoms, and duration of symptoms were statistically significantly associated with one or more of the three aspects of patient-centred outcome (y -standardised regression coefficients; -0.14 to 0.45, p -values; 0.007-0.048). There was no evidence, with the numbers available, that the strength of associations was different across the three aspects of outcomes for these factors, with the exception of weak evidence that pain self-efficacy may be more strongly associated with satisfaction and global rating of change than changes in pain and disability ($p=0.051$).

Conclusion: Three different aspects of patient-centered outcome provide similar information regarding a good or poor outcome from the individual's perspective at one-year after shoulder surgery. Depression, anxiety and stress symptomatology, pain self-efficacy, confidence in surgical outcome and symptom duration prior to surgery are associated with patient-centred outcome measures one year after surgery. Screening and targeting of psychological factors prior to surgery is warranted and may improve outcomes.

Overall conclusions:

The findings of this thesis highlight the increasing trend for shoulder surgery and associated costs in Western Australia, the lack of consensus amongst surgeons regarding decision making processes for shoulder surgery and the role of psychological factors in outcomes of shoulder surgery. Together these findings highlight the need for a biopsychosocial approach to the screening, examination and management of people with shoulder pain. Evidence based guidelines are needed to assist decision making processes for the management of shoulder pain and in particular for shoulder surgery.

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Publications Arising from this Thesis

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List of Abbreviations

AAOS	American Academy of Orthopaedic Surgeons
AIC	Akaike's information criterion
AOA	Australian Orthopaedic Association
ARC	Arthroscopic reconstruction
ASAD	Arthroscopic subacromial decompression
ASES	American Shoulder and Elbow Surgeons Score
BIC	Bayesian information criterion
BMI	Body mass index
CAIC	Consistent Akaike's information criterion
CI	Confidence interval
CPI	Consumer Price Index
DASH	Disabilities of the Arm, Shoulder and Hand
DASS	Depression, Anxiety and Stress Scale
DOH	Department of Health
DOS	Duration of symptoms
GRC	Global rating of change
IQR	Interquartile range
LCA	Latent class analysis
MCID	Minimal clinically important difference
MODEMS	Musculoskeletal Outcomes Data Evaluation and Management System
MRI	Magnetic resonance imaging
n	Number of participants
NRS	Numeric rating scale
OC	Outcome
OPH	Osborne Park Hospital
ORC	Open reconstruction (rotator cuff repair plus subacromial decompression)
ORCR	Open rotator cuff repair
OSAD	Open subacromial decompression
PCS	Pain Catastrophizing Scale
PSEQ	Pain Self-Efficacy Questionnaire
RCD	Rotator cuff disease
RCR	Rotator cuff repair

RCT	Randomised controlled trial
SAD	Subacromial decompression
SCGH	Sir Charles Gairdner Hospital
SD	Standard deviation
SPADI	Shoulder Pain and Disability Index
TSK-11	Tampa Scale of Kinesiophobia – 11 item questionnaire
UK	United Kingdom
USA	United States of America
VAS	Visual Analogue Scale
WA	Western Australia
WC	Workers compensation
3post	3-month follow-up
12post	12-month follow-up

Chapter 1 Introduction

Shoulder pain is one of the most common musculoskeletal complaints worldwide, with reported prevalence rates in the general population ranging from 7 to 24%.¹ Management options for shoulder pain are diverse with multiple pharmacological, conservative and surgical interventions reported. Despite the variety of management options available and the vast increase in published research investigating different interventions for shoulder pain over the past decade, the optimum management pathway for individuals with shoulder pain continues to be elusive. Evidence-based clinical guidelines for management are limited due to a lack of high quality evidence.² ³ Added to this complexity, is the difficulty in comparing outcomes measured differently across studies.

Historically, management options for shoulder pain target the biological focus of pathology. Surgical management for shoulder pain has experienced dramatic increases in popularity over recent decades, with rising surgical trends evident in many countries.⁴⁻⁷ It is likely that Australia follows the same global trends, however shoulder surgery trends in Australia have not been reported. Despite the increase in surgical rates, current evidence does not support that surgery provides superior outcomes over more cost effective and less risky conservative measures.⁸⁻¹⁰

There is also a lack of robust criteria to inform which individuals make the best surgical candidates, with surgeons in the USA and UK lacking agreement regarding surgical indications.^{3 11, 12} It is likely that Australian surgeons also have disparate opinions, however, surgical criteria in Australia has not been reported.

Current evidence underpins a biopsychosocial approach to musculoskeletal pain. Factors from multiple dimensions, including demographics, general health, social, lifestyle, psychological, physical and biological all have the potential to influence symptoms in musculoskeletal disorders. Despite contemporary management for musculoskeletal disorders such as knee osteoarthritis¹³ and low back pain¹⁴ embracing a biopsychosocial approach, this approach is not well utilized for shoulder pain. Shoulder surgery targets the biological dimension with the assumption that symptoms arise from pathology. Psychological factors are now being considered as potentially playing an important role in shoulder pain ¹⁵⁻¹⁹ and may be important in mediating outcome after shoulder surgery.²⁰

Contemporary healthcare pathways not only advocate a whole person approach to management of conditions, but also outline the importance of individuals being active participants in the choice of intervention and healthcare process. This patient-centred approach to healthcare involves individuals in the decision-making process and also evaluates outcome from the individual's perspective. A patient-centred assessment of outcome may be measured in a variety of ways, including patient-reported pain and disability measures, global rating of change and satisfaction, however it is not clear how these outcomes relate to each other.

The studies in this program of research were designed to address the following research aims:

1.1 Research aims

1. To evaluate the current shoulder surgery trends in Western Australia;
2. To examine current surgeon opinion regarding indications for shoulder surgery for rotator cuff disease;
3. To explore
 - i) the presence of clusters of psychological factors in individuals scheduled for shoulder surgery and their association with factors from multiple other dimensions;
 - ii) the influence of psychological factors before surgery on outcome after shoulder surgery;
4. To evaluate
 - iii) the association between different aspects of patient-centred outcome;
 - iv) if psychological factors, and other factors previously associated with one or more aspects of outcome, are similarly associated with each of the three aspects of patient-centred outcome.

This chapter provides an overview of the literature pertaining to the development of each research question. The significance of each component in the program of research is discussed. The order of the studies is consistent with the order in which chapters 3 to 6 are presented.

1.2 Study 1

What are the current shoulder surgery trends in Western Australia?

1.2.1 Background

Increasing rates of shoulder surgery have been reported over the past decade in a number of countries including the United States of America (USA),^{4, 5} United Kingdom (UK),⁶ and Denmark.⁷ The rising global trends toward surgery to treat shoulder pain worldwide is concerning, with surgery failing to elicit superior outcomes than conservative management^{8, 21} and the efficacy of some surgical procedures currently under question.⁸ It is not known if surgical trends in Australia are escalating at similar rates.

1.2.2 Significance and novelty of the research

This study aimed to estimate the surgical trends and associated costs over time of shoulder surgery undertaken in Western Australia (WA) during the 13-year period 2001-2013. In addition, population-adjusted arthroscopic surgical trends were compared between private versus public hospital setting, gender and different age groups. Knowledge of the trends for shoulder surgery in Western Australia is important to determine if surgery rates in Australia are aligned with published global surgical trends. Regular monitoring of shoulder surgery trends are important and the identification of strategies to contain healthcare costs is necessary with increasing population age.

1.3 Study 2

What is current surgeon opinion regarding indications for shoulder surgery for rotator cuff disease in Western Australia?

1.3.1 Background

Surgical criteria for rotator cuff disease are not clear, with clinical practice guidelines and surveys of surgeon opinion outlining a lack of consensus between surgeons for the management of shoulder pain.^{3, 11, 12} The lack of robust clinical guidelines is a result of limited high quality evidence.^{2, 3} Evidence-based clinical guidelines, surgeon education, surgeon personal experience and individual patient factors may inform surgical decision-making. Surgical views may be similar in the Australian orthopaedic community to previous reports from the USA and UK.

1.3.2 Significance and novelty of the research

This study aimed to explore if Western Australian shoulder surgeon opinion is similar to previous reports from the USA and UK, regarding indications for shoulder surgery, physical tests most commonly used to support surgical decision-making, findings at surgery that may be predictive of outcome after shoulder surgery and opinion about what constitutes a successful outcome after shoulder surgery. Knowledge of current Western Australian shoulder surgeon opinion regarding shoulder surgery indications is important. The continued lack of consensus for shoulder surgical criteria highlight an urgent need for models of care to be developed for the management of shoulder pain.

1.4 Study 3

- i. Are there identifiable clusters (based on psychological functioning measures) in patients undergoing shoulder surgery?*
- ii. Is poorer psychological functioning associated with worse outcome (American Shoulder and Elbow Surgeons [ASES] score) after shoulder surgery?*

1.4.1 Background

Affective psychological factors, including depression and anxiety, are associated with longer duration of shoulder symptoms,¹⁵ higher levels of shoulder disability,^{16, 19} and poorer quality of life.¹⁶ Cognitive psychological factors, including negative pain beliefs and catastrophizing,^{19, 22-25} kinesiophobia,^{23, 24, 26, 27} and low pain self-efficacy^{28, 29} are associated with higher levels of shoulder pain and disability^{24, 26, 28} and predictive of poor outcome or nonrecovery after conservative management.^{22-24, 27, 29} To date, shoulder surgery studies have only explored the association of affective psychological factors on outcome after shoulder surgery, with three studies³⁰⁻³² reporting no association and one study²⁰ reporting that depressed mood and anxiety before surgery was associated with greater pain and disability after shoulder surgery. The association of cognitive factors such as pain beliefs, catastrophizing, kinesiophobia, and self-efficacy with outcome after shoulder surgery has not been reported.

1.4.2 Significance and novelty of the research

This study aimed to explore if differential patterns of affective and cognitive psychological factors were evident in individuals undergoing shoulder surgery and

associated with pain and disability levels before and after surgery. This study found two different clusters of individuals with shoulder pain, with differing psychological profiles, that displayed higher levels of pain and disability before and after shoulder surgery. A comprehensive assessment of affective and cognitive psychological factors before shoulder surgery could identify patients with poor psychological function. Alternative management pathways may be beneficial to improve clinical outcomes.

1.5 Study 4

- i. What is the association between three different aspects of patient-centred outcome (change in patient-reported pain and disability outcome measures, global rating of change, patient satisfaction)?*
- ii. Are psychological factors, and other factors previously associated with one or more aspects of outcome, similarly associated with each of the three aspects of patient-centred outcome?*

1.5.1 Background

Historically, outcome after shoulder surgery has been determined by metrics including clinical examination,³³ imaging,³⁴ complication rates³⁵ and patient symptoms such as pain on a visual analogue scale.³⁶ More recently, patient-centred care has gained greater importance and is considered the foundation of contemporary models of health care internationally, including those for musculoskeletal pain.³⁷ A patient-centred assessment of outcome considers individual patient preferences, needs and values.³⁸ Patient-centred outcome may be measured in a variety of ways, including the widely used patient-reported outcome measures, global rating of change and patient satisfaction. While these patient-centred outcomes appear somewhat similar, there is no clear understanding how these outcomes relate to each other.

Only a small number of factors are consistently reported to be predictive of outcome after shoulder surgery. Recent systematic reviews report that older age,³⁹⁻⁴¹ an active workers compensation claim^{39, 41, 42} and higher levels of pain and disability⁴¹ before surgery are predictive of poor pain and disability outcome after shoulder surgery. However, there is emerging evidence that psychological factors,³⁰⁻³² including cognitions related to surgery such as confidence in the outcome and expectations of surgery,⁴³⁻⁴⁵ are also associated with shoulder pain and disability and other outcomes after shoulder surgery.

1.5.2 Significance and novelty of the research

This study aimed firstly to explore how strongly three different aspects of patient-centred outcome (pain and disability, global rating of change and patient satisfaction) relate to each other and secondly to explore whether psychological factors, and other factors previously associated with one or more of these particular aspects of outcome, are similarly associated with all three aspects of outcome after shoulder surgery. Knowledge of the association between the three different aspects of patient-centred outcome may allow comparison between studies of outcome after shoulder surgery that utilize different outcome measures.

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Chapter 2 Literature Review

2.1 Prevalence and burden of shoulder pain

Shoulder pain may arise from the shoulder joint or from surrounding muscles, ligaments and tendons. Shoulder pain has historically been considered under the biomedical model, where specific structures or pathology are considered to be the primary source of symptoms due to injury or disease. Occasionally shoulder pain can be referred from other structures, such as the spine or visceral organs. Shoulder pain is commonly associated with weakness, stiffness and disability and can often impact an individual's ability to sleep comfortably, participate in recreational activities, complete occupational tasks¹ or undertake activities of daily living.

Prevalence and incidence rates of shoulder pain have been reported in a systematic review.² Of eighteen studies included in the review, prevalence figures differed from 7 to 26% for point prevalence, 19 – 31% for 1-month prevalence, 5 – 47% for 1-year prevalence and 7 – 67% for lifetime prevalence. Older age and being female increased the likelihood of shoulder pain prevalence in these studies. Prevalence rates in adults older than 70 years range from 13– 26% and younger than 70 years range from 7 – 27%.² With increasing prevalence associated with older age and a global ageing population, greater strain on healthcare budgets is a likely consequence. Older adults have an increased life expectancy, higher levels of physical activity in later decades of life and expectations for maintaining an independent and active lifestyle.³ Only one study investigating incidence rates was included in the systematic review². The annual incidence for newly diagnosed cases of shoulder pain in the general population, in a previously pain-free population, was 1% for those aged 31 – 35 years, 2.5% for 42 – 46 years, 1% for 56 – 60 years, 2% for those aged 70 – 74 years.⁴

Shoulder disorders contribute significantly to the financial burden of musculoskeletal disease worldwide. The Global Burden of Disease (GBD) 2010 study⁵ identified five main musculoskeletal (MSK) diseases globally, categorised as osteoarthritis, rheumatoid arthritis, gout, low back pain and neck pain. The remaining musculoskeletal diseases were categorised into a group termed 'Other MSK' disorders⁶ with a global prevalence of 8.4% and considered a major contributor to global disability. Within the 'Other MSK' category shoulder pain was one of eight distinct areas of higher prevalence. This report

recommended that further shoulder specific data needed to be collected. The subsequent Global Burden of Disease (GBD) 2016 study⁷ reported a further increased global burden of musculoskeletal disease of nearly 15% from the previous 2010 study, however no specific shoulder data was reported in the latter study. Within Australia, The Australian Burden of Disease Study 2011⁸ reported that musculoskeletal conditions ranked as the fourth leading contributor and that they were responsible for 12% of the total burden of disease and injury in Australia in 2011. However, specific data regarding the proportion of shoulder disorders within this musculoskeletal conditions classification was not available. In a South Australian population study, 22% of 3000 adults over 18 years in the North West Adelaide Health Study reported shoulder symptoms in either shoulder for most days for more than a month.⁹

Specific reports of the burden of shoulder pain and disability in other countries are available. The Burden of Musculoskeletal Disease United States 2014 Report¹⁰ determined from a National Health Survey 2012, that chronic shoulder pain was the second most common musculoskeletal complaint in the USA during 2012. A large UK population survey of 6000 male and female adults with an age range of 16 to 75 + years across three medical practices, reported that shoulder pain was the third most common musculoskeletal complaint.¹¹ Persistent shoulder symptoms were also common in a further UK population study of 500 adults aged 18-75 years, reporting that for those individuals with shoulder pain, more than 54% of individuals reported ongoing shoulder symptoms three years after initial onset, with almost all shoulder pain cases also reporting ongoing physical or sleep related disabilities.¹² These studies reinforce the significant burden of shoulder disorders to global healthcare systems. Work related shoulder pain presents an additional burden with significant time lost from work, sick leave¹, lost productivity, impaired function and cost to healthcare systems.¹³

Key points

- Shoulder pain prevalence increases with age, posing a health concern given the global ageing population
- Shoulder disorders are a significant contributor to the global burden of musculoskeletal disease

2.2 Factors associated with shoulder pain

There have been a large number of shoulder studies over the past decade investigating factors that have a possible relationship with shoulder symptoms. Shoulder pain and disability has been reported to be associated with a broad range of factors from multiple dimensions including the demographic, health, social (including work), lifestyle (including sport), biological, physical and psychological dimensions (Figure 2.1).

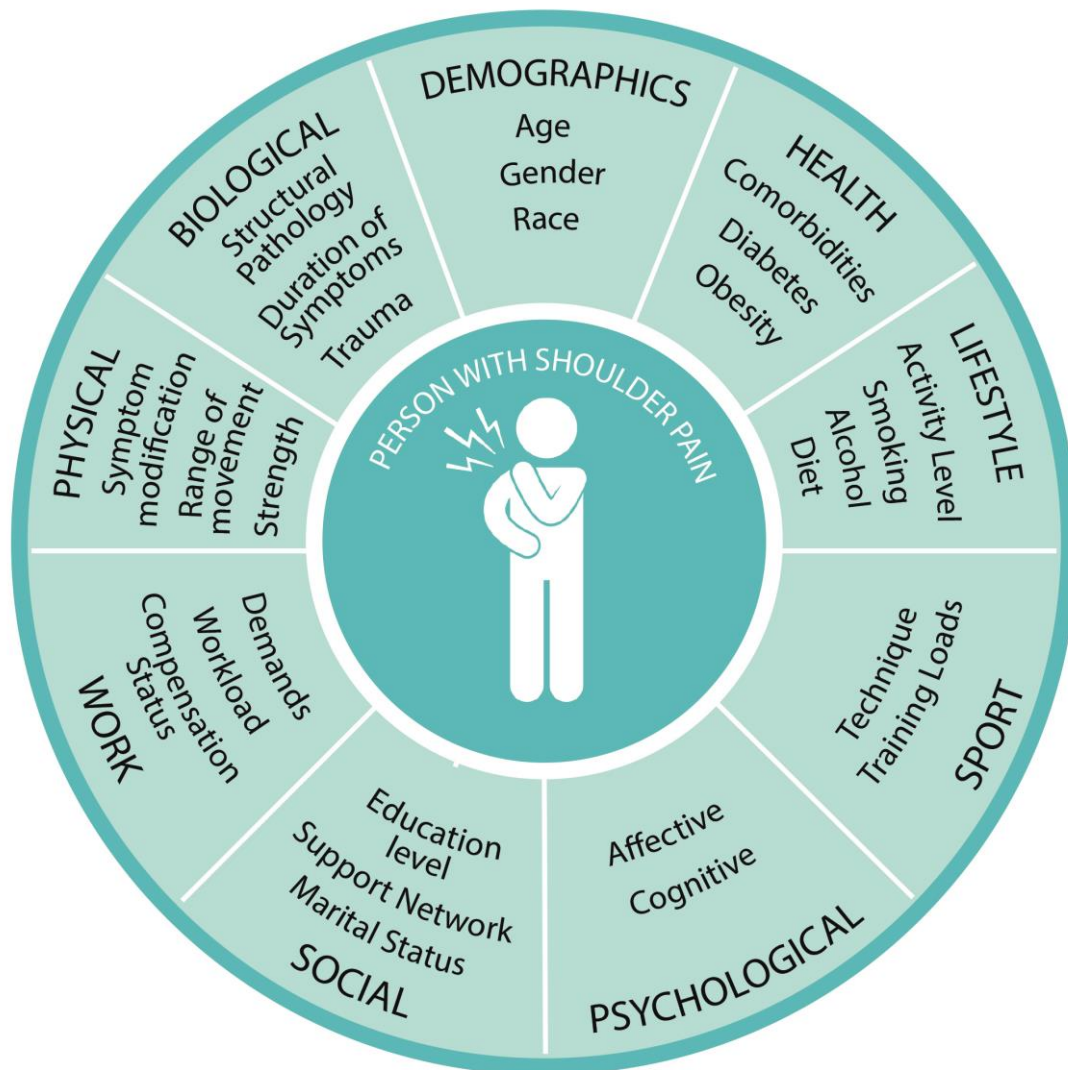


Figure 2.1 Model of a person with shoulder pain considering multiple interacting dimensions

2.2.1 Demographic dimension

Older adults report higher levels of shoulder pain and disability ^{14, 15} than younger adults, with some shoulder conditions such as rotator cuff pathology, considered to be normal correlates of ageing.^{14, 15} It is not clear whether the presence of pathology, that

is potentially age-related, is directly linked to shoulder symptoms. Gender differences are evident for shoulder pain with females demonstrating higher prevalence rates.^{2, 16} Females experience increased levels of shoulder pain and disability than their male counterparts¹⁷⁻²¹ and more emotional disturbances with higher levels of frustration, depression and concern due to their shoulder problem, similar to other areas of musculoskeletal pain.¹⁷ For shoulder pain in the work environment, males are reported to be at greater risk of shoulder pain as a result of work involving vibration and repetitive movements, whereas women are reported to be at greater risk due to lifting heavy loads and working in awkward postures.²²

2.2.2 Biological dimension

The biological aspect of shoulder pain and disability is underpinned by a belief that structural pathology is the primary source of shoulder symptoms. For some individuals with shoulder disorders, biological factors may be the primary source of symptoms following a traumatic event resulting in bone fractures, joint dislocations or acute tendon tear.²³ Early surgery after trauma, within three weeks, has been previously recommended for optimal recovery of tendon repair²⁴ and is a continued recommendation by healthcare providers today.²⁵ However, this is only supported by weak evidence from clinical guidelines.²⁶ The contribution of the biological dimension for insidious onset shoulder pain is less certain. Current evidence highlights the multidimensional nature of shoulder pain with multiple factors potentially associated with pain and disability. In some cases, initial shoulder symptoms may potentially be due to biological factors, such as subacromial bursitis, however the persistent nature of many shoulder disorders^{9, 12} can implicate factors from other dimensions, such as psychological factors.²⁷⁻³⁰ A longer duration of symptoms has been associated with greater shoulder pain and disability,³¹ however it is not clear whether symptoms relate to biological factors or other multidimensional factors. For other cases, Dunn³² showed that biological factors, such as rotator cuff tear severity, showed no correlation with pain level for a larger cross-sectional study of atraumatic, symptomatic, full thickness rotator cuff tears.³² Further supporting that the biological dimension may be less important for persistent shoulder pain, is that poor rotator cuff tendon health has been shown in both symptomatic and non-symptomatic older individuals and is considered a normal correlate of ageing.³³

2.2.3 Physical dimension

Physical factors such as limitations in range of movement,^{18 23} strength deficits^{18 23, 34, 35} and altered patterns of movement^{118, 119} are associated with shoulder pain and disability. For individuals with shoulder pain, a limitation in active shoulder flexion is often observed.⁴³ Strength deficits may also be observed for individuals with shoulder pain. Lower levels of muscle strength have been associated with shoulder pain in the general population.⁴³ Individuals with shoulder pain may adopt postures or move in patterns that may be provocative of symptoms, or alternatively are a consequence of symptoms. Regardless of the cause or effect, they may continue to perpetuate shoulder pain and disability. Previous research in low back pain disorders has suggested that pain provocative movement patterns are suggestive of peripheral nociceptive pain mechanisms, rather than inflammatory or central pain mechanisms that may be a predictor of treatment outcome.^{36, 37}

2.2.4 Health dimension

Higher levels of shoulder pain are associated with poor general health status and comorbidities³² including obesity^{38 39 40} and diabetes.^{41, 42 43} Obesity is risk factor for shoulder pain and has been associated with increased incidence of shoulder disorders in the work environment^{44, 45} and predictive of upper limb tendinopathy in clerical and industrial workers.⁴⁶ Higher adiposity levels are associated with elevated blood glucose, increased systemic lipids, high cholesterol levels and hypertension which are factors that can contribute to tendon disease through altered tendon vasculature, impaired healing and fatty deposition.^{38 39} The mechanism for the association of shoulder pain with obesity is likely to be multifactorial, which may include increased levels of adiposity potentially affecting an individual's desire to participate in physical activity and opting for more sedentary activities⁴⁷ or a reduction in physical activity potentially contributing to the accumulation of adipose tissue.^{48 49}

Diabetics are at increased risk of developing shoulder pain^{41, 42} and report a higher incidence of shoulder stiffness.⁴³ The direct mechanism for this association is not clear and may relate to factors associated with obesity, or to changes in the structural morphology of tendon tissue due to factors such as poorly controlled or elevated blood glucose levels or mechanical derangement in collagen tendon tissue.³⁹ Diabetic individuals fail to improve to the same degree as non-diabetics following shoulder surgery.^{50, 51}

2.2.5 Social dimension

Individuals with a lower education level^{32, 52} report greater pain severity and higher levels of disability. In workers, a lower level of education has been reported to pose an increased risk of non-traumatic shoulder disorders and permanent disability after surgery.⁵² This finding may relate to higher physical work demands, limited access to healthcare or a lack of understanding of their shoulder problem.⁵²

An active workers compensation claim is associated with greater shoulder pain severity^{19, 20} and with higher levels of disability before and after surgery.⁵³ A recent systematic review showed that compensation status of an individual undergoing shoulder surgery is a positive predictor of poor functional outcome⁵⁴ which may be due to factors such as reporting of elevated pain levels, a litigation process or work-related issues such as work satisfaction or motivation.

2.2.6 Lifestyle dimension

Higher levels of shoulder pain are associated with smoking^{19, 42, 55, 56} and there are mixed reports for the association with alcohol use.⁵⁷ Smokers report greater shoulder pain severity, reduced functional capacity and greater risk for poor tendon health in the shoulder,^{19, 42, 55, 56, 58} as has been reported for a range of musculoskeletal conditions.⁵⁹⁻⁶¹ The mechanism for this association is not clear, however smoking may lead to physiological changes potentially increasing pain sensitivity and pain perception, accelerated bony degeneration and delayed tissue healing.⁶² Cadaveric studies support these findings with poor rotator cuff tendon health observed in a greater number of cadavers with a history of smoking, supporting that smoking may facilitate tissue failure and an impaired healing response.⁶³ Smoking is also associated with other factors, such as obesity⁴⁷ and psychological factors such as depression, anxiety and chronic pain conditions, whereby smoking may be a means to cope with pain and psychological distress.^{60, 61}

The association of alcohol consumption and shoulder pain is uncertain, with one study reporting excessive alcohol consumption was a risk factor for shoulder pain and poor tendon health in both males and females⁵⁷ and other studies reporting no association between alcohol consumption and shoulder pain.^{42, 64} The effects of excess alcohol intake may relate to poor tissue health as a consequence of impaired vascularisation, however there is a lack of robust evidence available to make this definitive association.

Demands placed on the shoulder can vary according to age, gender, occupation, sport and other recreational pursuits. The shoulder facilitates skills ranging from positioning the hand for daily function through to highly skilled sporting or occupational activities, often performed under load or at high velocity.⁶⁵ Sports such as throwing⁶⁶ or swimming⁶⁷ place the shoulder at an increased risk of injury due to repetitive overhead motions.⁶⁵ Occupations such as labourers or factory workers may undertake duties involving repetitive or sustained overhead tasks, lifting heavy loads, forceful overhead exertions and exposure to vibration, all known to be risk factors for shoulder pain.⁶⁸ Highly skilled workers such as ophthalmologists and dentists are also prone to shoulder pain due to undertaking work tasks characterised by relatively low muscular efforts that are sustained or repetitive in nature. The cumulative effect of sustained posture over time poses a significant additional risk factor⁶⁹ that may relate to muscular fatigue, or work stress due to time pressures. Thus, multiple factors have the potential to influence the prevalence and severity of shoulder pain and disability in the work environment, with recurrence and persistent symptoms common.

2.2.7 Psychological dimension

Affective and cognitive psychological factors are associated with chronic shoulder pain and disability^{27-30, 70} as has been similarly reported for other musculoskeletal conditions,⁷¹ low back pain,^{37, 72-75} neck pain,⁷⁶ knee osteoarthritis⁷⁷ and elbow and hand conditions.⁷⁸⁻⁸⁰

Affective psychological factors, including depressed mood, anxiety and stress, relate to a mental process in which disturbance of mood is the primary symptom. For individuals with shoulder disorders, affective psychological factors have been investigated in a small number of recent studies, with depressed mood associated with longer duration of symptoms,²⁷ higher disability levels,²⁸ greater pain severity³⁰ and poorer quality of life.²⁸ Cho²⁷ reported higher prevalence of depression and anxiety in people with shoulder pain compared to healthy individuals and Wolfensberger³⁰ reported higher levels of depressive symptoms were associated with higher levels of shoulder pain and disability. For individuals scheduled for shoulder surgery, both Cho²⁸ and Potter²⁹ reported an association of higher levels of depression and anxiety with greater pain and disability levels and worse quality of life. Badcock⁸¹ reported that anxiety and depression were more strongly associated with shoulder disability than pain severity, highlighting that both pain and disability affect psychological health. The

mechanism behind this relationship may reflect emotional distress due to a perception that shoulder pain is unpredictable, uncontrollable and impacting on quality of life, restricting recreation and activities of daily living.

Cognitive psychological factors, such as kinesiophobia, pain catastrophizing and pain self-efficacy relate to a mental process in which understandings, beliefs and attitudes frame thought processes. Cognitive psychological factors, including negative pain beliefs and catastrophizing,^{30, 73, 82-84} kinesiophobia,^{82, 83, 85, 86} and low pain self-efficacy,^{87, 88} are associated with higher levels of shoulder pain and disability^{83, 85, 87} and predictive of poor outcome or nonrecovery after conservative management.^{73, 82, 83, 86, 88} The mechanism for this association may relate to a hesitancy to move due to a fear that movement may exacerbate symptoms or a fear of causing damage to underlying structures, as has been similarly reported in individuals with low back pain.⁸⁹ Other important aspects of cognitive psychological functioning relate to patient expectations and confidence in the outcome of an intervention. Greater patient expectations before surgery are associated with improvement in pain and disability levels from before to after shoulder surgery^{13, 14} and greater patient satisfaction after shoulder surgery.^{17, 18} Patient confidence in the outcome of surgery, not previously explored for shoulder surgery, also relates closely to cognitive psychological functioning, in terms of expectations and beliefs.

The mechanism for the association of psychological factors with shoulder pain and disability is not clear. Campbell suggests that most psychological factors are associated with pain incidence and once pain is removed, so are psychological factors.⁹⁰ Conversely, Taylor suggests that an increased incidence of psychological factors is followed by the development and maintenance of musculoskeletal pain.⁹¹ Anxiety and depression may potentially be a risk factor for the development of shoulder pain, as has been reported for other musculoskeletal conditions.^{75, 77} Alternatively, persistent shoulder pain may place individuals at greater risk of developing anxiety, depression, pain catastrophizing, kinesiophobia or low pain self-efficacy due to the ongoing nature of pain and associated disability. An understanding of subgroups of patients with shoulder pain, with differing psychological profiles, may inform targeted management strategies prior to surgical management.

Conceptual overlap between affective and cognitive factors has been reported in chronic musculoskeletal pain,⁹² low back pain^{75, 93} and knee osteoarthritis⁷⁷ and may reflect a level of general psychological distress. However, there may be distinctions

between these factors that are important with regard to the drivers of pain and disability before and after shoulder surgery. Conceptual overlap versus distinction of psychological disorders was explored in a study by Rabey,⁷⁵ in which people with chronic low back pain were grouped statistically (clustered) according to their individual pattern across a number of different measures of affective and cognitive psychological functioning. Three psychological clusters were identified⁷⁵: one cluster scoring low on all affective and cognitive measures representing better psychological functioning, another scoring high on cognitive measures only, and one scoring high across all affective and cognitive measures, representing poorer psychological function. The latter cluster was associated with greater levels of tissue sensitivity, pain responses to movement, more pain areas and a higher number of comorbidities.⁷⁵ Conceptual overlap of psychological factors for individuals with shoulder pain has not been well explored. Only one recent study by Wolfensberger³⁰ reported that depressive symptoms and pain catastrophizing were more strongly associated with worse shoulder pain and disability than biological factors. A greater understanding of the influence of psychological factors in shoulder pain, and any distinction between them, may allow psychologically-based interventions to be implemented in the management pathway.

Key points

- Individuals with affective psychological factors, relating to moods and emotions, display greater shoulder pain severity, higher levels of disability and poorer quality of life
- Cognitive psychological factors, relating to thoughts and beliefs, are associated with greater levels of pain and disability and poorer outcome after conservative management
- The conceptual distinction of affective and cognitive factors in people with shoulder pain and disability has not yet been explored

2.3 Biomedical model of shoulder pain

The biomedical model of shoulder pain focuses on structural pathology as the primary source of symptoms, with assessment, diagnosis and management based on a strong belief that shoulder pain is driven predominantly by pathoanatomical changes. Within this biomedical model, shoulder pain is believed to arise from multiple structures including bone, muscle, tendon, ligament and bursae, or conditions, such as rotator cuff tendinopathy, glenohumeral joint osteoarthritis, instability, synovitis, capsulitis or acromioclavicular joint

problems.⁹⁴ However, current evidence indicates that differentiation between multiple structures in the shoulder, and the different pathological entities that potentially exist for those structures, is not possible even for experienced clinicians.⁹⁵

Rotator cuff disorders, rotator cuff disease and rotator cuff related shoulder pain are interchangeable terms that account for the majority of shoulder diagnoses seen in clinical practice under the biomedical model, with prevalence rates as high as 85%⁹⁶ of all shoulder disorders. To add further complexity, within the realm of rotator cuff disorders, multiple diagnostic labels have been used including subacromial bursitis, rotator cuff tendinopathy, partial and full thickness rotator cuff tears. There is no uniform agreement regarding the stages of pathology for rotator cuff disorders, which are difficult to define and not able to be differentiated by clinical signs alone. Equivalent findings in the pathological processes, patient history and clinical examination have been reported for patients presenting with both subacromial impingement, rotator cuff tendinopathy, partial and full thickness rotator cuff tears, making clinical differentiation complex.⁹⁷

Early views for the pathogenesis of rotator cuff disorders related to a belief that external mechanical compression of the rotator cuff tendons and subacromial bursa was caused by the coracacromial arch or altered acromion morphology,^{98, 99} leading to subsequent tendon or bursal impingement and trauma to the rotator cuff tendons.^{98, 99} These early views resulted in a dramatic increase in shoulder surgery in an attempt to provide more space for subacromial structures and rotator cuff tendon repair. However, these early proposed mechanisms have since been refuted, with the external acromial impingement model now not considered to be the primary pathological process.⁹⁵

A more contemporary view of pathogenesis of rotator cuff disorders is intrinsic tendon failure as the result of a degenerative process.¹⁰⁰ Early tendon failure can be manifested by the tendon demonstrating increased tenocyte numbers and water retention, leading to tendon swelling, potentially resulting in subacromial impingement.¹⁰¹ Advanced tendinopathy, indicating more advanced tendon disease, results in breakdown in tendon structure, with progression to a thickened degenerative tendon and tendon tears.¹⁰¹ A partial thickness tear suggests partial disruption of tendon fibres, whereas a full thickness tear suggests complete disruption of tendon fibres with the potential of tendon fibre retraction. The intrinsic tendon failure view purports the primary pathological process causes swelling, thickening or tears of the rotator cuff tendons, with ensuing upward pressure on the bursa, acromion and coracoacromial ligament.⁹⁵ Despite a more advanced understanding of intrinsic tendon failure over the past decade, surgical

rates have continued to rise. Under the extrinsic or the intrinsic pathogenesis model, the rationale for surgical procedures such as subacromial decompression to increase the area in the subacromial space for the rotator cuff tendons and bursa is not supported by current evidence.^{102, 103}

The natural history of rotator cuff disorders is not clear with many studies reporting the presence of rotator cuff tears in asymptomatic populations, suggesting the presence of structural pathology may be insignificant.^{14, 104, 105} In addition, as there are high prevalence rates of rotator cuff tears, with no associated functional deficits, reported in asymptomatic older adults,¹⁰⁶ rotator cuff tears appear to be a normal correlate of aging.^{14, 15} Magnetic resonance imaging demonstrates rotator cuff tears in up to 50% of asymptomatic individuals over the age of 60 and as high as 80% over the age of 80.^{14, 33} These findings importantly indicate that when an individual presents to a healthcare provider with shoulder pain, a structural deficit observed on imaging may or may not be a major contributor to symptoms.^{105, 107}

Interventions such as shoulder surgery are undertaken to correct structural deficits under the biomedical model, however if non-biological factors contribute to symptoms, surgery may fail to provide a benefit. In addition, improvement in shoulder pain after surgery cannot solely be attributed to tendon repair, with a recent meta-analysis outlining that shoulder pain and disability consistently improve after rotator cuff repair despite evidence of failed healing.¹⁰⁸ Other factors such as placebo, enforced rest or rehabilitation may also play an integral part in improved pain and disability levels after surgery. This lack of correlation between structural integrity and shoulder pain contributes to the uncertainty surrounding optimum management for many shoulder disorders. Surgeons may also recommend rotator cuff repair surgery with the view that small rotator cuff tears may progress and enlarge to become substantial tears that may become irreparable.¹⁰⁹ In addition, concerns that approximately half of asymptomatic rotator cuff tears become symptomatic over time¹¹⁰ or increase in size^{111 112} may contribute to early surgical recommendations. However as current evidence also supports that shoulder pain is multifactorial, symptom onset may or may not relate to an increase in tear size, and rather, may relate to other non-biological factors.

2.3.1 Diagnostic labels for shoulder pain

Historically, diagnosis of the cause of shoulder pain is based on a combination of clinical history, clinical examination findings and diagnostic imaging.¹¹³ This diagnostic

approach has a focus on assessing specific structures in the shoulder as possible sources of symptoms.

Clinical history is an integral component of assessment for shoulder pain with factors such as history of trauma, duration of symptoms, pain level and functional impairment among the factors considered most relevant.¹¹⁴ However, as shoulder pain may be mediated and moderated by variables from multiple other dimensions such as demographics, health co-morbidities, social and lifestyle factors, physical factors and psychological factors, clinical history must encompass clinical assessment across multiple dimensions.^{28, 29, 115}

Current evidence indicates that clinical examination using orthopaedic tests does not reliably differentiate between shoulder disorders, nor confirm that specific structures are a source of symptoms. Recent systematic reviews report that clinical test findings alone are not reliable indicators of specific pathology due to poor diagnostic specificity.¹¹⁶⁻¹¹⁸

Diagnostic imaging is frequently undertaken for shoulder disorders and may further complicate the diagnostic process. Structural abnormalities in the shoulder may be detected that are not correlated with patient symptoms.^{107, 119} These imaging findings in turn lead to diagnostic labels such as rotator cuff tendinosis, partial or full thickness rotator cuff tear, calcific tendinopathy, and subacromial bursitis, with no firm evidence that these pathological entities are a source of symptoms for the individual. These diagnostic labels may have significant implications for engagement with, and the success of conservative management such as physiotherapy,¹²⁰ if individuals believe their symptoms relate to pathology such as rotator cuff tear. An added associated risk with the increased use of imaging is the perception by both individuals with shoulder pain and their healthcare providers to pursue interventions such as surgery, based on potentially incidental findings observed on such readily accessible imaging.

A diagnostic approach utilising imaging and clinical examination has merit to provide evidence of specific pathology, such as fractures or displaced glenohumeral joint dislocation, for acute or sub-acute onset of shoulder pain following a history of trauma. However, these diagnostic measures have less utility in shoulder pain of insidious onset and chronic shoulder pain, as the evidence to support the association of shoulder pain with specific shoulder disorders is limited^{32, 107} and contemporary evidence supports the multidimensional nature of shoulder pain.

Key points

- The biomedical model underpins that structural pathology is the primary source of symptoms
- Natural history and pathogenesis of rotator cuff disorders is uncertain
- Surgery targets structural pathology and does not consider the multidimensional aspect of shoulder pain
- Orthopaedic tests are not reliable indicators of specific pathology, nor do they confirm that specific structures are a source of shoulder symptoms
- Diagnostic imaging may detect structural abnormalities in the shoulder that are not correlated with symptoms

2.4 Biopsychosocial model of shoulder pain

Contemporary management of musculoskeletal pain supports a biopsychosocial approach to pain, with the pain experience variable among individuals due to social, cultural, environmental, psychological and genetic factors, with all having the potential to contribute to the pain experience.⁸⁴ The biopsychosocial approach acknowledges the different dimensions that can contribute to an individual's pain experience. Consideration of the multidimensional aspects of shoulder pain is important, even in instances where trauma is associated with onset of shoulder symptoms. In the absence of a clear cause of symptom onset (insidious), this biopsychosocial approach becomes even more important, as pathoanatomic factors are less likely to explain symptoms. While there is broad clinical evidence and contemporary models of care that support this approach, the traditional biomedical approach to assessment and diagnosis of shoulder pain persists in clinical practice.²⁵ For shoulder research, vast numbers of studies over the past decade measuring outcome after shoulder surgery, or prognostic factors for successful surgical outcome have a primary focus on structural pathology and tendon repair under the biomedical model.

Pain is complex, and may be a measure of potential threat rather than tissue damage,^{121, 122} with greater pain severity associated with greater perceived threat.¹²² Management of shoulder pain under a purely biomedical model that aims to treat tissue damage does not adequately address this complex nature of pain.¹²³ A shift towards the assessment, diagnosis and management of shoulder disorders under a more contemporary biopsychosocial model is needed, where the focus is directed towards managing shoulder symptoms and not shoulder structural pathology.

Key points

- Contemporary evidence supports that shoulder pain is multidimensional, supporting the biopsychosocial model
- The biomedical model continues to underpin the assessment, diagnosis and management of shoulder disorders
- A shift towards the assessment, diagnosis and management of shoulder disorders under the biopsychosocial model is needed

2.5 Management of shoulder pain

Shoulder pain can be managed conservatively or surgically. Conservative management options range from pharmacology, injection therapy, physiotherapy and exercise therapy. Surgical management can take the form of an open, mini-open or arthroscopic surgery with various procedures possible to address potential structural defects in bone, muscle, tendon, capsule or ligament. For fractures or joint dislocations in the shoulder, published guidelines inform early intervention and management for some shoulder disorders such as fractures in adults¹²⁴ and glenohumeral joint dislocations in young adults.¹²⁵ For rotator cuff disorders, clinical guidelines for management based on current evidence are available, however they provide inconclusive evidence for optimum management.²⁶

2.5.1 Conservative management

Conservative (non-surgical) treatments for shoulder pain are rarely used in isolation and clinical guidelines for evidence based conservative management are lacking. A model of care for the conservative management of rotator cuff disorders in the workplace has been reported¹²⁶ and provides 32 recommendations to assist health care providers make informed decisions regarding management and optimized recovery.

Pharmacological interventions, such as paracetamol or non-steroidal anti-inflammatory medication (NSAIDs), are commonly used in the management of shoulder pain, to facilitate resumption of usual activity and undertake an appropriate rehabilitation exercise program. Persistent and more severe pain may have adverse psychological and physiological side effects that can impact recovery and necessitate additional pain management. The workplace model of care recommends initial paracetamol for mild to moderate shoulder pain and NSAIDs alone or in combination with paracetamol for acute shoulder pain.¹²⁶

Injection therapy is commonly used both as a treatment and diagnostic tool in the management of shoulder pain. Efficacy for injection therapy is varied, with cortisone injection reported to provide limited short-term benefit¹²⁷ and platelet-rich plasma no benefit¹²⁸ for the management of rotator cuff disorders. The workplace model of care recommends that a subacromial cortisone injection combined with local anaesthetic may be beneficial for workers with persistent pain, or those who fail to progress after an exercise therapy program.¹²⁶ However, the long term results of cortisone injection are reportedly equivocal, and no better than other conservative measures.¹²⁷

Physiotherapy management with targeted exercise therapy is a useful conservative measure in the management of shoulder pain, with current evidence supporting exercise therapy for shoulder pain due to subacromial pain syndrome^{129, 130} and rotator cuff tears.³ Two recent systematic reviews exploring exercise therapy for full thickness rotator cuff tears and rotator cuff tendinopathy report marked heterogeneity amongst the studies reviewed with regards to outcomes measured, inclusion criteria and exercise prescription, making meta-analysis not possible.^{131, 132} Ainsworth¹³¹ reported low level evidence from 8 observational case series and two single case series, to support exercise therapy in the management of full thickness rotator cuff tears. Littlewood¹³² reported findings from 12 studies included in the review, that there was no evidence that one form of exercise was superior to others, however resistance exercise was considered an integral component of exercise therapy. In a large prospective cohort study, Kuhn¹³³ showed that a specific physiotherapy protocol was effective for treating individuals with atraumatic full thickness rotator cuff tears. This program resulted in 75% of individuals satisfied with outcome at two-year follow up. As physiotherapy can take many different formats,¹³² a lack of evidence for the optimum physiotherapy program makes it difficult for surgeons to determine if an individual has undertaken an appropriate and targeted program prior to recommending surgery.

There are mixed reports about the potential negative sequelae of conservatively managed rotator cuff tears, such as tear progression and fatty degeneration.¹³⁴⁻¹³⁶ However, the relationship between tear progression and higher levels of pain and disability is uncertain. Current evidence does not support that tear progression is a given consequence of conservative management, with satisfactory shoulder function often maintained despite progression of pathology.¹³⁷ These reports reinforce the dilemma regarding surgical decision-making.

2.5.2 Surgical management

Shoulder surgery is based on a biomedical model of pain where surgical repair of damaged tissues is purported to lead to a reduction in symptoms.¹³⁸ Surgical management, including subacromial decompression and rotator cuff repair, is often recommended when conservative management fails, with individuals experiencing persistent pain and functional impairment.^{126, 139} However over recent decades, shoulder surgery has gained in popularity and may be an initial treatment choice for some individuals.

Surgical management can take the form of an open, mini-open or arthroscopic procedure. Under any of these three different procedures, the surgical interventions performed may include acromioplasty, bursectomy, subacromial decompression, debridement or rotator cuff repair, along with concomitant procedures involving the clavicle, biceps tendon or labrum. Acromioplasty involves removal of bone from the undersurface of the acromion. Bursectomy involves removal of the subacromial bursa. Subacromial decompression may include subacromial bursectomy and removal of the coracoacromial ligament in combination with acromioplasty. Debridement involves the removal of damaged tendon tissue or bursal fragments in the subacromial space. Rotator cuff repair may be a partial or full repair to restore integrity of the tendon by surgical suture of the tendon defect. For massive tears involving more than one tendon, or a large tear with tendon fibre retraction, repair may not be possible.

Efficacy for shoulder surgery is limited,²⁶ with the American Academy of Orthopaedic Surgeons (AAOS) clinical practice guidelines for rotator cuff disorders providing only low level evidence for surgical repair of full thickness tears in symptomatic individuals and early surgical repair after acute injury.²⁶ For younger individuals with rotator cuff tendon tears following a history of trauma, early tendon repair within three weeks to six months, has been recommended¹⁴⁰ and supported by weak evidence from the AAOS clinical practice guidelines.²⁶ For older adults, surgical concerns relate to high prevalence rates of rotator cuff disorders,¹⁵ the potential of poor healing with increasing age,^{141, 142} a decrease in vascularity of the tendons,¹⁴³ greater pathological changes seen on imaging (such as fatty degeneration)³ and less successful outcomes reported. If surgery is considered after a period of failed conservative management, the surgical challenge is to identify elderly individuals with the greatest chance of a successful outcome.³

Studies investigating outcomes after shoulder surgery for rotator cuff disorders have reported good to excellent results for symptomatic individuals undergoing subacromial

decompression¹⁰² and rotator cuff repair.¹⁴⁴⁻¹⁴⁶ However, as these studies have only investigated individuals undergoing surgery, there is no comparison to sham surgery, conservative management or no treatment, and the natural course of recovery is unknown. A recent randomised controlled trial compared subacromial decompression surgery, sham surgery and no treatment.¹⁰² Both surgical groups had better pain and disability outcome than no treatment, however the difference did not reach clinical significance. An important finding of this study was that subacromial decompression appeared to offer no extra benefit over sham surgery only, questioning the direct benefit of subacromial decompression as a treatment for shoulder pain. The benefit conferred by both surgical groups over the no treatment group suggests that the effect of the surgical procedure could be attributed to the placebo effect, or relative rest or physiotherapy after surgery.

Despite the limited efficacy for surgery for rotator cuff disorders, surgery remains a treatment of choice for shoulder pain worldwide¹⁴⁷⁻¹⁵⁰ and surgery rates are increasing in many countries.^{52, 148-151} Procedures such as subacromial decompression and rotator cuff repair target the pathoanatomical features of shoulder pain. However, recent research outlines that changes in pain and disability following surgery are not predicted by structural integrity of the rotator cuff.¹⁵² Many individuals report improvement in symptoms following surgery despite failed healing or re-tears of the rotator cuff tendon demonstrated on imaging.^{108, 153} This again challenges the biomedical model where the pathological tendon is not the primary source of shoulder pain symptoms. For those individuals who do show improvement after surgery, it is not clear if surgical management provides a placebo effect, facilitates a period of relative rest and rehabilitation after surgery, or improves on the course of natural history, as the natural history for rotator cuff disorders is not well-defined.^{154, 155}

2.5.3 Conservative versus surgical management

Several studies have compared conservative with surgical management for shoulder pain. A recent systematic review of 7 randomised controlled trials (RCTs) reports moderate evidence that surgery and exercise therapy are equally as effective in reducing pain intensity for individuals with rotator cuff related shoulder pain.¹⁵⁶ In support of this review, two additional RCTs have compared outcomes of surgery with physiotherapy (exercise rehabilitation) for individuals with rotator cuff tears. In the first RCT, Kukkonen¹⁰³ compared three groups: physiotherapy (exercise rehabilitation); acromioplasty and physiotherapy; and rotator cuff repair, acromioplasty and

physiotherapy, for the treatment of symptomatic, non-traumatic supraspinatus tears in 167 patients, older than 55 years. They reported no statistically significant, nor clinically important differences in outcome between the three groups for pain and disability scores and patient satisfaction at one year¹⁵⁷ and two year¹⁰³ follow up. They concluded that physiotherapy should be considered as a primary initial treatment for shoulder pain in the presence of isolated, symptomatic, non-traumatic, rotator cuff tears. In the second RCT, Moosmayer¹⁵⁸ compared primary tendon repair with physiotherapy for small and medium sized full-thickness rotator cuff tears in 103 patients, older than 50 years. While improvements in disability and pain favoured the surgical group over the physiotherapy group for pain and disability scores at one, two and five year follow-up, the authors acknowledge the size of the effect was small and may not be of clinical importance.¹⁵⁸ An initial treatment strategy for a primary trial of physiotherapy for small and medium-sized rotator cuff tears was recommended.

Current conservative management is largely based on the biomedical model. There has been little evaluation of multidimensional or multidisciplinary care models for the management of shoulder disorders, with comparative studies evaluating the effectiveness of physiotherapy directed exercise therapy to surgery.^{103, 158} For other musculoskeletal areas, the landscape is currently changing toward psychologically informed physiotherapy.¹⁵⁹ A recent randomized controlled trial in people with knee osteoarthritis showed that a multidisciplinary model of care improves patient outcomes.¹⁶⁰ An integrated behavioural approach for the management of low back pain has recently been reported.³⁶ There may be a role for psychologically informed practice for individuals with shoulder pain, to address the behavioural aspects of pain, within a patient-centred approach.¹⁶¹

Key points

- Conservative management is largely based on the biomedical model and surgery targets the biomedical model of shoulder pain
- Physiotherapy directed exercise therapy should be recommended as initial treatment choice
- Limited guidelines for surgery are available due to low quality evidence
- Equivocal outcomes are reported for surgery and conservative management of shoulder pain
- A psychologically informed physiotherapy approach for shoulder pain management is needed

2.6 Shoulder surgery trends

Rates of shoulder surgery have been escalating in many countries over the past decade. In the United States of America, shoulder surgery rates were reported to have increased by 440% for subacromial decompression and by 353% for rotator cuff repair¹⁴⁹⁻¹⁵¹ from 1996 to 2006. In the United Kingdom, surgery rates were reported to have increased by 746% for subacromial decompression from 2000 to 2009.¹⁴⁸ In Denmark, shoulder surgery rates were reported to have increased by 300% from 1996 to 2008.⁵² These rising surgical trends are associated with concurrent increases in health care costs.^{144, 162-170}

A recent systematic review highlighted that future health care resource allocation for shoulder disorders will need to be based on feasibility of treatments that provide better health outcomes.¹⁶² These authors report that there is an inadequate quantity and quality of publications on the economics of shoulder care. A recent systematic review of 32 studies explored economic costs for several shoulder disorders and treatment and reported an urgent need for further research with rigorous economic evaluations.¹⁶²

Multiple factors may underpin the increase in shoulder surgery rates. First, patient demand for surgical intervention may be driving rates up. This may be as a result of an increased awareness and understanding of surgical procedures available for rotator cuff disorders, a greater expectation of quality of life linked with increased life expectancy and greater access to private health insurance. Second, a greater supply of orthopaedic surgeons may increase surgical rates. More surgeons trained in arthroscopic surgery techniques for rotator cuff disorders, with advances in surgical instrumentation, repair techniques and suture anchors, along with the advent of nerve blocks for high risk surgical patients may contribute to the rising rates.^{148, 149, 171, 172} Finally, both of these factors are likely to be reinforced by greater access to imaging modalities, such as magnetic resonance imaging and ultrasound, which are sensitive to detecting shoulder pathology.^{119, 173} This can lead to the perception by both consumers and their healthcare providers to pursue surgery, based on potentially incidental findings observed on imaging.

The rising surgical trends are occurring in spite of current evidence highlighting that shoulder pain is multidimensional and the lack of high-level evidence guiding treatment choice for shoulder pain.²⁶ Recent research suggests that there is little difference in clinical outcomes between conservative treatments and surgical approaches,^{103, 157, 158, 174} highlighting the urgent need for clinical research to better inform clear management guidelines for patients with shoulder pain. Surgical trends and associated costs have not

previously been reported for an Australian population. It is likely that Australian surgical trends for rotator cuff disorders are similar to other countries. It is important to understand if Australia follows the same surgical trends that have been reported worldwide to inform of the impact on the Australian healthcare system.

Key points

- Shoulder surgery rates and associated costs are rising worldwide
- Australian surgical trends and associated costs need to be investigated

2.7 Surgical decision-making

Shoulder surgery is an elective procedure, for which management decisions are complicated, influenced by both surgeon and patient preferences, and involve an evaluation of trade-offs between risks, costs and benefits. Surgical decision-making involves an evaluation of the individual patient factors considered relevant as indicators for and against surgery, with the ultimate decision based on a combination of evidence-based guidelines, prior learning and personal experience. There is a lack of robust surgical indications for shoulder pain associated with rotator cuff disorders, with clinical practice guidelines and surveys of surgeon opinion outlining a lack of consensus between surgeons for the management of rotator cuff disorders.^{26, 139, 175} Evidence-based clinical guidelines, surgeon education, surgeon personal experience and individual patient factors may inform surgical decision-making. The lack of robust clinical guidelines is a result of limited high quality evidence.^{26, 176} Clinical examination tests may assist with decision-making, however tests lack robust evidence and therefore are poor diagnostic tools.¹¹⁶ Contemporary health care pathways advocate the need for a shared decision-making process between individuals and their surgeon.^{177, 178}

Surgical opinions regarding indications for shoulder surgery are varied, as indicated by the results of a survey sent to American Academy of Orthopaedic Surgeons.¹⁷⁵ Fifteen questions relating to clinical decision-making for surgery, plus four clinical vignettes and association with reported surgical volumes were investigated. A lack of clinical agreement about indications for rotator cuff surgery was evident among surgeons. Surgeons performing higher volumes of surgery were more optimistic they would achieve a good outcome of rotator cuff surgery, than those performing fewer procedures. It is unknown if Australian Orthopaedic surgeons perceptions about indications for surgery are similar to those opinions previously reported in the USA¹⁷⁵ and UK.¹³⁹

Key points

- There is a lack of robust evidence to guide surgical decision-making for shoulder pain linked to rotator cuff disorders
- Australian surgical criteria needs to be investigated

2.8 Measuring outcome after shoulder surgery

2.8.1 Traditional methods of measuring outcome

Traditionally, outcome after shoulder surgery has been determined by metrics including clinical examination,¹⁷⁹ imaging¹⁸⁰ complication rates¹⁸¹ and patient report of progress such as pain on a visual analogue scale.³² Clinical examination by the surgeon can provide objective measures of range of movement and strength, however these do not always provide an accurate assessment of outcome that is clinically meaningful to an individual. Imaging such as ultrasound or MRI provide evidence of structural integrity after rotator cuff repair surgery, however the value of imaging as an outcome measure has recently been in question, as healing rates for rotator cuff repair are varied^{171, 182} and improvements in function and satisfaction have been reported despite failed healing evident on imaging.^{141, 183}

Complications after shoulder surgery such as anaesthetic reaction, wound infection, haemorrhage, failed healing and death¹⁸¹ are important metrics from the surgeon perspective, but these metrics do not provide an indication of clinically meaningful improvement for the individual after shoulder surgery.

2.8.2 Measuring patient-centred outcome

Over the last ten years, patient-centred care has gained greater importance and is considered the foundation of contemporary models of health care internationally, where individuals are partners in their healthcare.¹⁸⁴ Patient-centred care respects individual patient preferences, needs and values and ensures that the individual guides clinical decision-making.¹⁸⁵ Measuring patient-centred outcome after an intervention allows assessment of whether the preferences and needs of the individual have been met. Patient-centred outcome may be measured in a variety of ways, including shoulder-specific pain and disability outcome measures, health-related quality of life, global rating of change and satisfaction.

Patient-reported pain and disability outcome measures for the shoulder have increased in recent decades both in number and popularity. Over thirty different patient-reported pain and disability measures have been reported and are an important source of data for investigation of outcome after shoulder surgery.¹⁸⁶ The use of these measures prior to and after surgery capture changes in pain and disability from before to after surgery from the individual's perspective^{186, 187} and are widely accepted measures used clinically and in research. Previous studies have explored responsiveness and reliability of different pain and disability measures,¹⁸⁸⁻¹⁹⁰ with the American Shoulder and Elbow Surgeons score (ASES), Disabilities of the Arm, Shoulder and Hand (DASH) and Shoulder Pain and Disability Index (SPADI) reported to be the most extensively studied in research¹⁹¹ and to be similarly responsive.^{186, 188, 192}

Global rating of change (GRC) has been used in musculoskeletal research to quantify improvement or deterioration over time,¹⁹³ and has utility as an outcome measure due to its simplicity and time efficiency. GRC provides an overall rating of change over the course of an intervention. For example, an 'overall improvement' rating for pain can be scored from -7 (very much worse) to +7 (very much better). GRC is commonly used in anchor-based methods to determine minimal clinically important change for musculoskeletal patient-reported outcomes,¹⁹⁴ based on the premise that these constructs are closely linked. GRC has not been reported as an outcome measure for studies investigating outcome after shoulder surgery.

A recent systematic review exploring the conceptualisation of patient satisfaction reported that patient satisfaction is a crucial, multidimensional and widely measured outcome of health service.¹⁹⁵ However the review also showed that most of the patient satisfaction theories and formulations are based on marketing theories and define satisfaction as how well a health service fulfils patient expectations. This review also found that the relationship between patient expectations and satisfaction is unclear. For orthopaedic surgery, higher satisfaction rates following total hip arthroplasty^{196, 197} and spinal surgery^{198, 199} are associated with better pain and disability scores after surgery. Measuring patient satisfaction with surgical outcome is not new, but has only more recently been utilized as a measure after shoulder surgery as an important indicator of outcome in patient-centered care models.²⁰⁰⁻²⁰² Although individuals may report improvements in pain and disability scores after shoulder surgery, they may report dissatisfaction after surgery. Satisfaction has also been used in anchor-based methods to determine minimal clinically important change for musculoskeletal patient-reported

outcomes,²⁰³ based on the premise that these constructs are closely linked. Higher satisfaction after shoulder surgery has been associated with lower pain and disability levels pre-surgery²⁰⁰⁻²⁰² and post-surgery.²⁰⁴

An understanding of what constitutes a successful outcome after shoulder surgery is important as it may influence whether or not an individual seeks additional or alternative care. Different measures of patient-centred outcome may reflect similar or importantly different aspects of outcome after shoulder surgery, that reflect meaningful improvements to an individual. While these patient-centred outcomes appear somewhat similar, there is no clear understanding how these outcomes relate to each other in the context of shoulder surgery. An understanding of these similarities or differences will facilitate comparison between the large number of studies that investigate prognostic factors for outcome after shoulder surgery using a range of different measures of patient-centred outcome.

Key points

- Traditional measures of outcome such as imaging and complication rates are not aligned with measures of patient-centred outcome
- A patient-centred model of care that engages individuals as partners in their own healthcare is underpinned by the use of patient-centred outcomes, and assesses improvement after an intervention that is meaningful to an individual
- It is not clear how different measures of patient-centred outcome relate to each other and if they reflect similar or different aspects of outcome after shoulder surgery

2.9 Factors associated with outcomes after shoulder surgery

Over sixty different prognostic factors have been investigated for an association with outcomes after shoulder surgery. These factors can be broadly classified into three categories: patient-related factors; disease-related factors; and procedure-related factors. Disease-related (eg. rotator cuff tear size, tendon retraction, fatty degeneration) and procedure-related (eg. concomitant surgical procedures) factors are aligned with the biomedical model of shoulder pain that assumes shoulder pain and disability is a direct consequence of pathology, and do not support the multi-dimensional nature of shoulder pain under the biopsychosocial model.

2.9.1 Patient-related factors

Multiple patient-related factors have been investigated as prognostic indicators of worse pain and disability outcome after shoulder surgery across multiple studies and include demographic (older age,^{35, 146, 204-210} female gender^{35, 205-207}), health (poorer general health status,²⁰⁷ higher body mass index,²¹¹ presence of comorbidities²⁰⁷ including diabetes^{212, 213} and obesity³⁸), lifestyle (smoking^{207, 214-216}), social (lower education level,²⁰¹ an active workers compensation claim,^{53, 54, 207} higher physical occupational demands²¹⁷), physical (pre-operative stiffness,²¹⁸ deficits in range of movement^{34, 35} and strength^{34, 35}), psychological (anxiety,^{218, 219} depression^{218, 219} and psychological distress²²⁰) and lower patient expectations of surgery.^{207, 221}

Despite the large number of reported prognostic factors, five recent systematic review papers^{152, 222-225} and one review²²⁶ report that only older age, an active workers compensation claim and worse pain and disability scores before surgery are consistently associated with poorer pain and disability scores after shoulder surgery. However, with contemporary evidence supporting a biopsychosocial model of shoulder pain, a recent report highlighted the need for future studies to further investigate the association between psychological factors and patient expectations before surgery with patient-centred outcome after shoulder surgery.²²⁷

2.9.2 Psychological factors

Psychological factors, both cognitive and affective, have been previously associated with poorer outcomes after surgery, including increased pain and disability following orthopaedic procedures such as hip and knee arthroplasty,²²⁸⁻²³¹ anterior cruciate ligament reconstruction,²³² spinal surgery^{233, 234} and recovery from an acute fracture.²³⁵ A recent narrative review highlighted the need for surgeons to be cognisant of the potential association of psychological factors with outcomes after shoulder surgery.²³⁶ The review recommended the use of screening tools to measure psychological factors before surgery, in order to identify individuals who may benefit from more detailed psychological assessment, as psychological distress may not be discerned from patient history and physical examination.

For shoulder surgery, previous studies exploring the association of affective psychological factors with outcome after surgery have reported conflicting findings.^{218, 219, 237, 238} Koorevaar²¹⁹ reported symptoms of distress, depression, anxiety and

somatisation were not associated with worse pain and disability outcome at one year follow-up after shoulder surgery. Potter²³⁷ reported that psychologically distressed patients achieve similar pain and disability outcome as non-distressed patients at one-year after rotator cuff repair. Cho²¹⁸ reported that depression, anxiety and insomnia before surgery did not predict worse pain and disability outcome at one-year after rotator cuff repair. In contrast, Dekker²³⁸ reported that higher anxiety and depression scores before shoulder surgery were associated with worse pain and disability outcomes, however these individuals still showed improvement from before to six months after surgery. None of these recent studies considered cognitive factors for their association with outcome after surgery, despite their association with worse pain and disability outcome after conservative management.^{73, 82, 83, 86, 88}

Cognitive factors are an important consideration in people undergoing shoulder surgery, as individuals displaying kinesiophobia may be apprehensive to move their arm due to fear of pain or fear of damaging a repaired tendon after rotator cuff repair surgery. People with low levels of pain self-efficacy, meaning a lack of belief in their own ability to manage pain, cope and function in the presence of persistent pain,²³⁹ may continue to experience shoulder symptoms in the absence of any nociceptive source of symptoms before and after shoulder surgery, and beyond the expected recovery time after surgery. People with persistent shoulder pain may catastrophize about their symptoms and display negative pain responses such as magnification, rumination and helplessness that amplify their pain response before and after shoulder surgery.²⁴⁰

Differential patterns of affective and cognitive psychological factors in patients undergoing shoulder surgery may be evident, and potentially associated with pain and disability levels before and after surgery, however this remains unexplored. Conceptual overlap between affective and cognitive factors has been reported in chronic musculoskeletal pain,⁹² low back pain,^{75, 93} and knee osteoarthritis⁷⁷ and may reflect a level of general psychological distress. Alternatively, there may be important distinctions between these two factors, as identified in a study by Rabey⁷⁵ in which people with chronic low back pain were grouped statistically (clustered) according to their individual pattern across a number of different measures of affective and cognitive psychological functioning. Three psychological clusters were identified: one cluster scoring low on all affective and cognitive measures representing better psychological functioning, another scoring high on cognitive measures only, and one scoring high across all affective and cognitive measures, representing poorer psychological function.

Patient expectations and confidence in the outcome of surgery are important aspects of cognitive psychological function to consider in the context of people undergoing surgery. An individual may agree to surgery with the belief that symptoms may be very much improved. A recent systematic review of 60 studies investigating expectations of surgery reported that greater expectations for a positive outcome have been associated with improved outcome in 47% of studies and with worse outcome in 15% of studies.²⁴¹ For orthopaedic surgery, greater patient expectations are associated with improvements in pain and disability after hip, knee and spine surgery.^{197-199, 242} For shoulder surgery, greater expectations before surgery have been associated with higher levels of pain and disability level before surgery,^{221, 243-245} lower pain and disability levels after surgery,^{221, 243} and greater satisfaction after surgery.²⁰² These studies are in contrast to other aspects of orthopaedic surgery reporting that overly optimistic expectations for knee arthroscopy²⁴⁶ or knee arthroplasty^{247, 248} are associated with lower patient satisfaction, or that expectations have no influence on satisfaction after knee arthroplasty.^{249, 250} Positive expectations are influenced by education regarding surgery and the protocol after surgery.²⁵¹ Consideration of patient expectations before surgery may assist surgeons to identify those individuals who are most likely to benefit from surgery and contribute information to the surgical decision-making process.

An understanding of factors associated with outcome after shoulder surgery enables identification of individuals before surgery who are most likely to benefit from surgery and also identify those individuals at risk of poor outcome.

Key points

- Multiple studies have reported over 60 prognostic factors are associated with patient-centred outcome
- Patient-related factors consistently associated with worse outcome after surgery are older age, an active workers compensation claim and higher levels pain and disability before surgery
- Disease-related (tear size, tendon retraction and fatty degeneration) and procedure-related (concomitant surgical procedures) factors, although consistently associated with outcome after surgery, are related to pathology or the surgical procedure and are aligned with the biomedical model of shoulder pain
- Only a small number of recent studies have investigated the association of affective psychological factors (moods and emotions) with outcome after shoulder surgery

- Cognitive psychological factors (thoughts and beliefs) have not been explored for their association with outcome after shoulder surgery, despite numerous reports of their association with shoulder pain and disability
- Not yet explored is whether differential patterns of affective and cognitive psychological factors in patients undergoing shoulder surgery are evident

2.10 Brief summary and gaps in knowledge

Shoulder surgery has dramatically increased in popularity over recent decades, with rising trends evident in many countries. It is likely that Australia follows the same global trends, however shoulder surgery trends in Australia have not been reported. There is also a lack of robust criteria to inform the decision for shoulder surgery, with surgeons in the USA and UK lacking agreement regarding surgical indications. It is likely that Australian surgeons also have disparate opinions, however surgical indications in Australia have not been reported.

Added to this complexity is current evidence underpinning a biopsychosocial approach to musculoskeletal pain. Shoulder surgery targets the structural aspects of shoulder pain. Other factors, such as health comorbidities, social, lifestyle and psychological factors have more recently been considered as important factors in a biopsychosocial understanding of shoulder pain. These factors may also be associated with surgical outcomes. The association of poor psychological function with outcome after shoulder surgery remains controversial with just a few recent shoulder surgery studies exploring the association of only affective psychological factors on outcome after shoulder surgery. Differential patterns of affective and cognitive psychological factors in individuals undergoing shoulder surgery may be evident, and potentially associated with pain and disability levels before and after surgery. However, this possibility remains unexplored.

Patient-centred outcome assesses whether the preferences and needs of the individual have been met. Outcome after shoulder surgery has been measured by a range of different metrics, however there is a lack of consistency across studies for their use. The strength of the association between different aspects of patient-centred outcome has not been clear. Factors identified before surgery that have previously been identified for their association with shoulder pain and disability, including psychological factors and expectations, may be similarly or differentially associated with all three aspects of patient-centred outcome (patient-reported pain and disability, global rating of change, patient satisfaction). However, this relationship has not yet been explored.

2.11 Research Aims

The aims of this thesis are:

1. To investigate the trends and associated costs over time of shoulder surgery for rotator cuff disease undertaken in Western Australia during the 13-year period 2001-2013;
2. To survey Western Australian shoulder surgeons for opinions regarding indications for shoulder surgery, clinical tests commonly used to aid surgical decision-making, intra-operative findings predictive of outcome and what constitutes a successful surgical outcome;
3. To explore if there are identifiable clusters (based on psychological functioning measures) in patients undergoing shoulder surgery;
4. To explore if poorer psychological functioning is associated with worse pain and disability outcome up to one year after shoulder surgery;
5. To investigate the association between three different aspects of patient-centred outcome (change in patient-reported pain and disability outcome measures, global rating of change, patient satisfaction);
6. To investigate if psychological factors, and other factors previously associated with one or more aspects of outcome, are similarly associated with these three aspects of patient-centred outcome (change in patient-reported pain and disability outcome measures, global rating of change, patient satisfaction).

2.12 Research Significance

The important significant and original contribution of this thesis will:

1. Provide knowledge of surgical trends in Western Australia in order to determine if the alarming increased rates of shoulder surgery reported for other countries is similar for an Australian population. This is important as the increased strain on healthcare budgets worldwide, including Australia, is not sustainable in light of an ageing population and an increasing prevalence of musculoskeletal disorders globally. Contemporary cost-effective healthcare necessitates the need for expensive interventions such as shoulder surgery to be targeted to those individuals most likely to benefit. Current evidence underpins a biopsychosocial approach to management for musculoskeletal pain, whereas shoulder surgery targets only the structural aspects of shoulder pain.

2. Provide an understanding of surgical criteria used by orthopaedic surgeons in Western Australia in order to determine if there is consensus for surgical indications within a community of surgeons that is different or similar to reports of the lack of consensus in the USA and UK. As the previous findings from the USA and UK studies highlighted a lack of consensus for surgical criteria, further targeted research is needed to demonstrate effectiveness of shoulder surgery and the subgroups for which it is potentially most effective. The development of more robust clinical guidelines for surgical decision-making criteria are needed in light of the contemporary understanding of the multidimensional nature of shoulder pain.
3. Identify whether subgroups of individuals with poor psychological function exist prior to shoulder surgery and if worse pain and disability scores are associated with poor psychological function before surgery and up to one year after shoulder surgery. This is important as current evidence highlights that psychological factors are important in a biopsychosocial understanding of shoulder pain and may also be associated with outcome after shoulder surgery. There may be a role for psychologically informed practice for individuals with shoulder pain, to address the behavioural aspects of pain, within a patient-centred care approach.¹⁶¹
4. Provide an understanding of how strongly three different aspects of patient-centred outcome relate to each other and whether different aspects of outcome are similarly associated with psychological factors or other variables previously identified to be associated with one or more aspects of outcome. This is important as there has been a lack of consistency across studies in the use of outcome measures, which has made the comparison and interpretation of studies complex.

2.14 References

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Chapter 3 Rising Trends in Surgery for Rotator Cuff Disease in Western Australia

Study One: Rising Trends in Surgery for Rotator Cuff Disease in Western Australia

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Introduction to Study One

Shoulder disorders are a common musculoskeletal complaint and contribute significantly to the financial burden of musculoskeletal disease worldwide. Shoulder pain is one of eight distinct areas of higher prevalence making up the ‘Other Musculoskeletal’ category in the Global Burden of Disease Study.¹ The prevalence of shoulder disorders is likely to continue to rise with an ageing population, remaining in the workforce in advancing years, with greater expectation of quality of life, the prevalence of shoulder disorders is likely to continue to rise.

Shoulder surgery is frequently undertaken for individuals with shoulder pain. The global increased rates of shoulder surgery and associated costs over the past decade are discussed in this study. No previous reports of surgical trends for individuals with shoulder pain for Australian populations were available to determine if Australian trends follow the same worldwide pattern. The current landscape for surgical trends in Western Australia was explored in study 1.

Therefore, the aim of study 1 was to investigate the trends and associated costs over time of surgery for rotator cuff disease undertaken in Western Australia (WA) during the 13-year period 2001-2013. The Western Australian Department of Health data set was accessed to extract numbers of surgical procedures performed from 2001-2013, hospital setting, demographics and average cost per procedure. The surgical trends were explored across hospital setting, gender and age. Costs to the healthcare system associated with the increasing shoulder surgery trends were also investigated.

Study 1 is reproduced in this chapter as published in the Australian New Zealand Journal of Surgery. A supplementary table for this paper, to support Figure 3.1, is included in Appendix A.

Rising Trends in Surgery for Rotator Cuff Disease in Western Australia

3.1 Abstract

3.1.1 Background

Increasing rates of surgery for rotator cuff disease have been reported in the past decade in a number of countries worldwide. Rising surgery rates do not correspond with equivalent increases in shoulder pain prevalence. The aims of the study were: to investigate trends in population-adjusted surgical rates for rotator cuff disease in Western Australia from 2001-2013; to compare population-adjusted arthroscopic surgical trends between (i) private versus public hospital setting, (ii) sex and (iii) different age groups; and to evaluate rising healthcare costs associated with arthroscopic surgical rates for rotator cuff disease.

3.1.2 Methods

Numbers and costs for surgical procedures for rotator cuff disease performed in Western Australia were extracted from the Western Australian Department of Health database for the 13-year period 2001 – 2013.

3.1.3 Results

Rising surgical trends were demonstrated with arthroscopic subacromial decompression and arthroscopic reconstruction showing large proportional increases of 108.7% and 68.4% respectively. Increasing trends were mostly linear across private and public hospital settings, gender groups and different age groups. The rise in CPI-adjusted costs for ASAD in private and public hospitals was 273.7% and 320.8% respectively, and for arthroscopic reconstruction 220.2% and 472.5% respectively.

3.1.4 Conclusions

The substantial increase in arthroscopic surgery rates for rotator cuff disease and associated costs in WA over the period 2001-2013 is in spite of evidence that surgical outcomes are no different to exercise interventions. Conservative treatments should be recommended as an initial treatment choice, to arrest escalating health care costs.

3.2 Introduction

Lifetime shoulder pain prevalence has been reported to be between 7-26% in the general adult population, with prevalence increasing with age.²⁻⁴ Rotator cuff disease (RCD) and pathology of the subacromial bursa account for up to 85% of shoulder complaints.^{5, 6} Indications for surgical interventions such as subacromial decompression (SAD) and rotator cuff repair (RCR) include failure to respond to conservative management, persistent pain and functional impairment. Increasing rates of surgery for RCD have been reported over the past decade in a number of countries including the United States of America (USA),⁷⁻⁹ United Kingdom (UK),⁵ Denmark¹⁰ and Finland,¹¹ with rising trends associated with concurrent increases in health care costs.¹²⁻²¹ Surgical trends, variations in hospital setting, gender, age and associated costs for RCD in Australian populations have not been reported.

The purpose of this study was to investigate the trends and associated costs over time of surgery for RCD undertaken in Western Australia (WA) during the 13-year period 2001-2013. The aims of this study were threefold: (i) assess population-adjusted surgical rates for surgery for RCD in WA; (ii) compare population-adjusted arthroscopic surgical trends between private versus public hospital setting, gender and different age groups; (iii) evaluate costs associated with arthroscopic surgical rates for RCD.

3.3 Methods

Annual numbers of surgical procedures performed and average cost per procedure for RCD were extracted from the Western Australian Department of Health database for the period 2001 – 2013. All surgical procedures undertaken for RCD as the primary procedure in public and private hospital settings in the state of WA for this time period were included. Five categories of primary surgical procedures (three open and two arthroscopic item codes outlined in (Table 3.1) were obtained. Isolated RCR as an arthroscopic or mini-open procedure is included in the arthroscopic reconstruction code (ARC). Ethical approval was attained from the Human Research and Ethics Committee at Curtin University (approval number HR 178/2013).

Table 3.1 Allocated codes associated with surgical procedures obtained from the Western Australian Hospital Morbidity Data System

Allocated Code	Primary Surgical Procedure	Abbreviation
48951-00	Arthroscopic subacromial decompression	ASAD
48960-00	Arthroscopic reconstruction of shoulder including rotator cuff repair with or without subacromial decompression	ARC
48903-00	Open subacromial decompression	OSAD
48909-00	Open rotator cuff repair with subacromial decompression	ORC
48906-00	Open rotator cuff repair without subacromial decompression	ORCR

3.4 Statistical analysis

For Aim one, population-adjusted surgical rates per 100,000 persons were calculated for the five surgical procedure codes using annual population counts for the state of WA from census data obtained from the Australian Bureau of Statistics. For Aim two, arthroscopic subacromial decompression (ASAD) and arthroscopic reconstruction (ARC) rates per 100,000 persons were calculated separately by hospital setting (private versus public), gender and age categories (15-34yrs, 35-54yrs and >55yrs). Negative binomial regression was used to compare population-adjusted ASAD and ARC surgical trends for differences between (i) private versus public hospital setting; (ii) gender; and (iii) the three age group categories. For Aim three, the inflation-adjusted total cost for ASAD and ARC procedures per year was calculated from the consumer price index extracted from the Reserve Bank of Australia Inflation Calculator and adjusted to 2013 prices²². To examine how much the increase in total costs may be driven by cost per procedure, the proportional increase from 2001 to 2013 in CPI-adjusted average cost per procedure was calculated. STATA software version release 13 was used for all statistical analyses.

3.5 Results

3.5.1 Surgical rates

The population-adjusted rates for all surgical procedures undertaken for RCD in WA showed an increase of 55.1% from 2001 to 2013, with arthroscopic procedures (ASAD and ARC) demonstrating large proportional increases of 102.0% and 68.4% respectively, illustrated in Figure 3.1. All open procedures (open subacromial decompression, open reconstruction and open rotator cuff repair) displayed decreases in surgical rates of 36.7%, 74.0% and 25.0% respectively, with open reconstruction showing the greatest decline.

Further analysis only considered arthroscopic procedures. Procedure codes in the WA Department of Health have remained unchanged from 2001 to 2013.

Surgical trends for ASAD and ARC, reported in Table 3.2, showed mostly linear increases equally across hospital setting, gender and age. For ASAD surgery, there was no significant difference over time with regards to hospital setting, gender and age. For ARC surgery, there was a significantly higher growth in the public hospital system (8.1% versus private 3.2%, $p < 0.001$) and a significant decrease in surgery rates in the 15-34 year age group (2.4% decrease, versus 2.5% and 3.8% increase respectively in the 35-54 and >55 age-groups, $p < 0.001$).

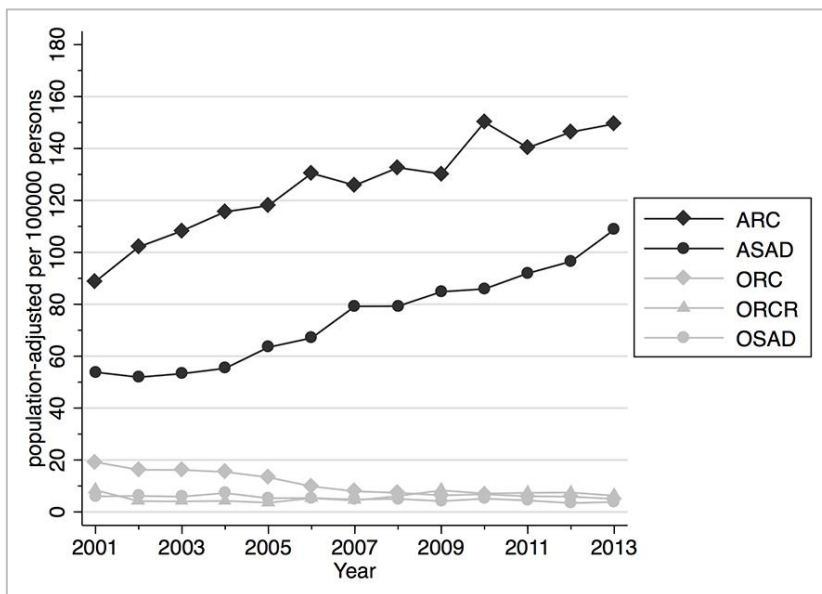


Figure 3.1 Population adjusted surgical trends for rotator cuff disease per 100,000 persons

Abbreviations: ASAD - arthroscopic subacromial decompression; ARC - arthroscopic reconstruction; OSAD - open subacromial decompression; ORC – open rotator cuff repair with subacromial decompression; ORCR – open rotator cuff repair without subacromial decompression

Table 3.2 Percentage change in surgical rates for ASAD and ARC by hospital setting, gender and age

	ASAD				ARC			
	% change 2001-2013	IRR	95% CI	Estimated annual increase in surgery	% change 2001-2013	IRR	95% CI	Estimated annual increase in surgery
Hospital setting								
Private	95.7%	1.064	(95% CI: 1.057-1.072)	6.4%	54.5%	1.032	(95% CI: 1.024-1.040)	3.2%
Public	143.5%	1.072	(95% CI: 1.052-1.093)	7.2%	175.2%	1.081	(95% CI: 1.071-1.090)	8.1%*
Gender								
Males	74.6%	1.059	(95% CI: 1.050-1.068)	5.9%	68.7%	1.038	(95% CI: 1.032-1.045)	3.8%
Females	104.1%	1.065	(95% CI: 1.056-1.074)	6.5%	68.3%	1.040	(95% CI: 1.030-1.050)	4.0%
Age								
15-34	69.6%	1.051	(95% CI: 1.037-1.065)	5.1%	- 14.0%	0.976	(95% CI: 0.962-0.991)	- 2.4%*
35-54	82.8%	1.064	(95% CI: 1.053-1.074)	6.4%	41.5%	1.025	(95% CI: 1.020-1.031)	2.5%
> 55	76.8%	1.055	(95% CI: 1.047-1.064)	5.5%	63.3%	1.038	(95% CI: 1.029-1.047)	3.8%

*(p<0.001)

Abbreviations: ASAD-arthroscopic subacromial decompression; ARC- arthroscopic reconstruction; IRR- Incident rate ratio; CI-confidence interval

3.5.2 CPI-adjusted costs for ASAD and ARC

Consumer price index (CPI)-adjusted total cost increases were shown in private and public hospitals both for ASAD (273.7% and 320.8% respectively) and for ARC (220.2% and 472.5% respectively) as demonstrated in Figure 3.2. Although there was a proportional increase in CPI-adjusted average cost per procedure in private and public hospitals for ASAD (57.1% and 36.7% respectively) and for ARC (56.9% and 55.4% respectively), this was much smaller than the proportional increases in corresponding total costs.

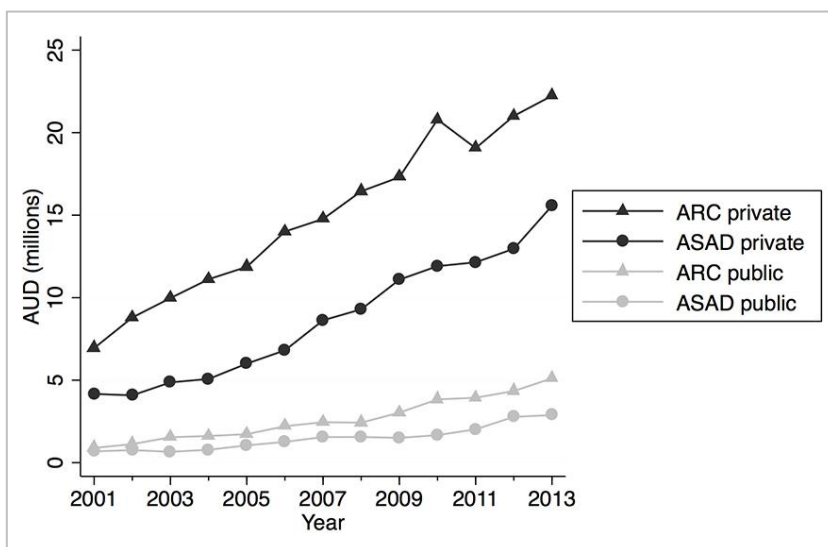


Figure 3.2 CPI-adjusted total costs for surgical rates for ASAD and ARC

Abbreviations: ASAD - arthroscopic subacromial decompression; ARC - arthroscopic reconstruction; CPI – consumer price index

3.6 Discussion

This is the first study to report findings in Australia for RCD surgical rates, demonstrating a rising trend of arthroscopic surgery for RCD, in line with previous reports of rising surgical trends in the UK,⁵ USA,^{7, 8} and Denmark.¹⁰ The shift towards arthroscopic procedures in this study is consistent with recent USA reports,²³ however the rise in arthroscopic surgery cannot be attributed merely to a shift in practice away from open procedures, as the rate of all surgeries combined has risen by 55.1% during this 13-year period.

Multiple factors may underpin the increase in RCD surgery rates. Firstly, patient demand for surgical intervention may be driving rates up, as a result of an increased awareness and understanding of surgical procedures available for RCD, a greater expectation of quality of life linked with increased life expectancy and greater access to private health insurance. Secondly, a greater number of specialist surgeons trained in arthroscopic surgery techniques for RCD, with advances in surgical instrumentation, repair techniques and suture anchors, along with the advent of nerve blocks for high risk surgical patients may contribute to the rising rates.^{5, 7, 24, 25} Finally, both of these factors are likely to be reinforced by greater access to imaging modalities, such as MRI and ultrasound, which are sensitive to detecting rotator cuff pathology.^{26, 27}

The rising surgical trends in Australia are occurring in spite of the lack of high level evidence guiding treatment choice for RCD.²⁸ Recent research suggests that there is little difference in clinical outcomes between conservative treatments and surgical approaches,²⁹⁻³² highlighting the urgent need for clinical research to better inform clear management guidelines for patients with RCD. A recent systematic review of 7 RCTs comparing surgery with exercise therapy for impingement-related shoulder pain, reported moderate evidence that surgery and active exercises are equally as effective in reducing pain intensity.³³ In support of this review, two additional RCTs have compared outcomes of surgery with physiotherapy (exercise rehabilitation) for rotator cuff tears. One study compared physiotherapy (exercise rehabilitation); acromioplasty and physiotherapy; and rotator cuff repair, acromioplasty and physiotherapy in the treatment of symptomatic, non-traumatic supraspinatus tears in 167 patients, older than 55 years. They reported no statistically significant, nor clinically important differences in outcome between the three groups for pain and disability scores and patient satisfaction at one year³⁰ and two year²⁹ follow up. They concluded that conservative treatment should be considered as a primary initial treatment for isolated, symptomatic, non-traumatic, rotator cuff tears. In a second study, surgical primary repair was compared with physiotherapy (exercise rehabilitation) for small and medium sized full-thickness rotator cuff tears in 103 patients, older than 50 years. While improvements in disability and pain favoured the surgical group over the physiotherapy group for pain and disability scores at one, two and five year follow up, the authors acknowledge the size of the effect was small and may not be of clinical importance.³² Given the high costs and risks associated with shoulder surgery, the current evidence supports that a trial of extensive conservative physiotherapy-led exercise rehabilitation is recommended prior to surgical intervention.

This study illustrated a marked rise in CPI-adjusted total costs associated with both ASAD and ARC surgery in the private and public hospital settings. Increases in total CPI-adjusted cost to the health care system is driven largely by the rising number of arthroscopic surgical procedures undertaken, however the CPI-adjusted average cost per procedure has also risen in both hospital settings. Increase in average cost per procedure may be associated with advances in arthroscopic surgical techniques, suture anchors and anaesthetic techniques, as has been previously reported, however this information was not able to be determined from the WA Department of Health data.¹³⁻¹⁵ Further studies investigating health care costs for ASAD and ARC surgery are warranted, as breakdown costs of each surgical procedure was not available from the data obtained from the WA Department of Health.

Regular monitoring of surgical trends and identification of strategies to contain healthcare costs is necessary with increasing population age and rises in surgery rates. If surgical trends for RCD continue at a similar rate over the coming decade with a continued trend for escalating costs, this will likely add further strain to healthcare budgets. Alternative cheaper treatments with lower risk such as exercise interventions should be recommended initially as a primary treatment choice. Prior to considering surgery, patients with RCD should undertake a 12-week physiotherapy-led exercise program providing education and targeting deficits in posture, mobility, muscle length and strength. Consideration should also be given to reduce the reliance on diagnostic imaging for clinical decision making. The high prevalence of RCD in asymptomatic populations,³⁴ coupled with the poor correlation between imaging findings, pain and disability levels^{35, 36} has lead to calls to place a greater emphasis on clinical examination in surgical decision-making.³⁵ Future studies that identify prognostic factors for shoulder pain and surgical outcome for RCD, will allow the targeting of surgery to those most likely to benefit, thus easing the financial burden on healthcare systems.

This study has a number of limitations. One limitation is that the study only considered surgery for RCD in the state of WA. A review of national data would determine if the current findings in WA are consistent nationally and whether geographical variations exist. Another potential limitation is variations in surgeon coding practices for the WA Department of Health procedure codes. Some surgeons may use the ARC code for isolated arthroscopic RCR, as well as RCR in combination with ASAD. Other surgeons may use for ARC code as well as the ASAD code when combining ARC with ASAD.

3.7 Conclusions

In summary, there has been a substantial increase in arthroscopic surgery rates for RCD in the state of WA over the period 2001 to 2013, associated with substantial increases in cost to the healthcare system. The trends mostly increased consistently across hospital setting, gender and age. These findings are consistent with surgical trends in other countries and are likely due to multiple factors such as patient desire to be active into older age with greater expectation of quality of life, increasing population age, increased number of trained surgeons, advances in surgical and anaesthetic techniques and greater access to and advances in imaging modalities. This is in spite of evidence that surgical outcomes are no different to exercise interventions. Conservative treatments should therefore be recommended as an initial treatment choice, to arrest escalating health care costs. In light of the increasing burden to the healthcare system, if the current rising trends and escalating costs continue, research into factors predictive of positive surgical outcomes and comparative trials of conservative versus surgical options for RCD and the effect on long-term outcome is imperative.

3.8 Acknowledgement

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3.9 Disclosure Statement

There are no conflicts of interest to disclose

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Chapter 4 Rotator Cuff Disease: Opinion Regarding Surgical Criteria and Likely Outcome

Study Two: Rotator Cuff Disease: Opinion Regarding Surgical Criteria and Likely Outcome

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Introduction to Study Two

With the rising surgical trends discussed in study 1, and the increased cost and risks associated with surgery, it is imperative that shoulder surgery is targeted to those individuals most likely to benefit.

Indications for shoulder surgery are not clear globally, nor in Australia. Current clinical practice guidelines and surveys of surgeon opinion for the management of shoulder pain are discussed in study 2. Surgical decision-making is typically informed by a combination of factors including available clinical guidelines, surgeon education, surgeon personal experience, and individual patient factors.

No previous reports of indications for shoulder surgery criteria in Australia have been reported, to determine if Australian surgeon opinion is aligned with reports from other countries. Western Australian shoulder surgeon opinion was explored regarding indications for shoulder surgery, physical tests most commonly used to support surgical decision-making, findings at surgery that may be predictive of outcome after shoulder surgery and opinion about what constitutes a successful outcome after shoulder surgery.

Study 2 is reproduced in this chapter as published in the Australian New Zealand Journal of Surgery. Supplementary documentation for this paper, the Rotator Cuff Survey part 1 and 2, is included in Appendix B.

ROTATOR CUFF DISEASE: OPINION REGARDING SURGICAL CRITERIA AND LIKELY OUTCOME

4.1 Abstract

4.1.1 Background

Clinical guidelines for the management of rotator cuff disease are not clear. Surgeon surveys in the USA and UK lack agreement regarding surgical indications. Physical examination tests aid surgical decision-making but also lack robust evidence. Study aims were to evaluate: Western Australian (WA) Orthopaedic Surgeons' perceptions about surgical indications; utility of physical examination tests; findings at surgery predictive of outcome and surgeon opinion of a successful surgical outcome.

4.1.2 Methods

An anonymous rotator cuff survey, previously reported by the American Academy of Orthopaedic Surgeons, was emailed to all surgeons listed with the Australian Orthopaedic Association (AOA) in WA. Surgeons who treated patients for rotator cuff disease during the previous 12 months were invited to complete the rotator cuff survey and four additional questions were included to capture the above criteria of interest.

4.1.3 Results

Within a close community of surgeons based in Western Australia (n=23) considerable heterogeneity exists in surgical decision-making criteria. A successful surgical outcome was considered to include reduced pain levels, restoration of movement and function and gains in muscle strength.

4.1.4 Conclusions

Research is required to inform robust clinical practice guidelines for rotator cuff surgery. Identification of prognostic factors for successful surgical outcome is imperative.

4.2 Introduction

Shoulder pain due to rotator cuff disease (RCD) is a frequently reported musculoskeletal complaint, with prevalence rates reported to be as high as 36% during adult life.¹ Surgery may be indicated after failure to respond to a conservative program that can include pharmacology, injection therapy, physiotherapy and exercise rehabilitation.

Surgical criteria for RCD are not clear, with clinical practice guidelines and surveys of surgeon opinion outlining a lack of consensus between surgeons for the management of RCD.^{2, 3, 4} Evidence-based clinical guidelines, surgeon education, surgeon personal experience and individual patient factors, may inform surgical decision-making. The lack of robust clinical guidelines is a result of limited high quality evidence.^{2, 5}

Clinical examination tests, such as weakness or pain on muscle testing⁴ or clinical orthopaedic tests⁶⁻⁸ may assist with decision-making, however tests also lack robust evidence. A systematic review determined that most tests for RCD are inconclusive, with limited recommendation for their clinical use.⁹

Surgical views may be similar in the Australian orthopaedic community as the USA and UK, however surgeon opinion in Australia has not been reported. The aims of this study were to survey Western Australian (WA) orthopaedic surgeons' for opinions regarding (i) indications for rotator cuff surgery; (ii) physical examination tests most commonly utilised; (iii) findings at surgery that may be predictive of outcome; and (iv) what constitutes a successful surgical outcome

4.3 Methods

A link to an anonymous rotator cuff survey, including questions previously reported by the American Academy of Orthopaedic Surgeons (AAOS)³ plus four additional questions, was emailed during December 2013 and January 2014 to all surgeons listed with the Australian Orthopaedic Association (AOA) in WA. Surgeons who treated patients for RCD during the previous 12 months were invited to complete the survey, with a cover letter from an AOA surgeon and co-investigator, M.H. included with the survey to encourage surgeon participation, with consent implied by participation. An initial screening question determined that only surgeons having performed surgery for RCD during the previous 12 months were directed to proceed with the survey. Ethical approval was attained from the Human Research and Ethics Committee at Curtin University (approval number HR 178/2013).

The survey (Appendix B) established surgeon characteristics (consultancy practice years, number of rotator cuff repairs (RCR) performed during the past year, preferred method of repair for a 2cm full thickness tear and estimated percentage annual failure rate (defined as patient dissatisfaction) for patients undergoing RCR in WA. Specific questions pertaining to RCD surgery included management of clinical case vignettes, opinion on clinical statements, number of steroid injections given safely in one year and factors facilitating greater patient involvement in surgical decision-making. The vignettes described four common clinical presentations, with a tear confirmed on magnetic resonance imaging, for which respondents were asked to select one of four management options; conservative treatment (with physiotherapy or cortisone injection) or surgery (with or without RCR). The clinical statements surveyed opinion about factors that might influence choice of management for patients with RCD and respondents were asked to rate the importance on a 5-point Likert scale (strongly disagree, disagree, indifferent, agree, and strongly agree). Responses for agree and strongly agree, and disagree and strongly disagree, were pooled to determine levels of clinical agreement or disagreement respectively. Clinical agreement was defined as 80% or higher consensus between surgeons answering similarly, as previously reported in the AAOS study.³ Four additional questions were developed in consultation with WA surgeons: three questions regarding physical examination tests most commonly used for surgical decision-making; findings at the time of surgery predictive of outcome at 12 months; and what would be considered a successful outcome for repair of a 1cm by 1cm supraspinatus tear in the critical zone.

4.4 Results

Twenty-six surgeons attempted the survey. Three respondents were excluded from further analysis (one indicated they had not performed shoulder surgery during the previous year and two only partly completed the survey), leaving a sample group of 23 respondents. While it is likely these respondents include all 24 surgeons listed on the AOA website as ‘Shoulder and Elbow surgeons’, suggesting a 100% response rate, the anonymous nature of the survey precludes this definitive conclusion.

4.4.1 Surgeon characteristics

The mean number of rotator cuff surgeries undertaken was 80 cases per year (ranging from 12-200 cases with a median of 75 cases). The mean years of consultation

practice was 8.5 years (ranging from 1 to 25 years with a median of 5 years). Annual estimated failure rate (defined as patient dissatisfaction) recorded a mean of 12% (ranging from 2-25% per year with a median of 10%). The preferred surgical technique for repair of a 2cm full thickness supraspinatus tear in the critical zone was mini-open (n=17, 74%) over arthroscopic (n=4, 16%) or open (n=2, 8%).

4.4.2 Clinical vignettes

Clinical agreement (>80%) was attained for only one vignette (vignette 2), with no consensus attained for management of the other three vignettes, with results summarised in Table 4.1.

4.4.3 Clinical statements regarding surgery for RCD

Only one statement achieved clinical agreement (>80%); that the duration and frequency of rehabilitation should be discussed pre-operatively with the patient (Table 4.2).

4.4.4 Steroid injections per year

Most surgeons (70%) believed that the maximum number of steroid injections safely administered in one year to patients with RCD was three injections. Other surgeons believed that one (4%), two (4%), four (9%) or five (13%) could safely be given per year.

4.4.5 Factors for patients to be more involved in the decision-making process for surgery

Most respondents (87%) reported their patients are already sufficiently involved in the decision-making process, however the provision of more information (26%), longer pre-operative appointments (13%) and a higher patient education level (13%) were also considered important factors.

Table 4.1 Percentage of clinical agreement among surgeons regarding rotator cuff clinical vignettes

Vignette	Vignette scenario	Conservative Physiotherapy	Conservative Cortisone	Surgery with RCR	Surgery without RCR
1	Young labourer with traumatic, partial thickness tear with pain but no weakness, who has failed to respond to three months of physical therapy	4 (17%)	6 (26%)	11 (48%)	2 (9%)
2	Young labourer with a traumatic, full thickness tear with minimal pain and the presence of muscle weakness	4 (17%)	0 (0%)	19 (83%)*	0 (0%)
3	Middle aged, insidious onset small full thickness tear, reporting mild discomfort for one year, with no treatment received to date	9 (39%)	5 (22%)	9 (39%)	0 (0%)
4	Active, older patient, who sustained a traumatic event one week ago and now has poor function and cannot lift the arm	12 (52%)	2 (9%)	8 (35%)	1 (4%)

*Denotes clinical agreement >80%

Abbreviation: RCR – rotator cuff repair

Table 4.2 Percentage of clinical agreement among surgeons regarding factors affecting surgical decision-making

Statement	Surgeon opinion on clinical statements	Total disagree	Indifferent	Total agree
1	Physiotherapy is useful for full-thickness rotator cuff tears	4 (17%)	5 (22%)	14 (61%)
2	The use of a steroid injection is contraindicated in potential surgical candidates	16 (70%)	3 (13%)	4 (17%)
3	Patients should expect to have a 'normal' shoulder after rotator cuff repair	13 (57%)	3 (13%)	7 (30%)
4	The surgeon should decide whether the patient should have a rotator cuff repair and then tell them to have (or not to have) surgery.	12 (52%)	6 (26%)	5 (22%)
5	When recommending rotator cuff surgery, the surgeon should explain the options and let the patient decide whether to have the surgery	3 (13%)	2 (9%)	18 (78%)
6	A major reason to repair rotator cuff tears is to prevent progression of the tear	6 (26%)	5 (22%)	12 (52%)
7	A major reason to repair rotator cuff tears is to prevent osteoarthritis of the shoulder	14 (61%)	6 (26%)	3 (13%)
8	Surgeons should spend more time discussing the pros and cons of rotator cuff repair with patients pre-operatively.	3 (13%)	9 (39%)	11 (48%)
9	The expected frequency and duration of post-operative rotator cuff rehabilitation should be discussed with patients pre-operatively	0 (0%)	0 (0%)	23(100%)*

* Denotes clinical agreement >80%

4.4.6 Physical examination tests used in decision-making for surgery

Active range (96%), Hawkins test (87%), passive range (78%), painful arc (78%), isometric muscle tests (57%), Neer sign (57%), empty can test (57%) and drop arm test (52%) were identified as the tests most frequently utilised, with most surgeons using a cluster of four or more tests.

4.4.7 Findings at surgery predictive of outcome

Intra-operative findings considered predictive of 12-month outcome related primarily to the presence of tendon pathology (quality of tissue (65%), degree of tendon retraction (39%), ease of tendon reduction (30%), size of tear (35%) or irreparable tendon (9%)). Other factors observed intra-operatively included co-morbidities such as glenohumeral joint osteoarthritis (13%), acromioclavicular joint pathology (9%), presence of inflammation (9%), long head of biceps pathology (4%) or presence of fat atrophy (4%).

4.4.8 Surgeon classification of a successful outcome

A successful surgical outcome was considered to relate to a cluster of three or more factors including minimal or no pain (74%), restoration of range of active and passive range (52%), return to functional activities (52%), minimal strength deficit (39%) and a healed tendon (13%).

4.5 Discussion

Within a close community of surgeons based in Western Australia (n=23) considerable heterogeneity exists in surgical decision-making criteria, consistent with previous studies from the USA and UK.^{3, 4} This study surveyed a younger surgeon sample (9 versus 18 years of consultancy practice in USA study), with a similar estimated failure rate (12% versus 15%).³ The trend towards mini-open and arthroscopic procedures in this study is likely to reflect advances in surgical techniques utilised by more recently trained shoulder surgeons.

Clinical agreement was achieved for only vignette 2 in this study, whereas the previous USA study failed to achieve agreement for any vignette. For Vignette 1, less than half of surgeons surveyed (48%) recommended surgery with RCR, despite weak

evidence that early surgical repair for tear after traumatic injury is indicated² and failure of a conservative physiotherapy program is considered to be an indication for surgery.⁴ For Vignette 2, clinical agreement (83%) was attained for surgery with RCR, in keeping with clinical guidelines recommending early surgical repair for full thickness tears after traumatic injury.² For Vignette 3 conservative management was recommended by 61%, with physiotherapy (39%) favoured over cortisone injection (22%). Evidence for physiotherapy and corticosteroid injection is inconclusive,² however surveys of surgeon opinion suggest a minimum three months of physiotherapy prior to considering surgery.³ ⁴ Surgery with RCR was recommended by only 39% of surgeons, which may reflect their awareness of weak evidence for RCR in patients with chronic, symptomatic, full thickness tears.² For Vignette 4 approximately one third (35%) recommended surgery with RCR despite the presence of poor tendon health on MRI, contrary to clinical guidelines that suggest the presence of fat atrophy on MRI correlates with less favourable outcome of surgery.²

The presence of pain is usually a reason why patients seek treatment, however a poor correlation between pain severity and rotator cuff tear severity has been reported.¹⁰ Both vignette 2 and 3 report minimal pain levels, however twice as many surgeons recommended surgery for vignette 2 over vignette 3 (83% versus 39%), suggesting the decision to operate is multifactorial. Traumatic onset, younger age, larger tendon tear and muscle weakness in vignette 2 may all influence surgical decision-making. Clinical guidelines report increasing age weakly correlates with less favourable outcomes after RCR surgery.^{2, 11} Younger age was a factor for consideration in vignette 1 and 2 with a young labourer reported to have a partial thickness tear in vignette 1 and a full thickness tear in vignette 2. Consensus for surgery with RCR was attained on vignette 2 only (83%), versus vignette 1 (48%), indicating that the presence of a full thickness tear in vignette 2 more strongly influenced the decision for surgery than age. Age-related degenerative changes are considered part of the natural history of RCD, are frequently asymptomatic^{12, 13} and full thickness tear prevalence in asymptomatic individuals over 60 is reported to range from 25% - 50%, increasing after 80 years.^{12, 14}

Clinical statements regarding surgery for RCD (Table 4.2) reached consensus (100%) on only one factor (expected frequency and duration of post-operative rotator cuff rehabilitation should be discussed with patients pre-operatively) and showed a trend towards consensus (78%) on another (surgeon should explain the options and let the patient decide whether to have surgery), which is aligned with previous results.³

Consensus (>80%) was not attained for the remaining seven statements: physiotherapy is useful for full thickness tears (61% agreement); the use of a steroid injection is contraindicated in potential surgical candidates (70% disagreement); patients should expect to have a normal shoulder after RCR (57% disagreement); surgeon should decide for or against RCR (52% disagreement); major reason for RCR is to prevent tear progression (52% agreement) or osteoarthritis (61% disagreement); and pros and cons of surgery should be discussed pre-operatively (48% agreement, 39% indifferent). The lack of consensus with clinical statements is despite evidence that exercise therapy has been associated with alleviation of symptoms in patients with full thickness tears¹⁵⁻¹⁷ and recommended for rotator cuff related symptoms, in the absence of full thickness tears.² Low patient expectations regarding the effectiveness of physiotherapy has been shown to be a strong predictor of the decision to undergo surgery.¹⁸ Evidence for the use of corticosteroid injections in patients with rotator cuff tears is inconclusive,² with weak evidence supporting corticosteroid injection for RCD,¹⁹ however a recent systematic review suggests emerging evidence of significant long-term harm to tendon tissue with corticosteroid injection.²⁰ There was a lack of consensus for the role of RCR surgery to prevent tear progression or osteoarthritis. Tear progression has been reported in 50% of asymptomatic full thickness tears that go on to develop symptoms within 2-3 years.¹² The pathogenesis of rotator cuff arthropathy in conservatively managed tears has been reported to relate to the number of ruptured rotator cuff tendons.²¹ However, poor correlation between pathological changes and functional status has been reported with superior migration of the humeral head and deterioration in tendon quality occurring without the loss of shoulder function.²¹

Multiple intra-operative factors were considered prognostic of outcome with tendon quality, tear size, location, ease of tendon repair and the presence of associated pathology considered most relevant. These findings are in keeping with clinical guidelines and surveys of surgical opinion undertaken in USA and UK that report that tear size and the presence of fat atrophy correlate with less favourable surgical outcome.^{2, 4} However these findings are at odds with a recent meta-analysis reporting that the structural integrity of the repaired tendon does not correlate with clinically important differences in patient function and pain relief after RCR.²² Most surgeons agree that successful outcome includes reduced pain levels, restoration of movement and function and gains in muscle strength.

Recent evidence suggests that shoulder pain is multifactorial and influenced by physical (movement behaviour, muscle control, mobility restriction),²³ psychological,²⁴

tissue sensitivity^{25, 26} and lifestyle (such as general health, smoking, diet and physical activity)²⁷ factors. Surgeons should be cognisant of multidimensional contributing factors, when deciding appropriate management for patients.

Given the current lack of evidence supporting surgery over conservative management for RCD, a minimum period of three months physiotherapy-led education regarding load management and lifestyle factors and targeted exercise rehabilitation should be undertaken prior to surgery.²⁸⁻³⁰ As patients who have low expectations regarding the effectiveness of physiotherapy are more likely to fail non-operative treatment,¹⁸ surgeons should not only consider promoting physiotherapy management as a first choice, but also reinforce a positive expectation regarding the outcome of a conservative approach. Surgical criteria should include failure to respond to an extended course of physiotherapy-led exercise rehabilitation, as well as consideration of multifactorial contributors to outcomes such as mental health.²⁴ This will likely result in a reduction in unnecessary surgery, minimise the cost and risk of surgery from the patient's perspective and improve indications for patient selection for rotator cuff surgery.

Future studies that identify prognostic factors for conservative and surgical outcomes are imperative. The development of a model of care for shoulder pain, similar to the national strategy for osteoarthritis,³¹ would facilitate an assessment process that includes general health, lifestyle and psychosocial screening alongside pathology specific considerations. Intervention studies targeting baseline physical, psychological or tissue sensitivity, such as physiotherapy-led exercise rehabilitation, cognitive functional approaches or targeted pharmacology may elucidate the influence of these factors on outcome.

There are a number of limitations noted in this study. Firstly, data collected was from the WA orthopaedic community resulting in a small sample size that may not be representative of surgical opinion throughout Australia, however findings are similar to those previously reported in the USA and UK. Secondly, only surgeons listed as members of the Australian Orthopaedic Association were invited to participate in the study and the sample group may not include all WA shoulder surgeons. Thirdly, the limited clinical information provided in the vignettes may lead to different interpretations between surgeons with regard to management choice. The rotator cuff survey was used as initially developed to allow comparison of responses between studies and changes in management views over the past decade.

4.6 Conclusions

Within a close community of surgeons based in Western Australia (n=23) considerable heterogeneity exists in surgical decision-making criteria, that is consistent with a previous USA study, and highlight the lack of robust clinical guidelines to inform patient selection for rotator cuff surgery. Research is required to inform robust clinical practice guidelines for rotator cuff surgery. Identification of prognostic factors for successful surgical outcome is imperative.

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Chapter 5 Are Psychological Factors Associated with Shoulder Scores After Rotator Cuff Surgery?

Study Three: Are Psychological Factors Associated with Shoulder Scores After Rotator Cuff Surgery?

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Introduction to Study Three

The rising surgical trends globally and in Western Australia discussed in study 1, and the lack of robust shoulder surgery criteria discussed in study 2, are a concern. Efficacy for some shoulder surgical procedures has also been questioned.

Shoulder surgery targets the structural aspects of shoulder pain. The contemporary understanding of shoulder pain underpins a biopsychosocial approach to assessment and management. This biopsychosocial approach is discussed in study 3. Multidimensional factors, such as health comorbidities, social, lifestyle, and psychological factors and patient expectations, have more recently been considered of important factors for their association with shoulder pain and disability. These factors may also be associated with surgical outcomes.

Psychological factors, such as moods and emotions, thoughts and beliefs, are known to be important for their association with shoulder pain and disability. Moods and emotions (affective factors) have been explored for their association with outcome after shoulder surgery. However, thoughts and beliefs (cognitive factors) have not yet been explored for their association with outcome after shoulder surgery. There may also be conceptual overlap between affective and cognitive factors, but this has not yet been explored for individuals undergoing shoulder surgery.

Therefore, study 3 explored the existence of clusters of individuals with shoulder pain with differing psychological profiles, and their association with pain and disability outcome after shoulder surgery.

Study 3 is reproduced in this chapter, as accepted for publication in *Clinical Orthopaedics and Related Research*. Supplementary documentation for this paper is included in Appendix C. This information includes: (1) Section C.1, Supplementary detail regarding Latent Class Analysis (2) Table C.1, Univariate association between potential confounding variables and ASES over time, and (3) Table C.2, Differences in potential confounding variables between the two psychological clusters.

ARE PSYCHOLOGICAL FACTORS ASSOCIATED WITH SHOULDER SCORES AFTER ROTATOR CUFF SURGERY?

5.1 Abstract

5.1.1 Background

Psychological factors are associated with pain and disability in patients with chronic shoulder pain. Recent research regarding the association of affective psychological factors (emotions) with patients' pain and disability outcome after surgery is not consistent; and the relationship between cognitive psychological factors (thoughts and beliefs) and outcome after surgery is unknown.

5.1.2 Questions/purposes

1. Are there identifiable clusters (based on psychological functioning measures) in patients undergoing shoulder surgery?
2. Is poorer psychological functioning associated with worse outcome (American Shoulder and Elbow Surgeons [ASES] score) after shoulder surgery?

5.1.3 Methods

This prospective cohort study investigated patients undergoing shoulder surgery for rotator cuff-related shoulder pain or rotator cuff tear by one of six surgeons between January 2014 and July 2015. Inclusion criteria were patients undergoing surgery for rotator cuff repair with or without subacromial decompression and arthroscopic subacromial decompression only. Of 153 patients who were recruited and consented to participate in the study, 16 withdrew before data collection, leaving 137 who underwent surgery and were included in analyses. Of these, 124 (46 of 124 [37%] female; median age, 54 years [range, 21-79 years]) had a complete set of four psychological measures before surgery: Depression, Anxiety and Stress Scale; Pain Catastrophizing Scale; Pain Self-Efficacy Questionnaire; and Tampa Scale for Kinesiophobia. The existence of clusters of people with different profiles of affective and cognitive factors was investigated using latent class analysis, which grouped people according to their pattern of scores on the four psychological measures. Resultant clusters were profiled on potential confounding variables. The ASES score was measured before surgery and 3

and 12 months after surgery. Linear mixed models assessed the association between psychological cluster membership before surgery and trajectories of ASES score over time adjusting for potential confounding variables.

5.1.4 Results

Two clusters were identified: one cluster (84 of 124 [68%]) had lower scores indicating better psychological functioning and a second cluster (40 of 124 [32%]) had higher scores indicating poorer psychological functioning. Accounting for all variables, the cluster with poorer psychological functioning was found to be independently associated with worse ASES score at all time points (regression coefficient for ASES: before surgery -9 [95% confidence interval {CI}, -16 to -2], $p = 0.011$); 3 months after surgery -15 [95% CI, -23 to -8], $p < 0.001$); and 12 months after surgery -9 [95% CI, -17 to -1], $p = 0.023$). However, both clusters showed improvement in ASES score from before to 12 months after surgery, and there was no difference in the amount of improvement between clusters (regression coefficient for ASES: cluster with poorer psychological function 31 [95% CI, 26-36], $p < 0.001$); cluster with better psychological function 31 [95% CI, 23-39], $p < 0.001$).

5.1.5 Conclusions

Patients who scored poorly on a range of psychological measures before shoulder surgery displayed worse ASES scores at 3 and 12 months after surgery. Screening of psychological factors before surgery is recommended to identify patients with poor psychological function. Such patients may warrant additional behavioural or psychological management before proceeding to surgery. However, further research is needed to determine the optimal management for patients with poorer psychological function to improve pain and disability levels before and after surgery.

Level of Evidence: Level II, therapeutic study.

5.2 Introduction

Psychological factors are associated with pain and disability in a range of musculoskeletal disorders¹⁻⁶ including the shoulder.⁷⁻¹⁰ Affective psychological factors, including depression and anxiety, are associated with longer duration of shoulder symptoms,¹⁰ higher levels of shoulder disability^{9, 11} and poorer quality of life.⁹ Cognitive psychological factors, including negative pain beliefs and catastrophizing,¹¹⁻¹⁵ kinesiophobia,^{13, 14, 16, 17} and low pain self-efficacy^{18, 19} are associated with higher levels of shoulder pain and disability^{14, 16, 18} and predictive of poor outcome or nonrecovery after conservative management.^{12-14, 17, 19}

For orthopaedic surgery, affective psychological factors, including depression and anxiety, are associated with worse outcomes for hip,^{20, 21} knee,^{20, 21} and spinal²² surgery. For shoulder surgery, recent studies investigating psychological factors have differed in their findings. Three studies reported no association of affective factors before surgery and pain and disability levels after surgery²³⁻²⁵ and one study reported an association of affective factors with greater pain and disability after surgery.²⁶ The association of cognitive factors such as pain beliefs, catastrophizing, kinesiophobia, and self-efficacy with outcome after surgery has not been reported; however, one study has reported an association of affective and cognitive factors with shoulder pain.¹¹

Conceptual overlap between affective and cognitive factors has been reported in chronic musculoskeletal pain,²⁷ low back pain^{4, 28} and knee osteoarthritis¹ and may reflect a level of general psychological distress. Alternatively, there may be important distinctions between these two factors, as identified in a study by Rabey⁴ in which people with chronic low back pain were grouped statistically (clustered) according to their individual pattern across a number of different measures of affective and cognitive psychological functioning. Three psychological clusters were identified: one cluster scoring low on all affective and cognitive measures representing better psychological functioning, another scoring high on cognitive measures only, and one-third scoring high across all affective and cognitive measures, representing poorer psychological function.

To date, most shoulder surgery studies have only explored the association of affective psychological factors on outcome. The association of poor psychological function with outcome after shoulder surgery remains controversial. Differential patterns of affective and cognitive psychological factors in patients undergoing shoulder surgery may be evident and potentially associated with pain and disability levels before and after

surgery; however, this remains unexplored. In view of the limited high-quality evidence to support some shoulder surgery procedures such as subacromial decompression surgery,²⁹ greater focus on the biopsychosocial dimension as a contributor to shoulder pain and disability is imperative.

Therefore, we asked: (1) Are there identifiable clusters (based on psychological functioning measures) in patients undergoing shoulder surgery? (2) Is poorer psychological functioning associated with worse outcome (American Shoulder and Elbow Surgeons [ASES] score) after shoulder surgery?

5.3 Patients and Methods

A prospective longitudinal observational study of adult patients undergoing shoulder surgery was undertaken at one private and two public hospitals in Perth, Western Australia, during an 18-month period from January 2014 to July 2015. Study approval was attained from the Human Research Ethics Committees at Curtin University and Sir Charles Gairdner Hospital, Perth, Western Australia. All patients scheduled for shoulder surgery (n = 184) by one of six participating surgeons (MH, JS, GB, SG, PK, AT) were invited to participate. Three surgeons (JS, PK, AT) operated across the three hospital settings. Data collection at 3 and 12 months after surgery was completed between April 2014 and July 2016. Inclusion criteria were patients scheduled for surgery for rotator cuff repair with or without subacromial decompression for partial or full thickness tears (n = 55) and arthroscopic subacromial decompression only (n = 43). The type of surgery was unable to be ascertained for 26 participants as a result of inaccessible surgical records. All participants underwent surgery on one shoulder only. Exclusion criteria were prior neck surgery, prior surgery on the same shoulder, presence of rheumatoid arthritis, fibromyalgia, local or malignant cancer, glenohumeral joint osteoarthritis, or an inability to comprehend English. Paper copies of all questionnaires were mailed for completion during the week before their scheduled surgery and the ASES questionnaire was mailed for completion at 3 and 12 months after surgery. A physical assessment was undertaken during the week before surgery in the surgical or physiotherapy clinic. Of the 184 patients who were invited to take part in the study, 14 were excluded, six were not able to be contacted, and 11 declined to participate, leaving 153 who were recruited and consented to participate. Of these, 16 patients withdrew before data collection as a result of cancellation of surgery, conservative management, or they changed their mind about study participation, leaving 137 patients who underwent

surgery and were included in analyses. Of these, 124 had a complete set of psychological measures before surgery and were included in the primary analyses of this study (Figure 5.1). Median age was 54 years (range, 21-79 years) and 46 of 124 (37%) were women.

5.3.1 Measurement of ASES score

The primary outcome variable was the ASES score³⁰ that was completed before surgery and 3 and 12 months after surgery. The ASES score contains a pain subscale with one pain item (10-cm visual analog scale) and a function subscale with 10 functional items (questions are rated on a 4-point Likert scale for level of difficulty) with total score 0 to 100 (pain subscale 0-50; function/disability subscale 0-50) with lower scores indicating greater pain and disability. The ASES score has been reported to have good reliability and validity,³¹⁻³³ is a robust shoulder pain and disability measure able to differentiate between patients making small versus large gains in pain and disability level,³⁴ and change scores in the range of 12 to 17 are considered a minimal clinically important change.³⁵

5.3.2 Measurement of Psychological Function

Four self-report psychological questionnaires were completed before surgery. The Depression, Anxiety and Stress scale (DASS)³⁶ is a 42-item, valid,^{37, 38} and reliable³⁹ measure containing three subscales of depression, anxiety, and stress with scores ranging from 0 to 42. Higher scores reflect higher levels of depression (moderate 14-20; severe 21-27; extremely severe 28+), anxiety (moderate 10-14; severe 15-19; extremely severe 20+), or stress (moderate 19-25; severe 26-33; extremely severe 34+). The Pain Catastrophizing Scale (PCS)⁴⁰ is a 13-item, valid and reliable^{41, 42} measure of thoughts and feelings that may be experienced in the presence of pain with scores ranging from 0 to 52 with higher scores reflecting greater catastrophizing. The Pain Self-Efficacy Questionnaire (PSEQ)⁴³ is a 10-item, valid and reliable questionnaire⁴³⁻⁴⁵ evaluating the pain self-efficacy of an individual for a range of issues with scores ranging from 0 to 60 with lower scores reflecting poorer self-efficacy beliefs. The Tampa Scale of Kinesiophobia (TSK-11)⁴⁶ is an 11-item, valid and reliable⁴⁷⁻⁴⁹ questionnaire that examines fear of movement or reinjury with scores ranging from 11 to 44 with higher scores reflecting greater pain-related fear. Recommendations regarding missing data management were followed where available. If there were two or less missing items, the average of the other items was imputed to calculate a total score; otherwise, totals were recorded as missing.

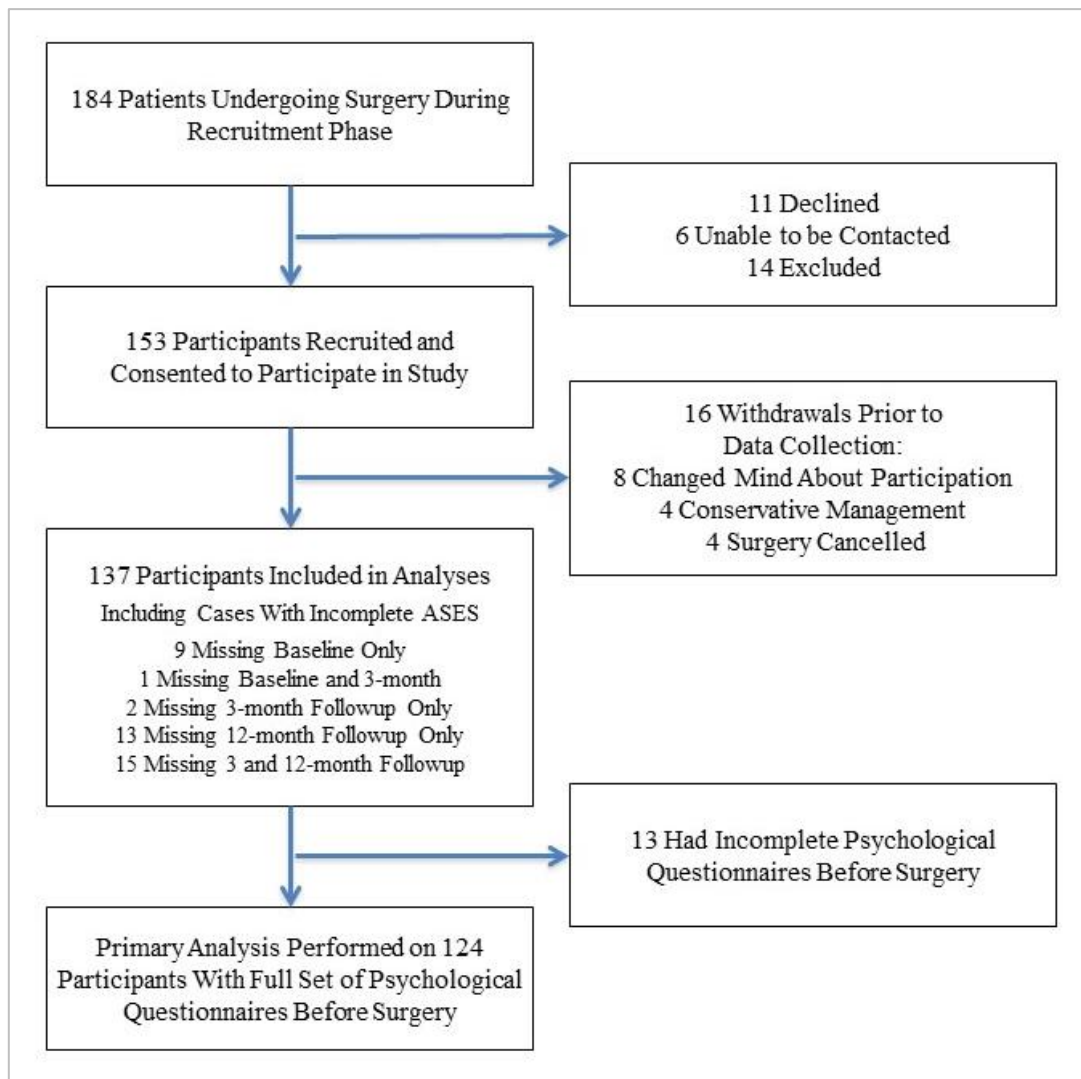


Figure 5.1 Flow chart illustrating the recruitment of participants into the study with psychological indicator measures and ASES score

Abbreviations: ASES = American Shoulder and Elbow Surgeons Score

Statistical Analysis

Latent class analysis is a statistical technique used to subgroup people according to their scoring patterns across a number of variables (indicators) in such a way that people within a particular subgroup have a similar scoring pattern across the variables and the difference in scoring patterns across subgroups is as distinct as possible.⁵⁰ This technique was chosen to investigate the existence of clusters of people with differential profiles of psychological functioning using measures of pain self-efficacy (PSEQ), pain catastrophizing (PCS), fear of movement (TSK), and depression, anxiety and stress (DASS) as indicators. Thus, the resultant subgroups can be considered a “latent” variable identified by the indicator variables, which represent a more complex construct, in this case combined affective and cognitive functioning. Latent class analysis was used

because it has advantages over other statistical techniques for subgrouping individuals in that it uses maximum likelihood estimation to allow a statistical evaluation of the optimal number of clusters, allows inclusion of variables with nonnormal distributions, and provides classification probabilities for each person.⁵¹ All four indicator variables (PSEQ, PCS, DASS, and TSK) were used in continuous form in the latent class analysis with PCS and DASS set as zero truncated to adjust for right-skewed sample distributions of these variables and PSEQ reversed so that higher scores represented worse functioning across all four measures. Further details regarding latent class analysis are included in Appendix C, Section C.1.

5.3.3 Confounding Variables

Potential confounding variables of the relationship between psychological cluster membership and ASES scores were taken from the demographic, health and lifestyle, and surgical dimensions and based on previously established associations with shoulder pain and disability,^{9, 10, 12-14, 16-18} low back pain^{3, 4} and knee pain.¹

Height and weight measures were taken during the physical examination before surgery and used to calculate body mass index. The self-report questionnaire booklet before surgery recorded age, gender, smoking (yes/no), alcohol use (never, monthly or less, 2-4 days per month, 2-3 days per week, > 4 days per week), health comorbidities (none, one or more comorbidities), education level (high school or less, tertiary college, university), occupation (lifting tasks/no lifting), an active workers' compensation claim (yes/no), duration of symptom history (< 1 year, ≥ 1 year), hospital setting (public/private), primary surgical procedure group, and confidence in recovery from surgery. Confidence in recovery from surgery was determined on a 0 to 10 Likert scale in response to the question "How confident are you that your shoulder symptoms will improve after surgery?" with 0 representing "not confident" and 10 representing "completely confident." Responses were subgrouped into a binary variable, around the median score of 8, with higher confidence denoted by a score of ≥ 8 and lower confidence represented by a score of < 8.

Assessment of Potential Confounding Variables

Clusters were profiled according to potential confounding variables using an independent t-test (normally distributed data), chi-square analysis (categorical data), or Wilcoxon rank-sum (Mann-Whitney) test (ordinal/count data). Linear mixed-effects

regression models with random intercept and time as a factor variable were used to assess the association of each variable with ASES score. For each variable, an interaction with time was assessed to test if the association differed according to time and in the absence of interaction estimates were pooled over time. Variables demonstrating an association with ASES score at $p < 0.100$ were included as potential confounders in subsequent analyses testing the association between cluster membership and ASES score over time. Univariate associations between potential confounding variables and ASES scores are detailed (Appendix C, Table C.1) and differences in potential confounding variables between psychological clusters are detailed (Appendix C, Table C.2).

5.3.4 Assessment of the Association Between Cluster Membership and ASES score

A linear mixed-effects regression model with random intercept and time and psychological cluster membership as factor variables were used to assess the association of psychological cluster membership with ASES score over time. A time-by-psychological cluster interaction term was included to allow separate estimates for each group at each time point and thus test the difference between these measures according to psychological cluster membership at each time point as well as assess differential changes between groups over time. The model was adjusted for variables identified as potential confounders as described previously. Ninety-five percent confidence intervals and p values are provided for all contrasts of interest. Linear mixed-effects regression models have advantages over traditionally used repeated-measures analysis of variance in these circumstances because they (1) allow the correlation of the within-subject repeated measures to be explicitly accounted for; (2) allow flexible modeling of time; and (3) allow use of all cases including those with missing data at one or more time points, which allows for unbiased estimates for time points with missing data providing data are at least missing at random⁵². Cases were used in this final analysis if they had (1) measures of all four psychological indicator variables at baseline; and (2) ASES scores for least at one of the three time points. A sensitivity analysis was performed by imputing cluster membership for those cases missing psychological indicator variables at baseline based on any available psychological variables and variables associated with cluster membership.

Analyses were performed using LatentGold Version 5.0 (Statistical Innovations Inc, Belmont, MA, USA) and STATA Version 14.1 (StataCorp, College Station, TX, USA).

5.4 Results

5.4.1 Are There Psychological Clusters in Patients Undergoing Shoulder Surgery?

Two distinct clusters were identified (Figure 5.2): one cluster with better psychological functioning (84 of 124 [68%]) and a second cluster with poorer psychological functioning (40 of 124 [32%]). Akaike's information criterion, Bayesian information criterion, and consistent Akaike's information criterion were used to assess and compare the statistics of the one- to five-cluster models (Table 5.1).

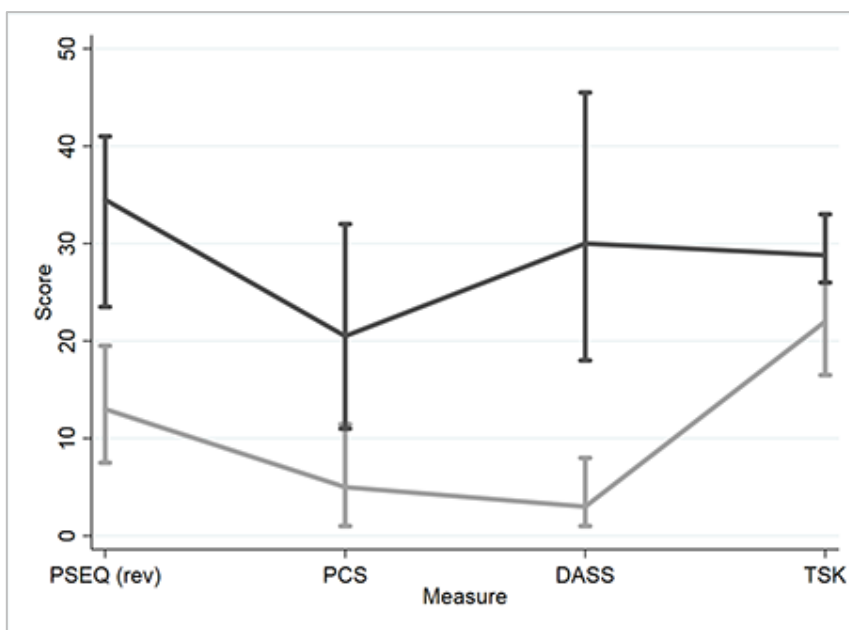


Figure 5.2 Cluster profiles identified from psychological indicator variables used in latent class analysis

Dark line represents cluster with poorer psychological function (32% of sample) and light line represents cluster with better psychological function (68% of sample). Data is presented as medians and interquartile range.

Abbreviations: PSEQ – Pain Self-Efficacy Questionnaire: (reversed score) possible range: 0-60 (higher score = lower pain self efficacy); PCS – Pain Catastrophising Scale; possible range: 0-52 (higher score = greater pain catastrophising); DASS – Depression Anxiety Stress Scale; possible range: 0-126 (higher score = greater psychological distress); TSK – Tampa Scale for Kinesiophobia: possible range: 1-44 (higher score = greater pain related fear of movement); C1: Better Psychological Function; C2: Worse Psychological Function; IQR – interquartile range.

Table 5.1 Latent Class Analysis measures of model fit and classification accuracy for 1 to 6 cluster models of psychological functioning

Number of classes	BIC(LL)*	AIC(LL)*	CAIC(LL)*	Classification error [†]	Entropy R ^{2‡}
1	3755	3732	3763	0.00	NA
2	3594	3546	3611	0.05	0.80
3	3587	3514	3613	0.10	0.76
4	3597	3499	3632	0.11	0.80
5	3612	3488	3656	0.13	0.78

*Adjusts the LL value for the number of parameters in the model, thus accounting for model parsimony with a lower value indicating a more preferable model; [†]classification error indicates the proportion of cases that are estimated to be misclassified when cases are classified to the class for which they have the highest posterior probability with values closer to 0 desirable; [‡]entropy R² value indicates how well class membership can be predicted based on the indicator variables with values closer to 1 desirable.

Abbreviations: BIC = Bayesian information criterion; AIC = Akaike's information criterion; CAIC = consistent Akaike's information criterion; LL = log likelihood; NA = not applicable.

These statistics supported a three-, five-, and two-cluster model, respectively, but graphic inspection showed a leveling out of all three statistics from the two-cluster model upward. The classification accuracy of the two-cluster model was good with classification error and entropy R² value equal to 0.05 and 0.80, respectively. The average (SD) posterior probability for better psychological function was 0.96 (0.08) and for poorer psychological function was 0.93 (0.13), which is well above the minimum value of 0.7 recommended for model adequacy,⁵³ and the odds of correct classification were 11.8 and 27.0 for better and poorer psychological function, respectively, also well above the value of ≥ 5 suggested to indicate high assignment accuracy.⁵³ Two- to five-cluster models all demonstrated varying distinctions of better and poorer psychological functioning across all measures similarly with no patterns indicating a class with high scores on some indicator variables and not others. Given this and the acceptable fit of the two-cluster model, a two-cluster solution was chosen as the most parsimonious solution and participants assigned to the cluster for which they displayed the maximum posterior probability of membership for cluster profiling. The cluster with poorer psychological function exhibited moderate levels of depression and stress, anxiety within normal limits, high levels of kinesiophobia, mild to moderate levels of catastrophizing, and low levels of pain self-efficacy (Table 5.2).

Table 5.2 Individual psychological measures and confounding variables for the two clusters derived using latent class analysis

Psychological measure	Cluster with better psychological function (n = 84 [68%])	Cluster with poorer psychological function (n = 40 [32%])	p value
DASS depression score			
(median [IQR])	0 (0, 2)	9.5 (5, 16)	< 0.001 [‡]
(minimum, maximum)	(0, 16)	(0, 42)	
DASS anxiety score			
(median [IQR])	0 (0,1)	4 (2, 11)	< 0.001 [‡]
(minimum, maximum)	(0, 7)	(0, 42)	
DASS stress score			
(median [IQR])	2 (0,4)	15.5 (10, 21)	< 0.001 [‡]
(minimum, maximum)	(0, 17)	(0, 38)	
PCS (rumination)			
(median [IQR])	2 (0,4)	7.5 (4, 12)	< 0.001 [‡]
(minimum, maximum)	(0, 12)	(0, 16)	
PCS (magnification)			
(median [IQR])	1 (0, 1.5)	4 (1.5, 7)	< 0.001 [‡]
(minimum, maximum)	(0, 5)	(0, 12)	
PCS (helplessness)			
(median [IQR])	2 (0, 5)	8.5 (4.5, 14)	< 0.001 [‡]
(minimum, maximum)	(0, 11)	(1, 23)	
PSEQ			
(median [IQR])	48 (41.5, 53.5)	26.5 (20, 37.5)	< 0.001 [‡]
(minimum, maximum)	(22, 60)	(4, 60)	
TSK			
(median [IQR])	22 (16.5, 26)	28.8 (26, 33)	< 0.001 [‡]
(minimum, maximum)	(11, 41)	(14, 43)	

Statistical test used: [‡]Wilcoxon rank-sum test

Abbreviations: DASS = Depression Anxiety Stress Scale; IQR = interquartile range; PCS = Pain

Catastrophising Scale; PSEQ = Pain Self-Efficacy Questionnaire; TSK = Tampa Scale for Kinesiophobia

5.4.2 Association of Psychological Function With ASES score

The adjusted ASES scores were consistently better for those patients with better psychological functioning, where the mean (SD) adjusted ASES score before surgery and 3 and 12 months after surgery was 54.3 (18.0), 71.6 (16.3), and 86.2 (17.6), respectively, for the cluster with better psychological function and 39.5 (15.2), 52.2 (18.4), and 74.9 (19.7), respectively, for the cluster with poorer psychological function (Figure 5.3). At all time points, differences above or close to the minimal clinically important difference.^{35, 54} Similar changes over time were evident between clusters with both clusters displaying a significant improvement in ASES score from before surgery to 3 months, from 3 to 12 months, and in total improvement over 12 months, but there was no difference in the amount of ASES score improvement between clusters (between-

cluster difference in overall change before to 12 months after surgery = -0.1 points; 95% confidence interval [CI], -9.1 to 8.9) (Table 5.3). A sensitivity analysis was conducted whereby the latent class membership for the 13 participants missing some or all of the psychological indicator variables was estimated, utilizing the available baseline psychological data and those covariates associated with class membership. This resulted in almost identical findings regarding the differences between the clusters at and between the time points with both clusters displaying a significant improvement over 12 months (change of 32 points for cluster with better psychological function and 31 for cluster with poorer psychological function) and no difference in the amount of ASES score improvement between clusters (between-cluster difference in overall change before to 12 months after surgery = -1.6 points; 95% CI, -9.9 to 6.7). The association between confounding variables and adjusted ASES score for all other variables showed that women had worse function (regression coefficient for ASES: -6.3 [95% CI, -11.1 to -1.5], $p = 0.010$); as did patients with workers' compensation (regression coefficient for ASES: -7.5 [95% CI, -13.5 to -1.5], $p = 0.014$), greater increment of alcohol use (regression coefficient for ASES: 2.2 [95% CI, 0.2-4.3], $p = 0.031$), and patients with a score of 8 or more for confidence in surgical outcome (regression coefficient for ASES: 5.6 [95% CI, 0.7-10.6], $p = 0.026$) (Table 5.4).

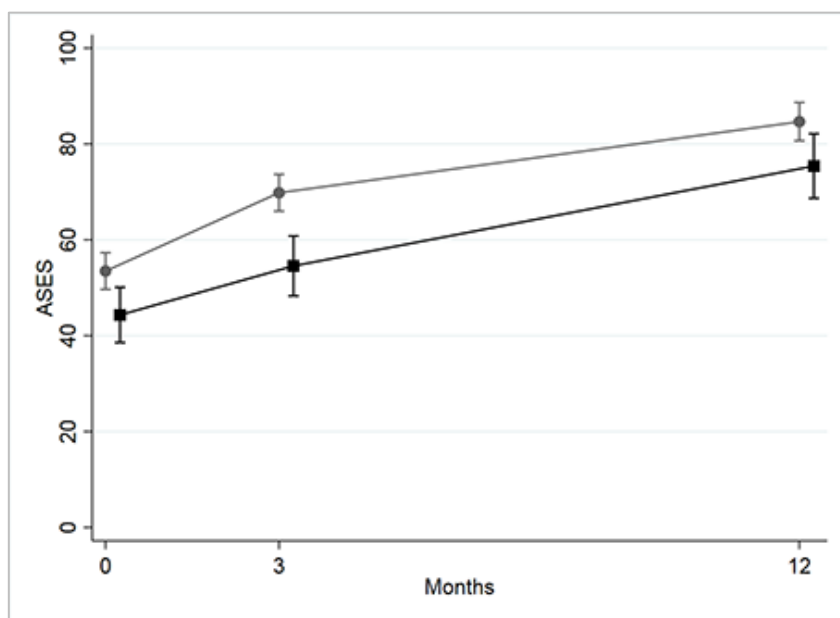


Figure 5.3 The adjusted predictions of ASES score over time by psychological cluster

Dark line represents cluster with poorer psychological function (32% of sample) and light line represents cluster with better psychological function (68% of sample). Data is presented as mean (95% confidence interval).

Abbreviations: ASES = American Shoulder and Elbow Score possible range: 0-100 (higher score = less pain and disability)

Table 5.3 Change in ASES before surgery, 3 months and 12 months after surgery by psychological cluster adjusted for potential confounders for gender, workers' compensation status, alcohol use, and confidence in surgical outcome

Time Point	Better psychological function					Poorer psychological function			Group difference at each time point (Col H – Col D)	Group difference in change over time points (Col I – Col E)
	Number	Observed mean (SD)	Predicted mean	Change from preceding time point (95% CI)	Number	Observed mean (SD)	Predicted mean	Change from preceding time point (95% CI)		
<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>E</i>	<i>F</i>	<i>G</i>	<i>H</i>	<i>I</i>	<i>J</i>	<i>K</i>
Before surgery	76	54 (18)	54		38	40 (15)	44		-9 (-16 to -2) p = 0.011	
3 months	76	72 (16)	70	16 (12-21) p < 0.001	30	52 (18)	55	10 (3-17) p = 0.005	-15 (-23 to -8) p < 0.001	-6 (-15 to 3) p = 0.162
12 months	71	86 (18)	85	15 (10-17) p < 0.001	25	75 (20)	75	21 (13-28) p < 0.001	-9 (-17 to -1) p = 0.023	6 (-3 to 15) p = 0.198
Total change from before surgery to 12 months				31 (23-39) p < 0.001				31 (26-36) p < 0.001		0 (-9 to 9) p = 0.984

ASES = American Shoulder and Elbow Surgeons score, CI = confidence interval

Table 5.4 Estimates for the independent association between confounders with ASES, pooled over timepoints, for all confounding variables in the multivariable model

Variables in model	Regression coefficient	95% CI		p value
Female gender	-6.3	-11.1	-1.5	0.010
WC	-7.5	-13.5	-1.5	0.014
Alcohol (per category increment)	2.2	0.2	4.3	0.031
Confidence 8 or more (63%)	5.6	0.7	10.6	0.026

Abbreviations: ASES = American Shoulder and Elbow Surgeons score; CI = confidence interval; WC = workers' compensation claim.

5.5 Discussion

Previous studies exploring the association of affective psychological factors with outcome after shoulder surgery have reported conflicting findings,²³⁻²⁶ and cognitive factors have not been considered. Therefore, we aimed to assess if differential patterns of affective and cognitive factors in people undergoing shoulder surgery were evident and if there was an association of these factors with pain and disability levels before and after surgery. This study identified two clusters of people, one with poorer psychological function before surgery that was associated with statistically and clinically important higher levels of shoulder pain and disability,^{35, 54} both before and up to 1 year after shoulder surgery, adjusting for gender, workers' compensation claim, alcohol consumption, and confidence in surgical outcome. However, both clusters showed very similar improvements in ASES score over time. The inclusion of both affective and cognitive psychological measures in this study encompass a broader analysis of psychological function than has previously been explored for shoulder surgery. The study findings support recent reports that both depression and catastrophizing are associated with higher levels of pain and disability in the shoulder¹¹ and other musculoskeletal conditions.^{4, 27, 28}

There were several limitations in this study. Participants in this study were recruited from surgical lists that may result in some patients scoring favorably on some cognitive measures as a result of a belief that surgery would "fix" their shoulder. Selection bias may have occurred during the recruitment phase, when not all patients undergoing surgery by the participating surgeons were recruited, and patients who declined to participate in the study may have scored differently on the psychological measures.

Psychological measures were not explored at 3- and 12-month followup, so it is unknown whether psychological measures change or not over time after shoulder surgery and how this links to changes in pain and disability. The confidence in surgical outcome with the Likert scale used in this study has not been previously validated. Because this study investigated patients undergoing shoulder surgery, there was no comparison to conservative management or no treatment, so the comparative course of recovery over time for conservative management or no treatment is unknown. Because this study included patients who underwent subacromial decompression only as well as patients who underwent rotator cuff repair, the findings cannot be attributed to one type of shoulder surgery; however, with the numbers available, there was no evidence that the proportions of people receiving each surgery type were different according to cluster membership or ASES scores. This study represents a sample of convenience, although the sample size obtained was sufficient to show statistically significant and clinically meaningful differences.

Although there were a number of limitations in this study, our important findings support an association of poor psychological function with higher levels of shoulder pain and disability before and after shoulder surgery. Psychological factors warrant consideration before shoulder surgery in view of recent literature that questions the benefit of subacromial decompression surgery,²⁹ a procedure commonly undertaken for impingement, which is a debatable condition⁵⁵ with limited surgical indication or efficacy.⁵⁶ Surgical management targeting the biologic dimension of shoulder pain only may fail to address factors such as poor psychological function, resulting in unnecessary surgery or poorer outcomes after surgery.

Two psychologically derived clusters were identified in this sample of patients who underwent either subacromial decompression only or rotator cuff repair with or without subacromial decompression. One cluster displayed better scores across all psychological measures, which reflected confidence in undertaking daily activity tasks despite pain, limited fear beliefs, or catastrophizing, and normal limits of depression, anxiety, and stress.³⁶ In contrast, a second cluster of patients had poorer psychological function with lower pain self-efficacy, mild to moderate levels of pain catastrophizing, moderately elevated levels of depression and stress, and high levels of kinesiophobia. The difference in kinesiophobia scores between clusters (6.8 points) was clinically meaningful⁴⁶ with the median score of 28.8 in the poorer psychological function cluster aligned with previous studies reporting elevated kinesiophobia and catastrophizing in patients with

shoulder pain and disability.^{13, 18, 57} Patients with poorer psychological function showed levels of moderate depression and stress but lower levels of anxiety, similar to a previous study of patients scheduled for rotator cuff repair.⁹

For all study participants, being female, having an active workers' compensation claim, less alcohol consumption, and lower levels of confidence in surgery were associated with lower ASES scores at all time points. However, psychological cluster membership was associated with ASES score independent of these variables. These findings are consistent with current evidence reporting that older age,^{58, 59} female gender,^{58, 60} smoking,⁶¹⁻⁶³ stiffness before surgery,²⁴ insulin-dependent diabetes,⁶⁴ obesity,⁶⁵ lower education level⁶⁶ and an active workers compensation claim^{67, 68} are negatively associated with pain and disability outcome after shoulder surgery, whereas greater expectations are positively associated with outcome.⁶⁹ This study did not find a significant association between age, education level, or comorbidities and ASES score after surgery. It is unknown why our findings showed more frequent alcohol consumption was associated with better ASES scores. Although participants with poorer psychological function reported significantly lower levels of confidence that surgery would relieve symptoms, a lower level of confidence in surgical outcome was associated with poorer scores on ASES score at all data collection time points independent of psychological cluster membership. A less optimistic outlook regarding surgical outcome is unsurprising in a group scoring poorly on psychological questionnaires, potentially associated with a more negative affect. However, the results show that even in those with better psychological function, optimism regarding surgery is associated with a better outcome. These findings are consistent with previous research suggesting that an optimistic outlook is strongly associated with improved outcome of surgery⁷⁰ and physiotherapy treatment.¹⁹ In this study, duration of symptoms of > 1 year was not significantly associated with ASES score, which is consistent with findings from other studies.^{58, 71} This study found no overall association with hospital setting (public/private) or primary surgical procedure and ASES score.

Participants who scored poorly on a range of psychological measures before shoulder surgery displayed worse ASES scores at 3 and 12 months after surgery, although both clusters showed similar improvements in ASES score over time. Screening of psychological factors before surgery is recommended to identify patients with poor psychological function with simple screening tools such as the Orebro⁷² or modified STarT Back musculoskeletal tool^{73, 74} that capture fear, mood, anxiety, and

beliefs. It could be speculated that patients with poor psychological function may benefit from pharmacology, psychological, or behavioural interventions before consideration of surgery; however, this an area that requires further research in the shoulder. Targeted interventions directed to psychological factors before or after shoulder surgery may improve clinical outcomes. Cognitive-behavioural therapy has been reported to be an effective treatment for the management of other musculoskeletal conditions such as low back pain⁷⁵ and idiopathic hand and arm pain.⁷⁶ Future randomized controlled trials are recommended to test behavioural and psychological intervention in patients with poor psychological function who are undergoing shoulder surgery.

5.6 Conclusions

This study supports that a comprehensive assessment of affective and cognitive psychological factors before shoulder surgery may identify patients with poor psychological function. Alternative management pathways may be beneficial to improve clinical outcomes; however, further research is needed to determine the optimal management for patients with poorer psychological function to improve pain and disability levels before and after surgery.

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Chapter 6 Different Aspects of Patient-Centred Outcome After Shoulder Surgery are Similarly Associated with Psychological Status Before Surgery

Study Four:

Different measures of patient-centred outcome after shoulder surgery are similarly associated with psychological status before surgery

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The following paper has been prepared for peer review

Introduction to Study Four

The rising surgical trends discussed in study 1, the lack of robust surgical criteria discussed in study 2 and the multidimensional nature of shoulder pain and disability discussed in study 3, highlight the complex nature of shoulder disorders.

Contemporary understanding of pain and disability underpins a biopsychosocial approach in the management of shoulder pain. The recent decade has shown a vast number of studies attempting to elucidate what prognostic factors before shoulder surgery are associated with better outcome after surgery. However, there is currently a lack of consistency in the use of different measures of outcome across shoulder studies, and it is not clear what factors before surgery are associated with these measures of outcome. Contemporary healthcare models are discussed in study 4 outlining the important patient-centred approach for the assessment and management of shoulder disorders.

Therefore, study 4 explored how strongly three different aspects of patient-centred outcome (pain and disability change scores, global rating of change and satisfaction) are associated with each other. In addition, psychological factors, along with other factors, previously identified to have an association with shoulder pain and disability and outcome after shoulder surgery, were explored with respect to the consistency of any association across all the three aspects of patient-centred outcome.

Study 4 is reproduced in this chapter, with supplementary documentation included in Appendix D. This information includes: (1) Table D.1, Comparison of descriptive statistics for all variables before surgery for participants with and without measures of all three aspects of patient-centred outcome at 12 months after surgery, (2) Section D.2, Global Rating of Change Scale, and (3) Section D.3, Satisfaction Scale.

DIFFERENT ASPECTS OF PATIENT-CENTRED OUTCOME AFTER SHOULDER SURGERY ARE SIMILARLY ASSOCIATED WITH PSYCHOLOGICAL STATUS BEFORE SURGERY

6.1 Abstract

6.1.1 Background

Different aspects of patient-centred outcome after shoulder surgery have been measured by a range of different metrics. How strongly these different aspects of outcome relate to each other is unknown. Also not clear, is whether different aspects of outcome are similarly associated with psychological factors, and other variables measured before surgery, that have previously been identified to be associated with one or more aspects of outcome.

6.1.2 Questions/purposes

- i. What is the association between three different aspects of patient-centred outcome (change in patient-reported pain and disability outcome measures, global rating of change, patient satisfaction)?
- ii. Are psychological factors, and other factors previously associated with one or more aspects of outcome, similarly associated with each of the three aspects of patient-centred outcome?

6.1.3 Methods

One hundred and fifty three patients scheduled for shoulder surgery completed a survey measuring factors from multiple dimensions (psychological, demographic, health, social, lifestyle, pain and disability) prior to surgery. Aspects of patient-centred outcome measured at 12 months after surgery were: change in pain and disability (using; American Shoulder and Elbow Surgeons score, Disabilities of the Arm, Shoulder and Hand, Shoulder Pain and Disability Index); global rating of change; and patient satisfaction. Correlations between the three aspects of patient-centred outcome were assessed, and multivariate regression analysis was used to determine and compare associations of each variable measured prior to surgery with the three aspects of outcome.

6.1.4 Results

All three aspects of patient-centred outcome were moderately to strongly associated with each other (pain and disability change and global rating of change $r=0.63$, $p<0.001$; pain and disability change and satisfaction $r=0.71$, $p<0.001$; satisfaction and global rating of change $r=0.81$, $p<0.001$). After adjustment for potential confounding factors, depression, anxiety and stress symptomatology, pain self-efficacy, confidence that surgery would relieve symptoms, and duration of symptoms were statistically significantly associated with one or more of the three aspects of patient-centred outcome (y-standardised regression coefficients; -0.14 to 0.45, p-values; 0.007-0.048). The strength of association of factors explored before surgery was similar across all three aspects of patient-centred outcome. However, there was weak evidence that pain self-efficacy was more strongly associated with satisfaction and global rating of change than change in pain and disability level ($p=0.051$).

6.1.5 Conclusions

Three different aspects of patient-centered outcome, provide similar information regarding a good or poor outcome from the individual's perspective at one-year after shoulder surgery. Depression, anxiety and stress symptomatology, pain self-efficacy, confidence in surgical outcome and symptom duration prior to surgery are associated with patient centred outcome measures one year after surgery. Screening and targeting of psychological factors prior to surgery is warranted and may improve outcomes.

6.2 Introduction

Shoulder surgery is a popular treatment for shoulder pain,¹⁻⁴ however the efficacy for some shoulder surgical procedures has been questioned.⁵ Studies investigating outcome after shoulder surgery report that structural integrity following rotator cuff repair does not correlate with pain and disability outcome.^{6, 7} This suggests that other non-structural factors may be more important for pain and disability outcomes than tendon healing.

Historically, outcome after shoulder surgery has been determined by metrics including clinical examination,⁸ imaging,⁹ complication rates.¹⁰ The value of patient-reported pain and disability outcome measures have been recognised in recent decades, with over thirty different measures being used in research studies of outcome after shoulder surgery.¹¹ Over the last decade, patient-centred care has gained greater importance and is considered the foundation of contemporary models of health care internationally, including those for musculoskeletal pain.¹² A patient-centred assessment of outcome considers individual patient preferences, needs and values¹³ and may be measured in a variety of ways, including patient-reported pain and disability measures, global rating of change and satisfaction.

Patient-reported pain and disability measures determine outcome by capturing the pain experience and disability from the individual's perspective,^{11, 14} and are widely accepted measures used clinically and in research. Previous studies have explored responsiveness and reliability of different pain and disability measures,¹⁵⁻¹⁷ with the American Shoulder and Elbow Surgeons score (ASES),¹⁸ Disabilities of the Arm, Shoulder and Hand (DASH)¹⁹ and Shoulder Pain and Disability Index (SPADI)²⁰ reported to be the most extensively studied²¹ and similarly responsive.^{11, 15, 22} Global rating of change (GRC),²³ used in musculoskeletal research to quantify improvement or deterioration over time, has utility as an outcome measure due to its simplicity and time efficiency. However, it has not been reported as an outcome measure after shoulder surgery. Patient satisfaction is considered to be another important indicator for measuring quality in health care.²⁴ Measuring patient satisfaction with surgical outcome is not new, but has only more recently been utilized as a measure after shoulder surgery, as an important indicator of outcome in patient-centred care models.²⁵⁻²⁷ Although individuals may report improvements in pain and disability scores after shoulder surgery, they may report dissatisfaction after surgery. An understanding of an individual's

perspective on outcome after shoulder surgery is important, as it may influence whether or not individuals seek additional or alternative care.

Psychological factors, both affective (moods and emotions) and cognitive (thoughts and beliefs), are an important consideration in persistent musculoskeletal pain.²⁸ These factors can influence an individual's subjective experience of pain and disability, before and after surgery. For individuals with shoulder pain, poor psychological function has been associated with higher levels of pain and disability²⁹⁻³² and poorer quality of life.²⁹ For individuals undergoing shoulder surgery, three studies have reported no association³³⁻³⁵ and one study did report an association³⁶ of poor psychological function with worse pain and disability outcome after surgery. In support of the findings by Dekker³⁶, we recently reported that a subgroup of individuals with poor psychological function before surgery displayed statistically and clinically important higher levels of pain and disability, both before and up to 12 months after shoulder surgery. This was in spite of these individuals showing similar levels of improvement in pain and disability scores over time, to a subgroup with better psychological function before surgery.³⁷

Expectations of outcome and confidence in the success of surgery are important cognitive factors specific to the surgical setting. Greater expectations before shoulder surgery have been associated with better pain and disability outcome^{38, 39} and greater satisfaction²⁷ after surgery. These studies are in contrast to other areas of orthopaedic surgery reporting that overly optimistic expectations for knee arthroscopy⁴⁰ or knee arthroplasty^{41, 42} are associated with lower patient satisfaction, or that expectations have no influence on satisfaction after knee arthroplasty.^{43, 44} Koorevaar⁴⁵ recently highlighted the need for future shoulder surgery studies to investigate the association between expectations, psychological factors and patient-centred outcome.

Not yet explored is how strongly these three different aspects of patient-centred outcome (pain and disability outcome, global rating of change and patient satisfaction) relate to each other. It is also not clear whether psychological factors, and other factors previously associated with outcomes, are similarly associated with all three aspects of patient-centred outcome after shoulder surgery.

Therefore, we asked (1) How strongly are the three different aspects of patient-centred outcome (patient-reported pain and disability measures, GRC and satisfaction) associated with each other? (2) Are psychological factors and other factors before surgery similarly associated with all three aspects of patient-centred outcome?

6.3 Materials and Methods

6.3.1 Study design and setting

A prospective longitudinal observational study of adult patients undergoing shoulder surgery for rotator cuff disorders was undertaken at one private and two public hospitals in Perth, Western Australia, during an 18-month period from January 2014 to July 2015. Study approval was attained from the Human Research Ethics Committees at Curtin University and Sir Charles Gairdner Hospital, Perth, Western Australia.

6.3.2 Participants

All patients scheduled for shoulder surgery ($n = 184$) by one of six participating surgeons (MH, JS, GB, SG, PK, AT) were invited to participate. Three surgeons (JS, PK, AT) operated across the three hospital settings. Data collection at 12 months after surgery was completed between April 2014 and July 2016. Inclusion criteria were patients scheduled for unilateral surgery for rotator cuff repair with or without subacromial decompression for partial and full thickness tears ($n=50$ in the analysis sample), and arthroscopic subacromial decompression only ($n=33$ in the analysis sample). The type of surgery was unable to be ascertained for 21 participants in the analysis sample due to inaccessible surgical records. Exclusion criteria were prior neck surgery, prior surgery on the same shoulder, presence of rheumatoid arthritis, fibromyalgia, local or malignant cancer, glenohumeral joint osteoarthritis or an inability to comprehend English. Paper copies of all questionnaires were mailed for completion during the week before their scheduled surgery and the ASES, DASH and SPADI, global rating of change and patient satisfaction questionnaires were mailed for completion at 12 months after surgery. A physical assessment was undertaken during the week before surgery in the surgical or physiotherapy clinic. Of the 184 patients who were invited to take part in the study, 14 were excluded, 6 were not able to be contacted and 11 declined to participate, leaving 153 that were recruited and consented to participate. Of these, 16 patients withdrew prior to data collection, due to cancellation of surgery, conservative management or changed their mind about study participation. Of the remaining 137 patients, 104 had measures available for all three aspects of outcome at 12 months after surgery and were included in the analyses of this study (Figure 6.1). Median age of the analysis sample was 54 years (range, 22-79 years) and 38 of 104 (37%) were women.

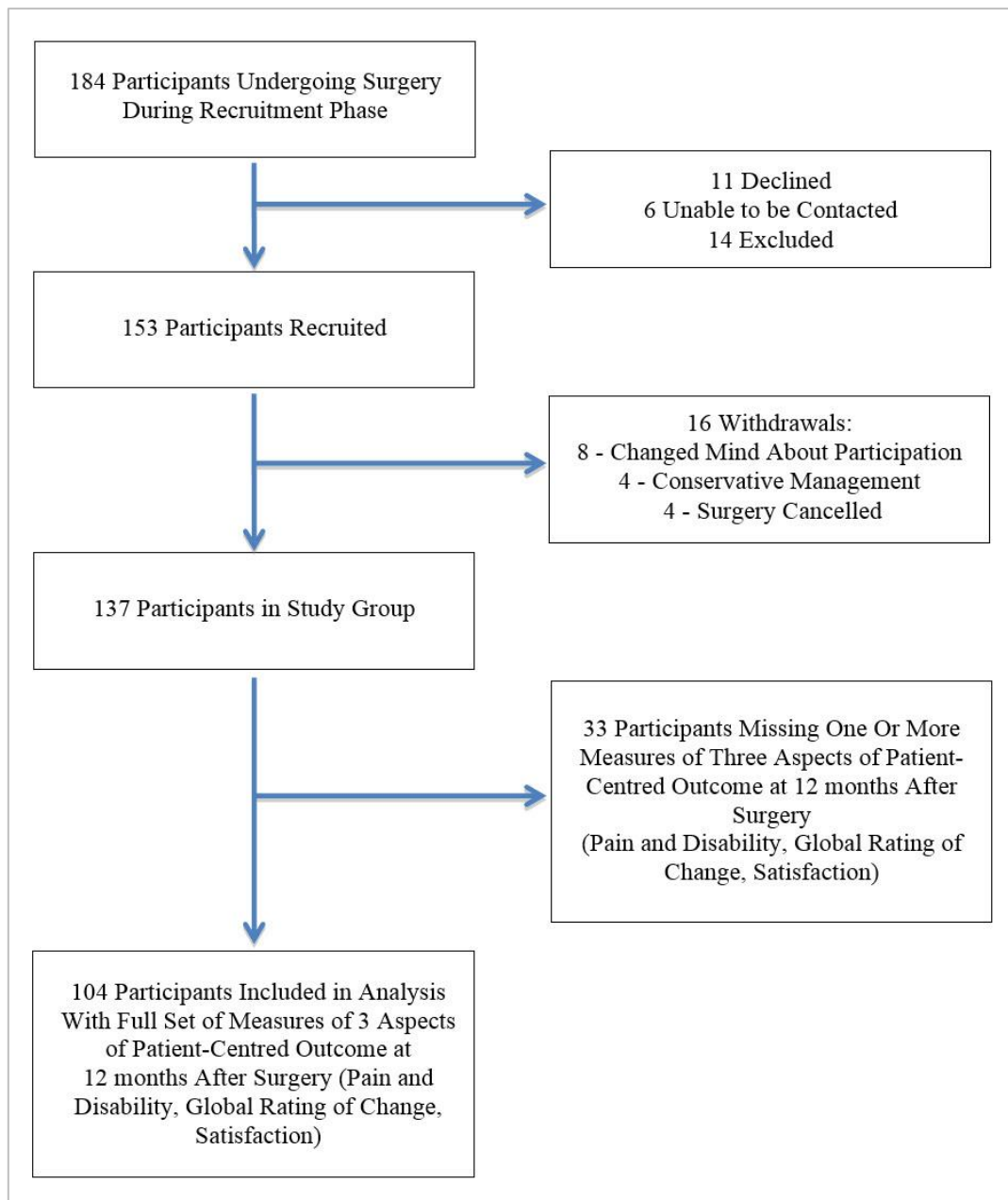


Figure 6.1 Flow chart illustrating recruitment of participants into the study with three measures of patient-centred outcome

6.3.3 Measurement of outcome variables

Measurement of DASH, SPADI and ASES score

The American Shoulder and Elbow Surgeons scale (ASES)¹⁸ contains a pain subscale with one item (10cm VAS) and a function subscale with 10 items (questions are rated on a 4-point Likert scale for level of difficulty), with total score 0-100 (pain subscale 0-50; function subscale 0-50), with lower score indicating greater pain and disability. The ASES has been reported to have good reliability and validity,^{15, 46, 47} has normative data reported⁴⁸ and change scores in the range 12-17 are considered a

minimal clinically important difference.⁴⁹ The Disabilities of the Arm Shoulder and Hand questionnaire (DASH)¹⁹ is a region specific questionnaire that contains 30 items, with 5 related to symptoms and 25 related to functional tasks. Items are scored on a 5 point ordinal scale, with total score converted to a percentage (0-100%), where a higher score means greater pain and disability. The DASH has been shown to have good reliability and validity.⁵⁰ The Shoulder Pain and Disability Index (SPADI)²⁰ contains a pain subscale with 5 items and a disability subscale with 8 items, with questions rated on a 10-point Likert scale from 0-10. A total score is calculated by adding the pain subscale (score multiplied by 5 to give a pain subscale of 0-50) to the disability subscale (score multiplied by 5 and divided by 8 to give a disability subscale of 0-50), where a higher score means greater pain and disability. The SPADI has been shown to have good reliability and responsiveness.^{15 46}

Measurement of global rating of change (GRC)

Two GRC scales²³ were completed at 12 months after surgery. Two questions were asked; *“With respect to your degree of shoulder pain, how would you describe your pain level now compared to immediately before your surgery?”* and *“With respect to your shoulder function, how would you describe your shoulder function now compared to immediately before your surgery?”* An ‘overall improvement rating’ for each scale was scored from -7 (very much worse) to +7 (very much better) to reflect how much better or worse the patient felt they were after surgery compared to before surgery with respect to pain and to function.

Measurement of patient satisfaction

Patient satisfaction was measured using a 10 point numeric rating scale from 1 ‘very unsatisfied’ to 10 ‘very satisfied’ in response to the question at one year after surgery; *“How satisfied are you with the outcome of your shoulder surgery?”* This measure has been previously used to determine patient satisfaction with surgical outcome.²⁵

6.3.4 Measurement of psychological and other variables before surgery

Psychological function before surgery was measured by four self-report psychological questionnaires. The Depression, Anxiety and Stress Scale (DASS)⁵¹ is a 42-item, valid^{52, 53} and reliable⁵⁴ measure containing 3 subscales of depression, anxiety and stress, with an overall score ranging from 0-126 with higher scores reflecting higher levels of psychological distress. The Pain Catastrophizing Scale (PCS)⁵⁵ is a 13-item,

valid and reliable ^{56, 57} measure of thoughts and feelings that may be experienced in the presence of pain, with scores ranging from 0-52, with higher scores reflecting greater catastrophizing. The Pain Self-Efficacy Questionnaire (PSEQ)⁵⁸ is a 10-item valid and reliable questionnaire ⁵⁸⁻⁶⁰ evaluating the coping ability of an individual for a range of issues with scores ranging from 0-60, with lower scores reflecting poorer self-efficacy beliefs. The Tampa Scale of Kinesiophobia (TSK-11)⁶¹ is an 11-item valid and reliable ⁶²⁻⁶⁴ questionnaire that examines fear of movement or re-injury, with scores ranging from 11-44, with higher scores reflecting higher pain-related fear.

Expectation of outcome after surgery was assessed using the 6-item Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) questionnaire³⁹. Participants were asked *“What results do you expect to get from your treatment for: relief from symptoms; ability to do more everyday household or yard activities; to sleep more comfortably; to go back to the usual job; to exercise and participate in recreational activities and; to prevent future disability”*. Responses were rated on a Likert scale with a score of 1 corresponding to the lowest level of expectation (not at all likely) and a score of 5 corresponding to the highest level of expectation (extremely likely). The average response to 6 questions was calculated to generate a mean expectations score, or for answers marked “not applicable”, the point value from this question was not included in the calculation of the mean expectation score.

Confidence in recovery from surgery was determined on an 11-point numerical rating scale in response to the question *“How confident are you that your shoulder symptoms will improve after surgery?”* with 0 representing ‘not confident’ and 10 representing ‘completely confident’. Responses were subgrouped into a binary variable, based on a median score of 8, with higher confidence denoted by a score of 8 or more and lower confidence represented by a score of less than 8. This question has not been previously used in shoulder research.

Variables tested for their association across all three measures of outcome were chosen if they had shown previous reported associations with outcome after shoulder surgery,^{29, 31, 32, 65-69} or shoulder pain and disability.^{6, 70-74} Height and weight measures were taken during the physical examination and used to calculate body mass index (BMI). The self-report questionnaire booklet before surgery recorded age, gender, smoking (yes/no), alcohol use (never, monthly or less, 2-4 days per month, 2-3 days per week, >4 days per week), health comorbidities (none, one or more comorbidities), education level (high school or less, Tertiary College, University), occupation (lifting

tasks /no lifting), an active workers' compensation claim (yes/no), duration of symptom history (<1 year, >=1year), hospital setting (public/private) and current recreational or competitive sport participation (yes/no).

6.3.5 Data management and statistical analysis

Descriptive statistics

Analyses were performed using STATA Version 14.1 (StataCorp, College Station, TX, USA). Characteristics of the study sample are described and variables compared for those participants with (n=104) and without (n=33) measures of all three aspects of outcome (Appendix D, Table D.1).

Outcome variables

For analysis, ASES, DASH and SPADI scores before and after surgery were all calculated as a score from 0-100, and SPADI and DASH scores were reversed so that a higher score represented less pain and disability for all three measures. As ASES, DASH and SPADI scores were highly correlated before surgery ($r= 0.82-0.87$, $p<0.001$) and 12 months after surgery ($0.80-0.86$, $p<0.001$), and some participants were missing some values for this set of data, two summary scores were calculated as i) the average of the available ASES, DASH and SPADI scores before surgery, and ii) the average of the available ASES, DASH and SPADI scores 12 months after surgery.

At 12 months, ASES, DASH and SPADI scores all displayed a strong ceiling effect, which meant that potentially, people with higher scores before surgery had smaller change scores partly as a result of the ceiling at 100 points. In some circumstances, variables were moderately associated with scores before surgery, and therefore associations between these variables and the change score from before to 12 months after surgery may have been biased due to the aforementioned influence on the change score from the ceiling effect in the 12-month scores.⁷⁵ Therefore, a residualised change score was calculated and used for subsequent analysis, by subtracting the predicted 12-month value of the average of the ASES, DASH and SPADI scores (from a regression of 12-month score on the score before surgery) from the observed 12-month average score, with a positive value representing improvement in pain and function. As GRC scales for pain and function were highly correlated (Pearson's $r=0.88$, $p<0.001$) a summary score was calculated as the mean of the two items. The correlation between the residualised mean pain and disability change score, GRC and satisfaction was estimated using Spearman's rho.

Assessment of the association between psychological and other factors and aspects of patient-centred outcome

Multivariate regression analysis was used to determine and compare associations of each independent variable measured before surgery, with measures of the three aspects of patient-centred outcome, using Stata's *mvreg* command and *test* post-estimation command, which enabled fitting a regression model for i) residualised pain and disability change score, ii) global rating of change and iii) satisfaction separately using the same set of independent variables, and a post-estimation test of the equivalence of the regression coefficients for each single independent variable over the three outcomes. The three measures of outcome were converted to standardised z-scores prior to analysis to enable quantitative comparison of regression coefficients on the same scale for each independent variable across the three outcomes. Bootstrapped standard errors for 95% confidence intervals were used to adjust for skewed distribution of GRC and satisfaction outcomes, and the p-value from the Wald test of equality of the three coefficients were estimated. For those variables for which unadjusted estimates had $p < 0.1$, estimates were then adjusted for potential confounding from other measured variables. Potential confounders were considered to be variables that were associated with at least one outcome at $p < 0.10$, and potentially a common cause of both the independent variable of interest and the outcome variable (rather than on the pathway between them), and not part of the same overlapping construct (e.g. the four psychological measures). An *a priori* sample size calculation indicated that a sample size of 150 would be needed to detect squared partial correlations of at least 0.22 (change in R^2 of 0.05) with 80% power at $\alpha = 0.05$ in a model with 3 control covariates.

6.4 Results

There were 33 individuals missing 12-month outcome data that showed statistically significant differences from participants in the study group for a number of variables before surgery, namely PSEQ, PCS, confidence in surgical outcome, workers compensation status, smoking, hospital setting and sport level (Appendix D, Table D.1).

Is there an association between three aspects of patient centred-outcome?

Each pain and disability measure significantly improved from before surgery to 12 months after surgery. This represented a clinically meaningful reduction in pain and disability level at 12 months after surgery (Table 6.1). The ASES score improved by mean (SD) of 29.9 (20.2), DASH improved by 27.2 (18.1) and SPADI improved by 32.8

(24.9). The average of the ASES, DASH and SPADI scores improved by a mean (SD) of 29.8 (19.5), from 56.2 (18.1) to 85.8 (17.4). For GRC, most participants reported being very much better at 12 months after surgery for pain and function. The median (interquartile range) GRC for pain was 6 (4,7) and for function 6 (4,7), and for the average of these measures was 6 (4,7), which was used in subsequent analysis. For satisfaction, most participants were very satisfied with outcome at 12 months after surgery, with a median score of 9 (interquartile range 7-10). Thirteen participants (12.5%) had a score of 5 or lower and 42 (40.4%) had the highest possible score of 10. All three measures of patient-centred outcome (residualised change score, GRC and satisfaction) were moderately to strongly associated with each other at 12 months after surgery (pain and disability change and GRC $r=0.63$, $p<0.001$; pain and disability change and satisfaction $r=0.71$, $p<0.001$; satisfaction and GRC $r=0.81$, $p<0.001$).

Table 6.1 Change in pain and disability score, global rating of change and satisfaction at 12 months after surgery (n=104)

Outcome measure	Before surgery	12-months after surgery	Change before to after surgery
Pain and Disability Measures	<i>Mean [SD]</i>	<i>Mean [SD]</i>	<i>Mean (95% CI, p-value)</i>
ASES (0-100)	52.6 (16.8)	82.5 (19.1)	29.9 (25.6-34.1, $p<.001$)
DASH (0-100)*	50.7 (18.1)	77.9 (15.4)	27.2 (23.6-30.8, $p<.001$)
SPADI (0-100)*	50.4 (22.0)	83.3 (18.9)	32.8 (27.9-37.7, $p<.001$)
Average of 3 Pain and Disability Measures	56.2 (18.1)	85.8 (17.4)	29.6 (25.8-33.4, $p<.001$)
GRC		<i>Median [IQR]</i>	
Pain		6 (4,7)	
Function		6 (4,7)	
Average		6 (4,7)	
Satisfaction		<i>Median [IQR]</i>	
Satisfaction NRS 12 month after surgery		9 (7,10)	

Abbreviations: ASES – American Shoulder and Elbow Surgeons score: possible range 0-100 (higher score = less pain and disability); *Reversed DASH – Disabilities of the Arm, Shoulder and Hand: reversed score range 0-100 (higher score = less pain and disability); *Reversed SPADI – Shoulder pain and disability index: possible range 0-100 (higher score = less pain and disability); GRC – global rating of change: possible range -7 to +7 (higher score = greater overall change); Satisfaction NRS – numeric rating scale: possible range 1-10 (higher score = greater satisfaction)

Are associations between psychological and other factors similar across all three aspects of patient-centred outcome?

The univariate associations of independent variables with the three aspects of patient-centred outcome are reported in Table 6.2. The unadjusted and adjusted associations of those variables that displayed an association with at least one of the three outcomes at $p < 0.05$ are presented in Table 6.3.

Depression, anxiety and stress symptomatology, as measured by DASS, was univariately associated with all three outcomes. The strength of the associations were attenuated after adjustment for workers compensation status, duration of symptoms and sport level before surgery. After adjustment, DASS was significantly associated with worse pain and disability outcome and lower GRC, with a 10 point increase in DASS estimated to be associated with a 0.14 standard deviation lower pain and disability change (95%CI: -0.28, -0.01, $p=0.048$) and GRC (95%CI: -0.28, 0.01, $p=0.035$). However, the Wald test for differences in the regression coefficients across outcomes was not significant ($p=0.274$), meaning that with the numbers available, there was no evidence that DASS was more strongly associated with one aspect of patient-centred outcome than others.

Greater pain self-efficacy, as measured by PSEQ, was univariately associated with greater satisfaction and GRC. The strength of the associations were slightly attenuated after adjustment for workers compensation status, duration of symptoms and sport level before surgery. After adjustment, PSEQ was significantly associated with more positive GRC and higher satisfaction, with a 10 point increase in PSEQ estimated to be associated with a 0.23 standard deviation higher GRC (95%CI: 0.06, 0.40, $p=0.007$) and a 0.20 standard deviation higher satisfaction rating (95%CI: 0.03, 0.36, $p=0.021$). The p -value for the Wald test for differences in the regression coefficients across outcomes was 0.051, indicating weak evidence that pain self-efficacy may be more strongly associated with satisfaction and GRC than pain and disability change.

Table 6.2 Univariate associations of independent variables measured before surgery with each of the three aspects of patient-centred outcome

Variable	n	Pain and disability residualised change score	GRC	Satisfaction	p-value for test of equivalence of coefficients across 3 outcomes
		Coefficient ^a (95% CI) p-value	Coefficient ^a (95% CI) p-value	Coefficient _a (95% CI) p-value	
DASS (per 10 point increment)	100	-0.19 (-0.33, -0.05) .006	-0.17 (-0.32, -0.03) .020	-0.13 (-0.25, -0.02) .022	.181
PSEQ (per 10 point increment)	98	0.17 (-0.02, 0.33) .085	0.25 (0.05, 0.45) .013	0.22 (0.03, 0.40) .022	.357
PCS (per 10 point increment)	99	-0.20 (-0.48, 0.08) .155	-0.18 (-0.44, 0.09) .193	-0.13 (-0.36, 0.09) .245	.503
TSK (per 10 point increment)	100	0.13 (-0.14, 0.39) .341	-0.12 (-0.41, 0.17) .401	0.05 (-0.19, 0.30) .680	.116
Patient expectations (per 1 point increment)	102	0.30 (-0.11, 0.70) p=.151	0.23 (-0.20, 0.66) p=.291	0.15 (-0.23, 0.53) p=.443	.334
Confidence that surgery will relieve symptoms (8 or more)	100	0.52 (0.05, 0.98) .029	0.30 (-0.14, 0.75) .183	0.53 (0.07, 0.99) .025	.266
Average of reversed DASH, reversed SPADI and ASES on	105	NA	0.06 (-0.06, 0.18)	0.05 (-0.08, 0.17)	.663

Variable	n	Pain and disability residualised change score	GRC	Satisfaction	p-value for test of equivalence of coefficients across 3 outcomes
		Coefficient ^a (95% CI) p-value	Coefficient ^a (95% CI) p-value	Coefficient _a (95% CI) p-value	
0-100 scale before surgery (per 10 point increment)			.305	.480	
Age (per 5 yr increment)	104	0.01 (-0.05, 0.08) .668	0.02 (-0.06, 0.10) .659	0.05 (-0.02, 0.11) .185	.432
Female gender	104	-0.35 (-0.76, 0.08) .110	-0.06 (-0.46, 0.33) .748	-0.30 (-0.70, 0.11) .155	.151
Surgical procedure (RCR vs ASAD only)	83	0.10 (-0.32, 0.52) .656	-0.03 (-0.49, 0.43) .898	0.19 (-0.27, 0.65) .425	.313
Workers compensation claim	100	-0.73 (-1.49, 0.03) .058	-0.58 (-1.35, 0.20) .145	-0.67 (-1.41, 0.07) .075	.602
BMI (per 5 point increment)	100	-0.12 (-0.34, 0.09) .269	-0.05 (-0.22, 0.12) .571	-0.16 (-0.41, 0.09) .216	.459

Variable	n	Pain and disability residualised change score	GRC	Satisfaction	p-value for test of equivalence of coefficients across 3 outcomes
		Coefficient ^a (95% CI) p-value	Coefficient ^a (95% CI) p-value	Coefficient _a (95% CI) p-value	
Duration of symptoms (≥1yr)	103	-0.38 (-0.77, 0.01) .056	-0.33 (-0.74, 0.08) .125	-0.32 (-0.71, 0.08) .118	.899
Smoker	104	-0.58 (-1.29, 0.14) .113	-0.59 (-1.31, 0.13) .107	-0.39 (-1.06, 0.28) .255	.283
Alcohol use	104	0.09 (-0.06, 0.24) .263	0.08 (-0.08, 0.25) .332	0.03 (-0.13, 0.18) .722	.472
Lifting occupation	104	0.09 (-0.31, 0.51) .644	0.12 (-0.26, 0.51) .537	0.10 (-0.30, 0.50) .624	.979
Private hospital setting	104	-0.40 (-1.01, 0.21) .193	-0.12 (-0.72, 0.48) .695	-0.26 (-0.86, 0.34) .393	.492
Comorbidity (1 or more)	104	0.05 (-0.33, 0.43) .796	0.09 (-0.30, 0.48) .645	0.22 (-0.17, 0.60) .267	.420

Variable	n	Pain and disability residualised change score	GRC	Satisfaction	p-value for test of equivalence of coefficients across 3 outcomes
		Coefficient ^a (95% CI) p-value	Coefficient ^a (95% CI) p-value	Coefficient _a (95% CI) p-value	
Education level (3 levels, base=Secondary)	104	.419 ^b	.420 ^b	.229 ^b	.846 ^c
Tertiary College		0.28 (-0.14, 0.70)	0.26 (-0.15, 0.67)	0.38 (-0.06, 0.81)	.710
University		.187 0.18 (-0.35, 0.70)	.218 0.07 (-0.50, 0.65)	.087 0.23 (-0.33, 0.79)	.653
Sport level (rec/comp vs none)	104	.503 0.35 (-0.04, 0.73)	.800 0.21 (-0.20, 0.61)	.415 0.18 (-0.22, 0.57)	.422
		.076	.317	.378	

*for test of equivalence of coefficients across 3 outcomes

^aY-standardised regression coefficient, represents expected increase in outcome (Y) variable in 1SD units, per unit (as indicated) increase in independent (X) variable.

^boverall test of significance for 3-category variable for each outcome

^ctest for significance for all coefficients across three regression equations

Abbreviations: DASS – Depression Anxiety Stress Scale; PSEQ – Pain Self-Efficacy Questionnaire; PCS – Pain Catastrophising Scale; TSK – Tampa Scale for Kinesiophobia; PROMs – Patient-reported outcome measures; ASAD – Arthroscopic subacromial decompression; RCR – Rotator cuff repair; BMI – Body mass index; GRC – global rating of change: possible range; rec – recreational; comp - competition

Table 6.3 Unadjusted and adjusted associations of each independent variable measured before surgery with each of the three patient-centred outcome measures

Variable	n ^a	Pain and disability residualised change score	GRC	Satisfaction	p-value for test of equivalence of coefficients across 3 outcomes
		Coefficient ^b (95% CI) p-value	Coefficient ^b (95% CI) p-value	Coefficient ^b (95% CI) p-value	
DASS (per 10 point increment)					
Unadjusted	95	-0.21 (-0.06,-0.34) .004	-0.19 (-0.33,-0.04) .012	-0.16 (-0.27, -0.04) .007	.366
Adjusted ^c	95	-0.14 (-0.28,-0.01) .048	-0.14 (-0.28,-0.01) .035	-0.09 (-0.21,0.02) .113	.274
PSEQ (per 10 point increment)					
Unadjusted	93	0.19 (-0.01,0.39) .064	0.27 (0.08,0.47) .005	0.25 (0.08,0.43) .005	.223
Adjusted ^c	93	0.10 (-0.06,0.26) .222	0.23 (0.06,0.40) .007	0.20 (0.03,0.36) .021	.051

Variable	n ^a	Pain and disability residualised change score	GRC	Satisfaction	p-value for test of equivalence of coefficients across 3 outcomes
		Coefficient ^b (95% CI) p-value	Coefficient ^b (95% CI) p-value	Coefficient ^b (95% CI) p-value	
Confidence that surgery will relieve symptoms (8 or more)					
Unadjusted	95	0.52 (0.05,0.99) .029	0.31 (-0.13,0.76) .167	0.56 (0.09,1.04) .020	.251
Adjusted ^c	95	0.37 (-0.02,0.77) .063	0.20 (-0.19,0.59) .322	0.45 (0.02,0.88) .038	.267
Workers compensation claim					
Unadjusted	95	-0.84 (-1.65,-0.03) .041	-0.66 (-1.50,0.18) .124	-0.79 (-1.58,-0.01) .048	.540
Adjusted ^d	95	-0.50 (-1.18,0.19) .154	-0.33 (-0.93,0.27) .281	-0.59 (-1.34,0.15) .120	.420
Duration of symptoms (≥1yr)					
Unadjusted	95	-0.41 (-0.81,-0.02) .040	-0.35 (-0.78,0.07) .102	-0.36 (-0.76,0.03) .069	.936
Adjusted ^e	95	-0.39 (-0.76,-0.03) .036	-0.33 (-0.74,0.09) .120	-0.37 (-0.77,0.03) .068	.945

Variable	n ^a	Pain and disability residualised change score	GRC	Satisfaction	p-value for test of equivalence of coefficients across 3 outcomes
		Coefficient ^b (95% CI) p-value	Coefficient ^b (95% CI) p-value	Coefficient ^b (95% CI) p-value	
Sport level (rec/comp vs none)					
Unadjusted	95	0.46 (0.06,0.87) .026	0.32 (-0.09,0.74) .124	0.30 (-0.10,0.70) .141	.483
Adjusted ^f	95	0.26 (-0.11,0.63) .172	0.15 (-0.22,0.51) .436	0.12 (-0.25,0.51) .511	.679

^aboth unadjusted and adjusted models estimated using same sample, i.e. those cases with no missing values for all covariates in the model, therefore coefficients for unadjusted estimates differ slightly from those presented in Table 6.3.

^bY-standardised regression coefficient, represents expected increase in outcome (Y) variable in 1SD units, per unit (as indicated) increase in independent (X) variable.

^cadjusted for workers compensation status, duration of symptoms and sport level at baseline.

^dadjusted for DASS, duration of symptoms and sport level at baseline.

^eadjusted for DASS, workers compensation status, and sport level at baseline.

^fadjusted for DASS, workers compensation status and duration of symptoms at baseline.

Abbreviations: DASS – Depression Anxiety Stress Scale; PSEQ – Pain Self-Efficacy; GRC – global rating of change: possible range; rec – recreational; comp - competition

Having a level of confidence of 8/10 or more that surgery would relieve symptoms was univariately associated with greater pain and disability improvement and higher satisfaction. After adjustment for workers compensation status, duration of symptoms and sport level before surgery, confidence was significantly associated with satisfaction, with those having 8/10 or more confidence expected to have 0.45 standard deviation higher satisfaction levels (95%CI: 0.02,0.88, $p=0.038$). Although the point estimate for the regression coefficient for confidence was higher for satisfaction as an outcome than pain and disability outcome or GRC, with the numbers available, this study did not provide evidence that confidence was more strongly associated with satisfaction than other aspects of patient-centred outcome.

An active workers compensation claim was univariately associated with less pain and disability change and lower satisfaction. However, regression coefficients were attenuated and non-significant after adjustment for DASS, duration of symptoms and sport level, and there was no evidence for differential associations across the three outcomes. Having a duration of symptoms for one year or more was associated with less pain and disability improvement, and estimates were similar after adjustment for DASS, workers' compensation status and sport level, with those having a duration of symptoms of one year or more expected to have 0.39 standard deviation lower pain and disability change (95%CI:-0.76,-0.03, $p=0.036$). Point estimates were similar for GRC (-0.33, 95%CI:-0.74,0.09) and satisfaction (-0.37, 95%CI: -0.77,0.03) (Table 6.3). The Wald test for differences in the regression coefficients was non-significant ($p=0.945$) indicating there was no evidence that the duration of symptoms was more strongly associated with some aspects of patient-centred outcome than others. Similarly, although sport participation before surgery was univariately associated with greater pain and disability change, coefficients were attenuated and non-significant for all outcomes after adjustment for DASS, workers compensation status and duration of symptoms. With the numbers available, no other variables before surgery, including patient expectations, were found to be associated with any aspect of patient-centred outcome in this study.

6.5 Discussion

This study found that three aspects of patient-centred outcome; pain and disability change scores, satisfaction and global rating of change, showed moderately strong correlations with each other. This suggests they provide some overlapping information regarding a good or poor outcome after shoulder surgery.

The three different measures provide some overlapping information with regard to outcome, indicating that it may not be necessary to collect different measures of patient-centred outcome in order to determine outcome from the individual's perspective. The correlations between outcome measures were moderately strong, based on previous reports of effect size,⁷⁶ suggesting they capture similar aspects of outcome. The strength of the correlations showed that the square of the correlation coefficients suggested that they have shared variance, with approximately 40-60% of overlapping constructs. As satisfaction and global rating of change are less burdensome to measure after surgery than many shoulder pain and disability questionnaires, our study findings suggest they may be of equal value. In addition, this finding is reinforced as minimal clinically important changes for patient-reported shoulder pain and disability measures are commonly estimated by anchoring to global rating of change.⁷⁷ Conversely, there may be additional benefits in the use of patient-reported pain and disability measures. Knowledge about provocative activities or functional limitations that may direct rehabilitation to the concerns of each individual could be identified from the more detailed pain and disability measures.

Comparison between studies investigating prognostic factors for outcome after shoulder surgery is difficult, due to the variability of outcome measures used.⁷⁸ As this study showed that the three aspects of patient-centred outcome are correlated, it could be speculated with reasonable confidence that there is some generalisability in terms of good or poor outcome across studies. In addition, as the factors investigated before surgery were similarly associated with each measure of patient-centred outcome, it could also be considered with reasonable confidence, that there is some generalisability in reports of associations with one aspect of outcome to other aspects of outcome. This may facilitate comparison of studies of outcome after shoulder surgery that have used differing measures of patient-centred outcome. However, as this study showed that change in pain and disability, GRC and satisfaction are moderately strongly correlated with each other, this may provide a greater ability to compare studies that use these outcome measures.

Depression, anxiety and stress symptomatology, pain self-efficacy, confidence that surgery would relieve symptoms, and duration of symptoms prior to surgery were similarly associated with each measure of patient-centred outcome in this study. Different psychological measures were explored to determine if they were similarly associated with pain and disability outcome, GRC and satisfaction. This study found that

there was evidence that DASS was similarly associated with all three measures, but PSEQ may not be similarly associated with all three measures. PSEQ appears to be more strongly associated with GRC and satisfaction, than change in pain and disability. The PSEQ may potentially capture a general feeling of positivity in these individuals that is not so influential on the pain and disability outcome measures. Our study is the first to explore the association of cognitive factors with outcome after shoulder surgery. However, our findings differ from recent findings that report pain self-efficacy was strongly associated with pain and disability in a cohort of individuals with shoulder pain receiving conservative management.⁷⁹

Our study did not find an association of greater expectations before surgery with greater pain and disability improvement, positive GRC scores or greater satisfaction after surgery. This finding was surprising and is in contrast to a previous report of positive associations between greater expectations and greater improvements in patient-reported outcome measures for pain and disability after shoulder surgery.³⁹ Participants in this current study had very high expectations before surgery (mean 4.4/5) and the outcome across all three aspects was generally positive.

This study supports the association of poor psychological function before surgery with worse outcome after shoulder surgery. Depression, anxiety and stress symptomatology was the factor most strongly associated with all three measures of patient-centred outcome. Screening for psychological factors prior to surgery using simple screening tools, like the Orebro⁸⁰ or STarT MSK Tool,⁸¹ which include questions about thoughts, mood, anxiety and beliefs would help identify individuals who may benefit from other management instead of surgery or prior to proceeding to surgery. Strategies such as psychological or behavioural interventions or pharmacology for patients with high levels of psychological distress may be warranted,⁸² however this is an area that requires further research in the field of shoulder pain.

There were a number of limitations in this study. Selection bias may have occurred during the recruitment phase, where not all eligible patients undergoing surgery by the participating surgeons consented to the study. Individuals that declined to participate in the study may have scored differently on psychological measures and expectations before surgery. Not all participants who completed data collection before surgery provided outcome data at 12-month follow-up. The group missing outcome data showed worse scores for PSEQ, PCS, confidence in surgical outcome, had a greater number of workers compensation cases, smokers, public hospital cases, individuals with a lower

education level and were less active in sport (Appendix D, Table D.1). Given the sample without outcome data had factors that might be associated with poorer outcome, this may have attenuated associations seen in the analysed sample. These differences suggest the study sample may not be fully representative of a typical cohort of individuals undergoing shoulder surgery.

This study represents a sample of convenience and was underpowered to detect the effect sizes specified in the power calculation. The sample size was smaller than intended due to recruitment and retention problems encountered in the public hospital setting. This study was an observational cohort study with no comparator group. Therefore it is not clear whether factors associated with better outcome after surgery were attributable to the surgical procedure or placebo, rest, rehabilitation or the natural course of recovery. The confidence in surgical outcome scale used in this study has not been previously validated

6.6 Conclusions

Three aspects of patient-centred outcome; pain and disability change scores, satisfaction and global rating of change, provide similar information regarding a good or poor outcome from the individual's perspective at one-year after shoulder surgery. Depression, anxiety and stress symptomatology, pain self-efficacy, confidence that surgery would relieve symptoms, and duration of symptoms prior to surgery were similarly associated with all three aspects of patient-centred outcome. Screening and targeting of psychological factors prior to surgery may improve outcomes.

6.7 References

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Chapter 7 Discussion

This thesis represents a body of work exploring surgical management of shoulder pain in Western Australia, to inform whether current management is aligned with contemporary evidence and to compare with current management in other countries. This body of work includes studies related to recent surgical trends, perspectives of shoulder surgeons and a sample of individuals undergoing shoulder surgery in Western Australia. These studies have been undertaken considering a contemporary biopsychosocial perspective of shoulder pain. The association of psychological factors with shoulder pain and disability in individuals scheduled for shoulder surgery, and the association of psychological factors with pain and disability outcome after shoulder surgery was explored in detail. In addition, three different aspects of patient-centred outcome were assessed following shoulder surgery to explore whether they reflect different aspects of outcome. Also explored was whether variables measured before surgery, were similarly or differentially associated with the three different aspects of outcome. Each of the studies will be summarised, highlighting the contribution to the literature made by each study. Discussion of the body of work undertaken in this thesis will follow, highlighting the clinical and research significance and also the implications for management of shoulder pain in the Australian healthcare landscape.

7.1 Summary of studies included in this thesis

7.1.1 Study 1: Rising surgical trends for rotator cuff disease in Western Australia

This study investigated trends and costs of surgery for rotator cuff disorders in Western Australia during the 13-year period 2001-2013.¹ No previous reports of surgical trends for individuals with shoulder pain for Australian populations were available. This is in contrast to reports from a number of other countries, which have highlighted alarming increases in shoulder surgery rates over recent decades.²⁻⁶ This study found a substantial increase in shoulder surgery rates in the state of Western Australia over the period 2001-2013, with arthroscopic procedures demonstrating large proportional increases of 102% for subacromial decompression and 68% for rotator cuff repair surgery. The rising trends were mostly consistent across hospital setting, gender and age, with associated increase in costs to the Australian healthcare system.

The key contribution to the literature for this study was to highlight that shoulder surgery trends for an Australian population are aligned with the concerning reports of increasing rates of shoulder surgery globally. For healthcare policy makers in Australia, this is an important finding for consideration of healthcare budgets, to ensure that expensive interventions such as surgery are aligned with contemporary models of care and targeted to those individuals most likely to benefit.

7.1.2 Study 2: Rotator cuff disease: opinion regarding surgical criteria and likely outcome

This study aimed to evaluate surgical criteria for rotator cuff disease by exploring current opinions with regards to surgical decision-making amongst a group of shoulder surgeons in Western Australia.⁷ The study evaluated Western Australian orthopaedic surgeons' perceptions about surgical criteria, utility of physical examination tests, findings at surgery predictive of outcome and surgeon opinion of a successful surgical outcome. No previous reports of surgical criteria for shoulder surgery in Australia were available. However, studies from the UK and USA reported disparate opinions regarding surgical criteria.⁸⁻¹⁰

This study found that within a community of surgeons based in Western Australia, considerable heterogeneity exists in surgical decision-making criteria.⁷ Overall, surgeons reported four or more physical examination tests were used to aid surgical decision-making. Intra-operative factors that surgeons considered predictive of outcome related to the degree of tendon pathology and co-existing pathologies observed. Surgeons considered a successful outcome after shoulder surgery to include reduced pain levels, restoration of movement and function and gains in muscle strength.

The contribution to the literature for study 2 was to highlight that Western Australian shoulder surgeons have disparate levels of agreement regarding surgical decision-making, which is consistent with findings of surgical colleagues from other countries worldwide. This is an important finding for Australian healthcare policy makers who strive to contain healthcare costs and ensure that surgery is provided to those individuals most likely to benefit. The lack of consensus for surgical decision-making is concerning, when coupled with rising shoulder surgery trends, an ageing population and increased strain on healthcare budgets. This highlights the need for a model of care for shoulder pain that is informed by further research into which individuals are more likely to benefit from shoulder surgery, which individuals are less

likely to benefit from shoulder surgery and identifying less expensive alternative care pathways as a primary management choice.

7.1.3 Study 3: Are psychological factors associated with shoulder scores after rotator cuff surgery?

This study aimed to explore the association of both affective and cognitive psychological factors on pain and disability outcome after shoulder surgery.¹¹ Psychological factors are known to influence pain and disability in people with shoulder pain.¹²⁻¹⁶ Recent research has explored the influence of affective psychological factors such as depressed mood and anxiety on outcome after shoulder surgery.¹⁷⁻²⁰ However, the influence of cognitive psychological factors such as kinesiophobia, pain catastrophizing and pain self-efficacy has not been explored in studies of outcome after shoulder surgery.

This study explored the existence of clusters of individuals undergoing shoulder surgery, with different profiles of psychological measures. Two distinct psychological clusters were identified, with one cluster having lower scores on both affective and cognitive psychological measures, indicating better psychological functioning, and a second cluster having higher scores indicating poorer psychological functioning. Further analysis tested if membership of psychological clusters was associated with worse shoulder scores after surgery for pain and disability outcome (measured by the American Shoulder and Elbow [ASES] score).²¹ Membership of the cluster with poorer psychological functioning was associated with higher levels of pain and disability before and at three and twelve months after surgery. However, the improvement in ASES score, from before to after surgery, was similar for both clusters. The findings of this study suggest that psychological factors are associated with higher levels of pain and disability before and after surgery, however their presence may not preclude improvements in pain and disability after shoulder surgery.

This study contributed to the literature by highlighting that higher pain and disability levels before and after shoulder surgery may be associated with the presence of affective and cognitive psychological factors such as depression, anxiety, catastrophizing, kinesiophobia or low pain self-efficacy. This finding was independent of other significant correlates, that were potential confounding variables, namely gender, an active workers compensation claim, alcohol consumption and confidence in outcome of surgery. This study supports the importance of screening of psychological factors prior

to shoulder surgery and provides a basis for future studies to explore interventions addressing psychological factors prior to, or in addition to shoulder surgery in order to optimize outcomes.

7.1.4 Study 4: Different aspects of patient-centred outcomes after shoulder surgery are similarly associated with psychological status before surgery.

Outcome after shoulder surgery has historically been assessed by metrics including clinical examination, imaging and complication rates. Patient-centred care is considered the foundation of contemporary models of health care internationally, including musculoskeletal pain.²² This is reflected in the increasing use of patient-reported pain and disability measures in more recent shoulder research, with more than thirty different shoulder-specific measures available. Patient-centred outcome may be measured in a variety of ways, including the widely used patient-reported pain and disability measures, global rating of change and satisfaction. Satisfaction is considered an important measure in a patient-centred care approach.²² While these measures of outcome appear somewhat similar, there is no clear understanding how these outcomes relate to each other, or if variables before surgery are similarly or differentially associated across outcomes.

This study investigated the association between three aspects of patient-centred outcome (patient-reported pain and disability measures, global rating of change scale and a satisfaction scale) at 12 months after shoulder surgery and found that they were moderately associated. This study also explored if psychological and other variables measured before shoulder surgery, have similar associations across all aspects of patient-centred outcome. Depression, anxiety and stress symptomatology, as measured by the Depression, Anxiety and Stress Scale (DASS),²³ was univariately associated with all three aspects of patient-centred outcome, with the strength of associations attenuated after adjustment for workers compensation status, duration of symptoms and sport level before surgery.

The contribution to the literature for this study was to highlight that patient-centred outcome measures broadly provide similar information regarding individuals' perspectives of outcome after shoulder surgery. Psychological factors, identified before surgery, were most strongly and similarly associated with the three patient-centered aspects of outcome after surgery.

7.2 Shoulder pain as a health care crisis

Shoulder disorders make up a significant proportion of musculoskeletal conditions that are a major contributor to global disability, as determined by the Global Burden of Disease (GBD) 2010 study.²⁴ A subsequent Global Burden of Disease (GBD) 2016 study²⁵ reported a 15% increased burden of musculoskeletal conditions since the previous 2010 study, but statistics regarding shoulder specific data was not available in this study. These reports are supported by the Australian Burden of Disease Study 2011²⁶ that reported musculoskeletal conditions were responsible for 12% of the total burden of disease and injury in Australia in 2011. Musculoskeletal pain involves a real and significant burden on individuals and society, with indications that this burden is increasing, not decreasing.

Although these Australian and Global Burden of Disease studies do not contain specific statistics for shoulder disorders, a number of studies have highlighted the burden of shoulder disorders across the globe.²⁷⁻²⁹ Further literature highlights the persistence of shoulder disorders, which indicates the ongoing, long-term burden of shoulder pain for many individuals.³⁰⁻³² Study 1 and study 2 of this thesis highlight management concerns associated with increasing shoulder pain prevalence in Australian populations.

Shoulder surgery is a common orthopaedic procedure worldwide and the rising shoulder surgery rates in Western Australia reported in study 1 are aligned with rising shoulder surgery rates globally. These surgical trends have implications for increased strain on Australian healthcare budgets in light of the increasing shoulder pain prevalence. With indications for shoulder surgery not clear and equivocal outcomes reported for some shoulder surgery procedures,³³ the rising surgical trends shown in study 1 are concerning. The lack of consensus among Western Australian shoulder surgeons for surgical decision-making criteria in 2014 reported in study 2 is aligned with a previous report of similar findings in the USA in 2005.⁹ This finding reflects limited progress towards the development of robust shoulder surgery criteria over the past decade, despite the vast number of studies of outcome after shoulder surgery undertaken during this period. The implications for the lack of consensus for surgical decision-making criteria reported in these studies may result in inappropriate surgical recommendations for individuals who may benefit from other more cost effective and less risky conservative measures.

With one in four adults reporting shoulder pain at some point in their life,³⁴ often with symptoms persisting for six months or more,³⁵ appropriate care pathways are imperative to provide appropriate management and advice, in a timely and cost effective manner. Although less well investigated for shoulder disorders, it is likely that shoulder pain is also multifactorial in nature.

7.3 Failings of the biomedical model of shoulder pain

7.3.1 Biomedical model review

There is a strong belief in the current healthcare system that shoulder pain is predominantly driven by a one-dimensional focus on pathoanatomy. This biomedical view underpins a structural model of pathology as the primary source of shoulder symptoms, with symptoms potentially arising from one or more structures including bone, muscle, tendon, ligament and bursae.

Differentiation between multiple shoulder structures as a source of symptoms and the different pathological entities that potentially exist for those structures is not possible, even for experienced clinicians. The vast number of clinical tests reported for assessment of shoulder structures lack specificity and sensitivity, and do not allow for diagnosis of specific shoulder pathology.³⁶ This has led to a greater reliance on imaging modalities such as ultrasound and magnetic resonance imaging that frequently detect incidental findings in the shoulder in asymptomatic populations,^{37, 38} with additional evidence supporting that rotator cuff tear size observed on imaging does not correlate with shoulder pain severity.³⁹ Many asymptomatic individuals demonstrate partial and full thickness rotator cuff tears on imaging, and individuals with symptomatic rotator cuff tears in one shoulder are often shown to have an asymptomatic contralateral tear.^{40, 41}

The delivery of a pathoanatomical diagnosis, with questionable relevance to the individuals' clinical symptoms,^{40, 41} may result in a series of further tests, surgical intervention, increased healthcare costs or litigation in the case of an insurance claim. Despite this lack of clarity for the source of shoulder symptoms, there has been a dramatic increase in the number of shoulder surgeries during recent decades, as highlighted by study 1 of this thesis¹ and other studies,²⁻⁶ targeting specific structures such as a tendon tear, in an attempt to 'fix' these supposedly pathological structures.

The biomedical model of shoulder pain has been followed from the 1970s when Neer first reported that acromial morphology was responsible for irritation to

subacromial structures including the bursa and rotator cuff tendons.⁴² These reports resulted in dramatic increases in shoulder surgery over the ensuing decades with surgical procedures such as acromioplasty and bursectomy, undertaken in an attempt to provide more space for the bursa and rotator cuff tendons, and rotator cuff repair undertaken to restore tendon integrity. Contemporary views of rotator cuff disorders have recognised that tendon pathology stems from intrinsic tendon failure due to a degenerative process,⁴³ rather than the previously followed external acromial impingement model. To further complicate current understanding, there is no robust evidence to support that the experience of shoulder pain is due to rotator cuff tendon pathology or tear.

7.3.2 Why the biomedical model doesn't fit

Current research indicates that this one-dimensional biomedical view to inform surgical management is out of context with evidence^{33, 44} and supported by the lack of robust surgical criteria highlighted in study 2⁷ and other studies.⁸⁻¹⁰ Contemporary evidence suggests other non-structural factors contribute to shoulder pain.^{13, 14, 45} In spite of contemporary evidence, it is concerning that shoulder surgery rates are still high and increasing in many countries.²⁻⁶

Current evidence indicates that not all individuals undergoing shoulder surgery get relief from their symptoms and many individuals report improvement in symptoms after surgery despite failed healing or re-tears of the rotator cuff tendon demonstrated on imaging.^{46, 47} These facts again reject the biomedical model of shoulder pain and reinforce that structures such as a pathological tendon are not necessarily the primary source of shoulder symptoms. Significant pain relief can be achieved with conservative management of rotator cuff tears,⁴⁸⁻⁵⁰ with recent studies reporting similar outcomes for surgery, physiotherapy or no treatment,^{33, 51} suggesting that surgery or physiotherapy may provide no further benefit for many individuals over natural recovery, relative rest and education. Evidence from randomised controlled trials has not shown superior outcomes of shoulder surgery over conservative treatment for rotator cuff disorders.⁵²⁻⁵⁴ This diverse evidence for the lack of association between rotator cuff pathology and shoulder pain provides compelling evidence that symptoms of shoulder pain cannot be assumed to directly relate to tendon pathology, further refuting the biomedical model.

There is emerging understanding of the multidimensional nature of shoulder pain with the pain experience varied among individuals due to social, cultural, environmental, physical, psychological and genetic factors.⁵⁵ The association of non-biological factors

with shoulder pain and disability was explored in study 3, which found that poor psychological function before surgery was associated with higher levels of pain and disability before and after surgery.¹¹

7.4 Biopsychosocial model of shoulder pain

A contemporary understanding of shoulder pain supports a biopsychosocial approach for the assessment and management of shoulder disorders. Although there are a number of proposed biomedical conditions that may contribute to shoulder symptoms, for the majority of individuals with shoulder disorders a biomedical cause may not be clear. For acute onset shoulder pain, specific pathologies such as bone fractures and joint dislocations are typical examples of conditions that generally correlate well with pain and disability levels.^{56, 57} For persistent shoulder pain, identifying the source of symptoms is often unhelpful in terms of selecting appropriate management. Specific pathologies such as glenohumeral or acromioclavicular joint osteoarthritis may be identified through imaging, however as previously discussed, the correlation between pathology and pain and disability is often tenuous at best.³⁹

For some individuals with shoulder disorders, shoulder pain may be nociceptive in origin with physical factors such as limitations in range of movement, deficits in muscle strength or aberrant movement patterns potentially influencing load on different nociceptive structures in the shoulder. It is not possible to differentiate between specific nociceptive structures as a source of symptoms, however modification of physical factors with conservative measures such as exercise therapy can be an effective means to reduce this nociceptive sensitivity.⁴⁴

For a large number of individuals with shoulder pain, pain may persist in spite of surgery or traditional conservative measures.⁵⁸ It is important to also consider the contemporary evidence for musculoskeletal pain conditions where pain is not only nociceptive in origin.^{59, 60} Factors from other non-biological dimensions may also influence an individual's experience of pain. For some individuals, shoulder symptoms may predominantly be the result of biological factors such as tendon pathology. For others, symptoms may be the result of a complex interaction between biological factors and non-biological factors, such as health comorbidities, lifestyle, social and psychological factors. Failure to identify and manage the different multidimensional factors that contribute to shoulder pain may result in poor outcome after conservative management or shoulder surgery, or result in unnecessary surgery.

An area of emerging research for shoulder disorders is the psychological dimension, with affective and cognitive factors considered to contribute to the pain experience for a wide range of musculoskeletal conditions,^{60, 61} including the shoulder. The association of poor psychological function with outcome after shoulder surgery is uncertain. In study 3 it was found that a cluster of individuals with poor psychological function before surgery displayed higher levels of pain and disability before and after surgery. Under a biomedical model, higher levels of pain and disability may result in earlier consideration of surgery. However under a biopsychosocial model, it could be speculated that there may be potential benefits from pharmacological, psychological, or behavioural interventions before consideration of surgery. This is an area that requires further research in the shoulder. The biopsychosocial model supports a shift of focus away from pathoanatomical diagnoses, where the focus on structural pathology results in unnecessary imaging and more surgery illustrated in study 1.

There is a need for a shift in education of healthcare providers and consumers about the only weak association between shoulder pain and pathology, similar to that highlighted for low back pain.⁶² Less reliance on imaging will not only save healthcare dollars but will also reduce diagnostic pathological labels for potentially incidental findings observed on imaging and reduce unnecessary shoulder surgery for these incidental findings. Spending of the healthcare dollar for shoulder surgery urgently needs review, to better identify the most appropriate surgical candidates. This has been well documented for hip and knee osteoarthritis in a recently published model of care.⁶³

7.5 Rising shoulder surgery trends

The substantial increase in shoulder surgery rates and associated increase in costs in the state of Western Australia over the period 2001 to 2013 were reported in study 1.¹ This finding for a Western Australian population is aligned with the global reports of increasing rates of shoulder surgery. The trends were for large increases consistently across hospital setting, gender and age for both arthroscopic subacromial decompression and rotator cuff repair surgery.

For hospital setting, the total number of shoulder surgeries performed in both private and public hospitals increased across all time-points from 2001-2013. For population-adjusted surgical rates, for subacromial decompression surgery there was no difference in growth between hospital setting (private versus public), however for rotator cuff repair surgery there was a significantly higher growth in the public hospital setting

with an estimated annual increase of 3.2% in private versus 8.1% in public hospital setting. One possible explanation for the higher growth in the public hospital setting may be due to a greater number of shoulder surgeons undertaking surgical training for rotator cuff repair in the public system.

For gender, the proportional increases in shoulder surgery over time were comparable between males and females. However, males had an overall higher absolute rate of shoulder surgery, possibly reflecting a greater incidence of shoulder pain in males. As males tend to be more represented in occupations involving heavy physical demands that require forceful or repeated overhead exertions or heavy lifting, it may be that there is a tendency toward earlier investigation of symptoms with imaging for males, as the current biomedical model underpins that the presence of pathology is a direct consequence of load or injury.

For different age groups, the trends over time for subacromial decompression surgery were similar, however for rotator cuff repair surgery there was a significant difference between age groups with a 2.4% decrease in the 15-34 year age group, compared to a 2.5% and 3.8% increase respectively in the 35-54 year and >55 year age-groups. The proportional increase in rotator cuff repair surgeries for the older age group is likely to reflect the increased use of imaging and subsequent repair of observed pathology under a biomedical model and a move towards less invasive arthroscopic surgical techniques with lower risks.⁵ These rising surgical trends are in spite of contemporary evidence indicating that rotator cuff disorders are known to be a normal correlate of aging^{64, 65} and the higher prevalence rates of asymptomatic rotator cuff tears that are observed in older individuals.^{64, 66} Alternative management pathways, addressing the multidimensional factors discussed in study 3, may be considered for older individuals.

Older age has been consistently associated with poorer outcome after shoulder surgery.⁶⁷⁻⁷¹ These reports are concerning for the Australian healthcare system, in view of the rising shoulder surgery trends for older age groups shown in study 1. With an ageing population, individuals are increasingly active and continue to work into older age, often with continued high levels of functional demands and expectations for quality of life. Optimum shoulder function is required to maintain independent living, attend to self-care, fulfil caring roles and allow participation in recreational pursuits.

Alternative management pathways, including physiotherapy, exercise therapy, psychological and behavioural therapy, are needed to address multidimensional factors that

may be associated with shoulder pain and disability. These management options are more cost effective, carry lower risks, and are equally important for older and younger adults.

7.5.1 Factors underpinning rising shoulder surgery rates

With escalating shoulder surgery rates, increasing global burden of musculoskeletal diseases, including shoulder disorders, a worldwide ageing population, rising prevalence of shoulder pain and increased pressure on healthcare budgets, there is an urgent need to better understand the reasons behind the increased shoulder surgery rates observed both in study 1 and globally. There is a pressing need for research to identify any benefits of shoulder surgery over more potentially more cost-effective conservative options and evidence-based models of care need to be formulated for future management of shoulder pain. This will be a step towards arresting the escalating health care costs associated with shoulder surgery, that to date have not been shown to provide superior outcomes to other conservative measures. It is likely that multiple factors underpin the rising rates of shoulder surgery including factors related to the individual, the surgeon and the widespread use of imaging.

Individual patient demand for shoulder surgery may be driving surgical rates up, as a result of an increased awareness and understanding of surgical procedures available, a greater expectation of quality of life linked with increased life expectancy and greater access to private health insurance.⁷² It could be speculated that greater access to modern technology such as the internet allows individuals to explore potential causes and management alternatives for their shoulder disorder. There is an abundance of readily available literature describing numerous pathologies such as subacromial impingement, subacromial bursitis, rotator cuff tendinopathy, partial and full thickness rotator cuff tears and a range of management options including surgery.⁷³ These diagnostic labels reinforce the biomedical model of structural pathology, support beliefs that surgical management is necessary, and do not encourage individuals to associate shoulder symptoms with other non-pathoanatomical factors.⁷³ Individuals who have an expectation for surgical management may have low expectations for the success of a physiotherapy rehabilitation program, which have been shown to negatively influence outcome of conservative management.⁷⁴

Although not reported in the literature, general practitioners may recommend primary surgical review of shoulder pain and disability, without consideration of an appropriate conservative management in the first instance. Clinical guidelines and

consensus statements, although limited, are consistent in their recommendations for a period of a physiotherapy rehabilitation, pain management or injection therapy prior to consideration for surgery.¹⁰ Of the cohort participating in study 3 and 4, over half of the individuals scheduled for surgery (53%) had failed to undergo physiotherapy prior to surgery. It is not known if this is because individuals in this study had requested a primary surgical review, whether they had low expectations of success of physiotherapy, or whether the general practitioner or surgeon provided this initial recommendation for surgical intervention in the first instance, rather than a trial of physiotherapy. This finding may also reflect a lack of translation of the available evidence and clinical guidelines into contemporary medical practice.

Surgeon training and expertise may influence shoulder surgery rates with a higher number of more recently qualified surgeons trained in arthroscopic shoulder surgery techniques. Recent advances in surgical instrumentation, repair techniques and suture anchors, along with the advent of nerve blocks for high-risk surgical patients as an alternative to a general anaesthetic, may also have contributed to the rising surgical rates.^{2, 5, 75, 76} With these surgical advances, surgeons may opt for surgical intervention for individuals previously considered to be less suitable as a surgical candidate.

The widespread use of ultrasound or magnetic resonance imaging (MRI) may be due to increased reliance on imaging modalities to assist in providing a diagnostic label to explain shoulder symptoms, in the absence of robust clinical tests. As previously discussed, imaging focuses on a biomedical cause of shoulder symptoms in order to identify structural pathology or anatomic variants, therefore the contribution of non-biological factors to shoulder pain may be overlooked.¹²⁻¹⁴ Widespread imaging before shoulder surgery contributes to increased healthcare costs,⁷⁷ in addition to the increased costs of surgery reported in study 1. Over a five-year period in Australia during the 2000's, the use of shoulder ultrasonography more than doubled, corresponding to in excess of a two-fold increased cost to the Medicare Benefit Scheme in Australia.⁷⁸ Nearly \$21 million was spent on diagnostic ultrasound in 2006 alone, a figure that does not include costs for imaging guided injection under ultrasound, a commonly added diagnostic procedure used for shoulder disorders. Ultrasonography and MRI continue to play a substantial role in decision-making for surgery and although specific data was not collected for the cohort investigated in this study 3 and 4, a large proportion of individuals anecdotally reported having imaging undertaken prior to surgery.

7.5.2 Healthcare system strain

If shoulder surgery trends continue to rise over the coming decade, with escalating costs as shown in study 1 and globally, this will likely exceed capacity of healthcare budgets. In addition to the direct costs of surgery, the costs for evaluation of rotator cuff tears are substantial, with the majority of costs associated with MRI imaging. Furthermore, the indirect costs of surgery relate to prolonged time off work for recovery and rehabilitation that has implications for lost productivity in the work place. A recent systematic review reported an inadequate quality and quantity of publications on the economics of interventions for shoulder pain and recommended the need for further research with rigorous economic evaluations.⁷⁹

In study 1 marked increases in both CPI-adjusted total costs of shoulder surgery and average cost per procedure in both private and public hospital settings were illustrated. Increase in total cost was driven largely by the rising number of shoulder surgeries undertaken from 2001 to 2013, while the increased average cost per procedure was likely to be associated with advances in arthroscopic surgical techniques, suture anchors and anaesthetic techniques, as has been previously reported for other economic shoulder studies.⁸⁰⁻⁸²

7.5.3 Alternative management pathways

Alternative management pathways are likely to be helpful in reducing healthcare costs associated with rising surgical trends. Current evidence supports an initial trial of conservative management for shoulder pain. A conservative approach may include education and advice, physiotherapy and exercise therapy, psychological and behavioural therapy and pharmacology. These approaches could be used in isolation or as a combined approach, depending on assessment findings and based on the needs of each individual. Further research is needed to develop evidence-based models of care for delivery of optimized conservative care.

There has been a shift towards a reduction in subacromial decompression surgery during the past few years in light of recent evidence questioning the efficacy of this surgical procedure. A recent study from Finland reported a 20% decline in subacromial decompression surgery in the public hospital setting, however this decline was not observed in the private hospital setting.⁸³ Recent high quality scientific evidence reporting no difference in outcome between subacromial decompression and

conservative management was considered to be a major contributing factor to this change in clinical practice.⁵³ In the United States a reduction in isolated subacromial decompression surgery has also recently been reported.⁸⁴ Since these reports, a further landmark randomised controlled trial has shown no benefit of subacromial decompression over sham surgery or no treatment.³³

In contrast, for rotator cuff repair, surgical rates have continued to increase as shown in study 1¹ and supported by other studies.^{3, 4, 85} This is in spite of recent evidence demonstrating that rotator cuff repair surgery conferred no benefit nor clinically important differences over physiotherapy.^{54, 86} A systematic review of seven randomized controlled trials (RCTs) reported that the evidence for the effectiveness of both surgical and conservative management of shoulder pain was limited, however there was moderate evidence that surgery was no more effective than active exercises on reducing pain intensity.⁸⁷ Three additional RCTs with between one and five year follow-up^{33, 50, 51, 54, 86} reported that there is little difference in outcome between surgical and conservative management.

7.5.4 Recommendations to halt escalating shoulder surgery rates

Strategies to halt escalating shoulder surgery costs are needed in view of the rising surgical trends in Western Australia identified in study 1, the limited guidelines for surgery⁸ and current evidence that surgery does not provide superior outcomes to other conservative measures.^{87 51 33, 54}

Future healthcare resource allocation for shoulder disorders needs to be based on models of care that have been developed from evidence-based interventions that provide better health outcomes.⁷⁹ Given the high costs and risks associated with shoulder surgery, current evidence recommends a trial of conservative management and physiotherapy prior to consideration of surgery.^{10, 87} Physiotherapy clinicians must provide high value care that includes education, advice and targeted exercise therapy. Screening for psychological factors before surgery has been recommended, in order to identify the association of poor psychological function with shoulder pain and disability.⁸⁸ There may be potential benefits from psychological or behavioural interventions in addition to, or instead of physiotherapy prior to consideration of surgery.

Surgeons should be cognisant of previous management pathways already undertaken for individuals presenting for surgical review. For individuals reporting that they have

already undergone physiotherapy, clarification of the details of previous physiotherapy management is advised, as a targeted exercise rehabilitation program is an essential component of a conservative approach.⁴⁴ Often conservative management is considered to have failed after a period of months, however if the conservative program has only involved rest, medication, injection therapy or passive treatment modalities, then guideline based care has not been followed adequately.⁸ In this instance, proceeding to surgical management may not be justified and individuals may be referred for a period of supervised exercise therapy. When referring an individual for physiotherapy, surgeons should also relay positive expectations to the individual regarding the outcome of such a program, as recent evidence suggests that individuals who have low expectations regarding the effectiveness of physiotherapy are more likely to fail conservative management.⁷⁴

The current evidence for management recommendations should be provided to consumers by their health care practitioners, including general practitioners, surgeons or physiotherapists, in order to engage in collaborative management decision-making. There was close to consensus by surgeons in study 2 for one statement that the patient should decide whether to have surgery based on the surgeon's explanation of management options, however it is imperative that this explanation also includes the results of recent randomised controlled trials comparing outcome after surgery versus conservative management.

A reduction in the use of widespread imaging modalities would not only reduce healthcare costs in terms of unnecessary imaging, but also reduce the reliance on diagnostic imaging for surgical decision-making where surgery may be directed to incidental findings that may not be associated with symptoms. Although imaging modalities such as MRI or ultrasound may be extremely useful for diagnosis in some specific cases, such as following trauma, it is critical to correlate imaging findings with clinical history, clinical examination and consideration of other potentially non-pathoanatomical factors that may be associated with shoulder pain. Imaging findings in isolation should not be used as an indicator for surgery, as observed findings may relate to normal, age-related change.

When shoulder surgery is recommended, a clearer understanding of surgical decision-making criteria needs to be made available to healthcare providers. It is imperative to identify what factors are associated with the differential benefit of shoulder surgery over sham surgery, conservative interventions or natural history. This will facilitate the development of more robust surgical criteria and determine factors that are

predictive of pain and disability outcome following shoulder surgery. Shoulder surgery can then be targeted to those individuals most likely to benefit, thus easing the financial burden on healthcare systems.

7.6 Shoulder surgery decision-making criteria

The opinions of a group of Western Australian orthopaedic surgeons regarding shoulder surgery criteria were explored in study 2.⁷ The Western Australian surgeons opinion was aligned with previous reports from the USA and UK.^{9, 10} The findings of study 2 are reflective of the current lack of consensus for surgical criteria, which is indicative of poor evidence base on which clinical guidelines are reported.

Although the vignettes provided only limited clinical information, potentially leading to different interpretations between surgeons with regard to management choice, the rotator cuff survey was used in study 2 as initially developed and reported from 2005, in order to allow comparison of responses between studies and changes in management views over the past decade. In addition, over the past decade there has been a greater understanding of an association of multidimensional factors, such as psychological factors, with musculoskeletal pain. However, the vignettes used as part of the rotator cuff survey do not reflect the current biopsychosocial model, as they were largely based on biomedical model information.

Support for a patient-centred care approach to management was evident in the surgeon's responses to two clinical statements. Consensus (80%) was reached for the statement that the expected frequency and duration of rotator cuff rehabilitation after surgery should be discussed with patients before surgery. This finding is aligned with previous research.⁹ There was also a trend towards consensus (78%) on a second statement, that surgeons should explain the options and let the patient decide whether to have surgery. These findings are promising with regards to shared decision-making in keeping with patient-centred care. However, it is unknown in clinical practice how frequently individuals play a role in shared decision-making for surgery that is based on knowledge of current evidence, an understanding of different management options available and with realistic expectations. With contemporary healthcare advocating patient-centred care models, the role of the individual in making an informed decision regarding conservative or surgical care is paramount. Shared decision-making requires individuals to firstly have realistic expectations regarding the outcome of shoulder surgery with respect to their ability to return to work, participate in sports, reduced pain and

disability levels, secondly to have an awareness of the multidimensional nature of shoulder pain and finally to have an understanding of current evidence for shoulder surgery versus conservative management along with the risks associated with each intervention.

Consensus was not reached for the other clinical statements that covered different management options including physiotherapy and corticosteroid injections, expectations, and the role of surgery to prevent tear progression or osteoarthritis. Both physiotherapy and corticosteroid injection have inconclusive clinical guidelines for their use. For the cohort of people undergoing shoulder surgery in this thesis, 77 of 137 (56%) individuals in the cohort received corticosteroid injections before surgery, either by their general practitioner, surgeon or by a radiologist under ultrasound guidance. Of these 41 participants had received two or more injections with 2 reporting having received 10 corticosteroid injections before surgery. This is an alarming statistic due to the uncertain benefit of corticosteroid injection therapy. Patient expectations were explored in study 4 and found not to be associated with patient-centred outcome measures of pain and disability change scores, global rating of change or higher satisfaction rates after surgery. This finding may reflect a sample with overall very high expectations before surgery. There is a poor correlation between shoulder pain and disability and pathological changes, such as tear progression⁸⁹ or rotator cuff arthropathy,⁹⁰ that reinforces the lack of clarity regarding which individuals make the best surgical candidates and likely contributing to the lack of consensus for these statements.

7.6.1 Recommendations for future direction for surgical decision-making

The diversity of surgeon opinion in study 2 is consistent with disparate surgeon opinion in the previous USA study conducted a decade ago and reinforces the continued uncertainty regarding shoulder surgical decision-making. This is a major concern, especially in consideration of the rising surgical trends, an ageing population, continuing increased burden on healthcare systems globally and the lack of evidence that surgery provides superior outcomes to conservative management or natural recovery.

It is proposed that the research focus shift from identifying what is the best type of surgery, to what is the best type of treatment. It is imperative that models of care are developed for the management of shoulder pain, based on high quality evidence from comparative trials, and that more robust surgical criteria are established. The clinical translation of these models of care is also important, to ensure general practitioners, surgeons and other healthcare providers follow evidence-based models of care. And

perhaps more importantly, that the healthcare consumer has this information available to them to enable true shared decision-making.

7.7 Biopsychosocial management of shoulder pain

Management of shoulder pain from a pathoanatomical perspective may involve surgery for some individuals with rotator cuff related pathology, with weak evidence from clinical guidelines recommending early surgical repair of a rotator cuff tear for younger individuals with history of trauma⁸ or for those individuals who have failed to improve after a period of conservative management.¹⁰ However, these guidelines provide inconclusive evidence for surgery for asymptomatic full thickness rotator cuff tears and only weak evidence available for symptomatic full thickness rotator cuff tears.

Current conservative management has a predominantly biological focus. Physiotherapy may be targeted to improve limitations in range of movement or muscle length. Physiotherapy also includes exercise therapy targeted to address deficits in muscle strength or aberrant movement patterns that may be associated with shoulder symptoms. These impairments of physical function may alter load on different nociceptive structures in the shoulder, contributing to shoulder symptoms.⁴⁴ Pharmacological management such as simple analgesia, non-steroidal anti-inflammatory medication or injection therapy may be used for shoulder symptom relief in support of a predominantly biological focus. The rationale for pharmacology may be to potentially target an “inflamed” bursa or tissue that has been identified on imaging and is assumed to be a cause of the patient’s symptoms.

Differential patterns of affective and cognitive psychological factors in people undergoing shoulder surgery were found in study 3. Two different psychological clusters were identified, one cluster with better psychological functioning, and another with poorer psychological function. The cluster with poorer psychological function was associated with statistically and clinically important higher levels of shoulder pain and disability,^{91, 92} both before and at three and twelve months after shoulder surgery, adjusting for gender, workers compensation claim, alcohol consumption, and confidence in surgical outcome. However, both clusters showed very similar improvements in pain and disability scores over time, indicating psychological distress does not preclude improvement in pain and disability level after shoulder surgery.

The findings in study 3 agree with a study by Dekker²⁰ illustrating that individuals with poorer psychological function before surgery continue to experience higher levels of pain and disability after shoulder surgery, however show improvement in pain and disability levels from before to after surgery. Study 3 differed from previous studies as a range of affective and cognitive factors were explored, in contrast to Dekker²⁰ and others¹⁷⁻¹⁹ that explored affective factors only. Cognitive factors have not been considered for their association with pain and disability levels after shoulder surgery, despite reported associations of cognitive factors with poor outcome after conservative management.⁹³⁻⁹⁷ Cognitive factors are an important consideration in people undergoing shoulder surgery. For example, individuals displaying kinesiophobia may be apprehensive to move their arm due to fear of pain or fear of damaging their shoulder. This apprehension may be more profound following rotator cuff repair surgery for fear that the repaired tendon may be damaged.

Poor psychological function before surgery can be identified with the use of simple screening tools, such as the Orebro⁹⁸ or modified STarT MSK Tool.⁹⁹ These tools that capture constructs including thoughts, fear, mood, anxiety and beliefs, and can be followed up with specific questioning. A recently reported concise four question psychosocial screening tool for use in the work environment is another example of screening to identify risk of delayed recovery that may assist tailoring rehabilitation towards psychological barriers.¹⁰⁰ Management from a biopsychosocial perspective may involve psychologically informed practice to address the behavioural aspects of pain.¹⁰¹ Research supports the use of these interventions for other musculoskeletal pain conditions.^{102, 103} Exploring whether psychologically informed practice for individuals with high levels of psychological factors either before or after surgery can improve outcomes is warranted in further research. An important consideration from study 3 and 4 is that psychologically informed practice that addresses psychological factors before surgery has the potential to reduce the need for surgery, if psychological factors are a contributor to shoulder symptoms. In addition, management strategies that target psychological factors may also be beneficial after surgery for those individuals with persistent pain and disability. This is clearly an area needing further research.

Expectations and confidence in outcome of surgery are other important aspects of cognitive psychological function related to the surgery that were explored in study 3 and 4. For expectations, study 3 found no association of greater expectations before surgery with pain and disability change after surgery. This finding was in contrast to previous

reports that greater expectations before surgery were associated with improvement in pain and disability levels from before to after shoulder surgery^{13, 14} and greater patient satisfaction after shoulder surgery.^{17, 18} For confidence in surgery, study 3 found that a greater level of confidence in the outcome of surgery was associated with greater improvements in pain and disability level for participants. However, for the cluster with poorer psychological functioning before surgery, these individuals displayed less confidence in achieving a successful outcome after shoulder surgery. Patient confidence in the outcome of surgery has not been previously explored for shoulder surgery.

Social factors were investigated in study 3 and 4 and it was found that an active workers compensation claim was associated with poorer psychological function. In addition, although an active workers compensation claim overlapped with psychological distress, it was still found to be independently associated with pain and disability scores before and after surgery. These findings are in agreement with previous research that workers compensation status^{68-70, 104, 105} is associated with higher pain and disability levels after shoulder surgery and associated with significant, clinically important and consistently poorer outcomes of surgery.¹⁰⁶ The mechanisms for worse outcomes for individuals with an active workers compensation claim have been suggested to relate a number of factors including psychological factors related to the injury and compensation process, the potential for financial gain or sickness benefits and the maintenance of healthcare access.¹⁰⁶ Consideration of workers compensation cases is indicated under a biopsychosocial model of management. Management such as surgery, that has a pathoanatomical focus, is less likely to improve shoulder symptoms for individuals with an active workers compensation claim, if associated psychosocial factors have not been addressed.

7.8 Measuring patient-centred outcome after shoulder surgery

Patient-centred care has gained greater importance over recent decades and is considered the foundation of contemporary models of health care internationally, including musculoskeletal pain.²² Patient-centred outcome after shoulder surgery may be measured in a variety of ways, including the widely used shoulder pain and disability measures, global rating of change (GRC) and satisfaction. While these aspects of outcome appear somewhat similar, there has been no clear understanding how these outcomes relate to each other, so this was the focus of study 4. Shoulder pain and disability measures assess changes in pain and disability level if measured both before and after surgery,^{91, 107} however with over thirty different patient shoulder pain and

disability measures in clinical use and research, comparison of outcome between studies can be difficult as there is a lack of consistency for their use.^{108, 109}

Study 4 uniquely explored how strongly all three aspects correlated with each other. The widely used shoulder pain and disability measures were found to align with other aspects of patient-centred outcome. As GRC and satisfaction measures are less burdensome than shoulder pain and disability outcome measures, they may be useful in clinical practice if time limitations prevent the use of the more detailed shoulder pain and disability outcome measures. The overlap identified in study 4 potentially indicates that it may not be necessary to collect all three aspects of patient-centred outcome in order to gauge surgical success from the individuals' perspective. However, there may be additional benefits in the use of patient-reported pain and disability measures, such as knowledge about provocative activities or functional limitations. This additional knowledge may be beneficial to direct rehabilitation to the concerns of each individual and could be identified from the more detailed pain and disability measures.

All three measures of patient-centred outcome in study 4 were found to be similarly associated with both poorer psychological function and an active workers compensation claim, which highlights the importance of these factors to the long term outcome after shoulder surgery. Based on the findings from study 4, it could be assumed that if a variable before surgery is reported in the literature to be associated with changes in pain and disability after surgery, it is likely to also be similarly associated with GRC or satisfaction. This may help to interpret the diverse literature better when assessing the evidence for various correlates of outcome after shoulder surgery.

A greater understanding of patient-centred outcome after shoulder surgery is important as it may influence whether individuals seek additional or alternative care and allows evaluation of the benefit of interventions versus their risks and costs. Decision-making for interventions such as surgery should be shared between individuals and their surgeons, and based on the provision of the best available evidence for surgical efficacy, realistic expectations and a comprehensive understanding of alternative treatment pathways. In addition, it is imperative to consider factors that are important to an individual that reflect a meaningful improvement in symptoms after surgery.

The findings of study 4 have clarified the relationship of shoulder pain and disability measures to overall GRC or satisfaction that has not previously been clear. The use of

patient-centred outcome measures can assist in determining what factors are important from the individuals' perspective and inform future decision-making for management.

Traditional outcome measures of surgical success, such as imaging, are of limited utility from a patient-centred approach, due to the poor correlation between tendon healing and changes in pain and disability after surgery.⁴⁶ Even outcome measures such as clinical examination of range of movement and strength, may have limited utility in determining changes in pain and disability that is meaningful to an individual. However, clinical examination findings of range of movement or strength deficits may be useful in combination with measurement of patient-centred outcome, to direct exercise therapy rehabilitation.

7.9 Clinical implications

The findings of this thesis provide the following important recommendations for the management of shoulder pain.

1. Strategies need to be implemented to address rising shoulder surgery trends and costs. There is an increasing trend for shoulder surgery without clear evidence in the literature to support that it is superior to conservative interventions. For healthcare policy makers in Australia, this is an important consideration for healthcare budgets, to ensure that expensive interventions such as surgery are aligned with contemporary models of care and targeted to those individuals most likely to benefit. The clinical implications are to address the potential multiple factors that may be responsible for driving up the increasing surgical rates. Methods to address these factors include first, reducing the reliance on imaging findings as diagnostic criteria. Second, educate primary care providers, including general practitioners and physiotherapists, to provide recommendations for a conservative management program as a first line of care, prior to surgical consideration. Third, consumers need to be educated about the limitations of the current guidelines that are based on low level evidence, and the need for high value care for shoulder pain. Fourth, improve levels of funding for conservative management as a first line of care.
2. There is a lack of consensus as to which individuals are appropriate surgical candidates, and a lack of evidence for superiority of surgical over conservative management. Clear guidelines for management, based on a biopsychosocial understanding of shoulder pain have already been developed for some shoulder pain populations,¹¹⁰ but implementation of these guidelines remains problematic. These

guidelines promote simple, low-cost but high-value care management, including psychologically informed practice. While further research is needed to continue to better inform these guidelines, a model of care for shoulder pain that provides a “big picture” blueprint of how evidence informed care for shoulder pain can be delivered at the different tiers of the health system is required. Under a biopsychosocial model there may be potential benefits for a multidimensional conservative approach targeting psychologically informed practice, prior to consideration of surgery. These alternative management pathways are more cost effective and less risky, with current evidence indicating similar outcomes to surgery. A model of care for shoulder pain is needed that is informed by further research into which individuals are more or less likely to benefit from shoulder surgery, and identifying less expensive alternative care pathways as a primary management choice.

3. Multidisciplinary clinics are needed to provide consistent, evidence-informed messages by a team of like-minded health professionals including orthopaedic surgeons. For physiotherapists, high value care must be delivered that provides education, advice and targeted exercise therapy aimed to address individual impairments.
4. Psychological factors should be screened and clinically assessed for all individuals with persistent shoulder pain with simple screening tools, such as the Orebro⁹⁸ or modified STarT MSK Tool,⁹⁹ followed up by targeted clinical questioning. There is the potential that addressing psychological factors before surgery may enhance outcomes of surgery, however this is an area that requires further research.
5. If shoulder pain is in the context of a workers compensation claim, then additional consideration should be given to work related factors that may be additional barriers for recovery.
6. The overlap between the three aspects of patient-centred outcome identified in study 4 suggests that in clinical practice, the use of a simple measure of one aspect of outcome may suffice where the aim is to simply assess meaningful improvement from the individual’s perspective. This could be considered more time efficient, cost effective and less burdensome. However, there may be additional benefits in the use of patient-reported pain and disability measures, such as knowledge about provocative activities or functional limitations. This additional knowledge may be beneficial to direct rehabilitation to the concerns of each individual and could be identified from the more detailed pain and disability measures.

7.9.1 Developing a Model of Care

Clear pathways for the assessment and management of shoulder pain disorders are urgently needed. A Model of Care (MoC) is defined as an evidence and consultation-informed framework that describes what and how health services and other resources should be delivered to people who live with specific health conditions.¹¹¹ A MoC has recently been reported in Australia for the management of hip and knee osteoarthritis,⁶³ as osteoarthritis has been reported to be one of the five main contributors of global disability in the Global Burden of Disease Study.^{25, 112} Currently, there is no MoC for shoulder disorders to inform assessment and management, however there is a Western Australian MoC for musculoskeletal pain and health in general.¹¹³ A rationale for the development of models of care for musculoskeletal health has recently been reported.¹¹¹ This report provides healthcare practitioners a contemporary overview of models of care in Australia their relevance to musculoskeletal health and could be used as a basis for the future development of a MoC for the management of shoulder pain and disability. A MoC could describe what care and how care should be organised and delivered to provide optimal management for individuals with shoulder disorders.

A proposed MoC for shoulder pain disorders is illustrated in Figure 7.1 This MoC for shoulder pain should specify the identification of serious medical conditions and appropriate assessment and triage for traumatic onset shoulder pain. For gradual onset and persistent shoulder pain, the identification of contributing modifiable factors could facilitate a targeted care pathway based on assessment findings and current evidence. For the first line of care, self-management advice should include effective strategies for self-care, maintenance of physical activity, cessation of smoking and dietary advice. Education should include the uncertain etiology and natural history, the common finding of asymptomatic age-related changes and the multidimensional nature of shoulder pain. Physiotherapy should include a targeted exercise therapy program, and recommended as an initial management choice. Psychological or behavioural interventions may be indicated for individuals demonstrating evidence of altered moods and emotions or poor beliefs such as kinesiophobia or low pain self-efficacy. Pharmacology interventions may be indicated for integration with conservative measures, including simple analgesia and non-steroidal anti-inflammatory medication, injection therapy, or stronger short-term pain medications. Surgery may be considered for individuals with good tendon health, who have persistent symptoms despite a course of conservative management that has included targeted exercise therapy.

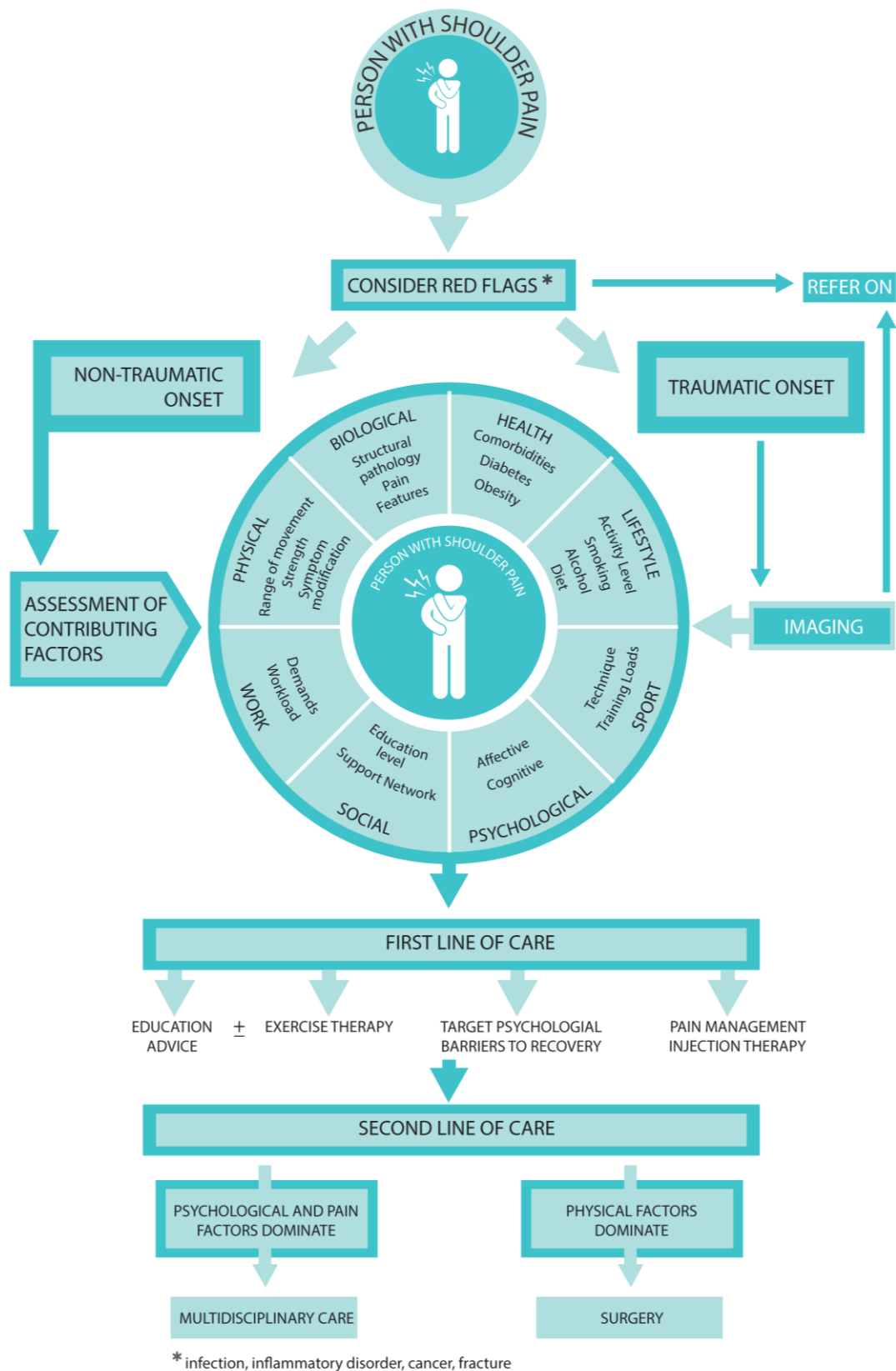


Figure 7.1 A proposed Model of Care for the assessment and management of a person with shoulder pain

7.10 Strengths and limitations

This is the first study to report surgical trends and surgical criteria for individuals with shoulder pain in an Australian population. Although not new from a global perspective, study 1 and 2 inform the current landscape for shoulder surgery in Western Australia. Only a single state of Australia was explored in study 1 and 2 which could be considered a limitation, however it is likely that these results would be replicated nationally in other states of Australia.

Study 3 is the first study to consider both affective and cognitive psychological factors in individuals undergoing shoulder surgery and their association with pain and disability outcome before and after shoulder surgery. Although explored in a low back pain cohort,¹¹⁴ this approach is novel for the shoulder. Study 4 is the first study to investigate the association between different aspects of patient-centred outcome in people undergoing shoulder surgery, and to confirm that psychological factors are, for the most part, similarly associated with change in pain and disability, GRC and satisfaction after shoulder surgery. One limitation of study 3 and 4 was that study participants were already scheduled for shoulder surgery, possibly resulting in some patients scoring better on cognitive psychological measures due to a belief that surgery would 'fix' their shoulder. A sample of individuals without a specific surgical management pathway in place may have shown a distinct cluster that scored highly on cognitive factors only, as was found in the previous low back pain sample.¹¹⁴ However, the findings from study 3 and 4 are in line with previous recent studies highlighting the multidimensional nature of shoulder disorders¹²⁻¹⁶ and together these results support a biopsychosocial model of shoulder pain.

There are a number of other limitations related to study 3 and 4 of this thesis. First, there was no comparison to sham surgery, conservative management or no treatment, so it is unknown if the outcome after surgery was attributable to the surgery itself or some other factor such as placebo, an enforced period of rest after surgery, natural progression of recovery, rehabilitation undertaken after surgery, or some other unknown factor. This also means that the associations between psychological and other factors with outcome that were identified in Study 3 and 4 cannot be interpreted as associations with a positive response to surgery, as they may be merely prognostic of a good outcome regardless of whether or not an alternative intervention was undertaken. Second, the loss to follow-up meant the size of the cohort being studied was smaller than anticipated, which reduced the power of study 3 and 4 and potentially limited the detection of differing

strengths of associations between variables and the three aspects of outcome. Finally, the study sample bias towards a greater number of participants in a private hospital setting was due to lower participant recruitment and retention in the public hospital setting, with a smaller number of public patients available, changes or cancellation of surgical lists and a greater participant loss to follow-up in the public hospital setting. The fewer number of public hospital participants may have influenced clusters and cluster membership in study 3, with a higher number of fee paying participants in a private hospital setting potentially having greater expectations of outcome after shoulder surgery, and beliefs that surgery would ‘fix’ their shoulder problem. However, there was no statistical evidence that study findings differed between hospital setting.

7.11 Directions for future research

The body of work undertaken for this thesis provides important directions for future research.

First, there is a pressing need for research to identify benefits of shoulder surgery over potentially more cost-effective conservative options. This will allow distinction between factors that are simply prognostic of pain and disability outcome and factors that are predictive of the benefit of surgery over other interventions. This will also allow for surgical interventions to be allocated to those who are most likely to benefit.

Second, evidence-based models of care need to be formulated for future management of shoulder pain. There is a need for comparative effectiveness trials of surgery versus integrated approaches using psychologically informed conservative care, such as pain education, psychologically informed physiotherapy,¹¹⁵ cognitive behavioural therapy, cognitive functional therapy, graded exposure, graded activity, acceptance and commitment therapy. When surgery is a consideration, there is an urgent need for research to inform robust evidence-based guidelines for surgical criteria.

Third, there is a need to validate screening tools for factors prognostic of poorer outcomes specifically in individuals with shoulder pain in both occupational and general population settings. The Keele STarT MSK tool⁹⁹ has recently been developed for musculoskeletal pain, but as this has been for a large cohort of mixed musculoskeletal areas, data specifically for shoulder disorders is not available. The Orebro screening tool⁹⁸ is useful for the assessment of psychosocial factors associated with poor outcomes

in an occupational setting, such as psychological distress, coping, beliefs, work perception, work absence and functional limitations.

It is still unclear as to the role that patient expectations play both in terms of making a decision to undergo surgery and the subsequent satisfaction with the outcome of surgery. Further exploration of this important topic could include assessment of benefit and risk preferences using techniques such as discrete choice experiments and qualitative methodology, such as is currently being conducted other areas of orthopaedic surgery.¹¹⁶

7.12 Conclusions

The findings of this thesis highlight the increasing trend for shoulder surgery and associated costs in Western Australia, the lack of consensus amongst surgeons regarding decision making processes for shoulder surgery and the role of psychological factors in outcomes of shoulder surgery. Together these findings highlight the need for a biopsychosocial approach to the screening, assessment and management of people with shoulder pain. Evidence based guidelines are needed to assist decision making processes for the management of shoulder pain and in particular for shoulder surgery.

7.13 References

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APPENDICES

Appendix A Study One Supplementary Documents

Table A.1 Total number of surgical procedures undertaken in Western Australia from 2001-2013

Procedure	Rate per 100,000 2001	Rate per 100,000 2013	Percentage change 2001-2013
Arthroscopic			
ASAD	53.8	108.7	102.0% increase
ARC	88.8	149.5	68.4% increase
All arthroscopic	142.6	258.2	81.1% increase
Open			
OSAD	6.0	3.8	36.7% decrease
ORC	19.2	5.0	74.0% decrease
ORCR	8.4	6.3	25.0% decrease
All open	33.6	15.1	55.1% decrease
All procedures	176.2	273.3	55.1% increase

Abbreviations: ASAD – arthroscopic subacromial decompression; ARC – arthroscopic reconstruction; OSAD – open subacromial decompression; ORC – open reconstruction (SAD and RCR combined); ORCR – open rotator cuff repair

Appendix B Study Two Supplementary Documents

B.1 Rotator Cuff Survey - Part 1

Rotator Cuff Survey

Surgeon code: _____ **Years of consultancy practice:** _____ yrs **Date:** _____

The Rotator Cuff Survey has previously been distributed to orthopaedic surgeons listed in the American Academy of Orthopaedic Surgeons directory and the results published in the Journal of Bone and Joint Surgery, 2005. We are interested to determine Western Australian Orthopaedic Surgeons' perceptions about the indications for rotator cuff surgery (Dunn et al, 2005).

In the past year, have you treated patients or referred patients for treatment of rotator cuff tears?

- Yes
- No If 'No' please STOP and return the survey 'as is'

Number of rotator cuff repairs that you performed in the PAST YEAR : _____ cases

Preferred type of primary rotator cuff tear for a 2cm full thickness tear:

- Arthroscopic
- Mini-open
- Open

What do you estimate is the failure rate (defined as patient dissatisfaction) for all patients undergoing rotator cuff repair in Western Australia this year? _____%

<i>For the following four questions, please assume any cuff pathology described has been confirmed on MR and indicate your treatment recommendation.</i>	
1. A 35 yo manual labourer fell at work 4 months ago onto his dominant arm and has a painful, 50% partial-thickness rotator cuff tear involving the entire supraspinatus tendon with no demonstrable weakness. His situation is unchanged after 3 months of physical therapy. What would you suggest for this patient (choose one):	<input type="radio"/> No surgery, physical therapy <input type="radio"/> Recommend surgery with cuff repair
<input type="radio"/> No surgery, give cortisone injection <input type="radio"/> Recommend surgery without cuff repair	2. A 45 yo manual labourer has a medium (2cm), full-thickness rotator cuff tear after an acute injury 3 months ago that involves his dominant arm with 4/5 weakness ER that is not particularly painful. What would you suggest for this patient (choose one):
<input type="radio"/> No surgery, physical therapy <input type="radio"/> Recommend surgery with cuff repair	<input type="radio"/> No surgery, give cortisone injection <input type="radio"/> Recommend surgery without cuff repair
3. An active 55 yo male with an insidious history of mild discomfort present for a year is found to have a small (1cm), full-thickness rotator cuff tear. He has received no treatment to date. What would you suggest for this patient (choose one):	<input type="radio"/> No surgery, physical therapy <input type="radio"/> Recommend surgery with cuff repair
<input type="radio"/> No surgery, give cortisone injection <input type="radio"/> Recommend surgery without cuff repair	4. An active, previously asymptomatic 65 yo female reports a traumatic event one week ago and now cannot lift her arm. MR reveals a large retracted (5cm) cuff tear with fatty infiltration of the involved cuff muscles. What would you suggest for this patient (choose one):
<input type="radio"/> No surgery, physical therapy <input type="radio"/> Recommend surgery with cuff repair	<input type="radio"/> No surgery, give cortisone injection <input type="radio"/> Recommend surgery without cuff repair

Please indicate whether you agree or disagree with the following statements:

	Strongly disagree	Disagree	Indifferent	Agree	Strongly agree
5. Physiotherapy is useful for full thickness rotator cuff tears.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. The use of a steroid injection is contraindicated in potential surgical candidates.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Patients should expect to have a "normal" shoulder after rotator cuff repair.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. The surgeon should decide whether the patient should have a rotator cuff repair and then tell them to have (or not to have) surgery.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. When recommending rotator cuff surgery, the surgeon should explain the options and let the patient decide whether to have the surgery.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. A major reason to repair rotator cuff tears is to prevent progression of the tear.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. A major reason to repair rotator cuff tears is to prevent osteoarthritis of the shoulder.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Surgeons should spend more time discussing the pros and cons of rotator cuff repair with patients pre-operatively.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. The expected frequency and duration of post-operative rotator cuff rehabilitation should be discussed with patients pre-operatively.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

14. What is the maximum number of steroid injections that can be safely given in one year?
 1 2 3 4 5

15. My patients could be more involved in the decision-making process for rotator cuff surgery **if:**
(check all that apply)

- They had a higher level of education
- They had longer pre-operative appointments
- They had more frequent pre-operative appointments
- They received more information (brochures, videos, computer software, internet etc)
- I received greater reimbursement for pre-operative consultations
- My patients are already sufficiently involved in the decision-making process

B.2 Rotator Cuff Survey - Part 2

Surgeon decision-making criteria Sub-acromial impingement and rotator cuff disease

Surgeon code:

Date:

1. Which of the following physical examination tests do you routinely use to determine criteria for surgery for subacromial impingement and rotator cuff disease?

- Active range of movement
- Passive range of movement
- Isometric strength tests
- Neer test
- Hawkins test
- Drop arm test
- Painful arc sign
- Empty can test
- Full can test
- Relocation test
- Other (please specify)

2. Please list any other physical examination tests that help guide your decision-making for surgery for subacromial impingement and rotator cuff disease?

3. What findings at the time of surgery would you consider are potentially predictive of 12 month outcome?

4. A successful outcome of surgery for rotator cuff disease has not been well defined in the literature from either the patient's or the surgeon's perspective.

We are interested in what you would classify as a successful 12-month outcome of surgery from a surgeon's perspective, for repair of a 1cm x 1 cm supraspinatus tear in the critical zone

Appendix C Study Three Supplementary Documents

C.1 Supplementary detail regarding Latent Class Analysis

One to five cluster models were estimated with 1000 random starts to ensure global rather than local solutions. Log-likelihood-based Akaike's information criterion, Bayesian information criterion, and consistent Akaike's information criterion were used to assess comparative fit of n-class models. Posterior probability diagnostics (classification error, entropy R^2 value, average posterior probability for each cluster, and odds of correct classification) were used to assess the classification accuracy of the models. Participants were assigned to the cluster for which they displayed the maximum posterior probability of membership.

C.2 Data Tables

Table C.1 Univariate association between potential confounding variables and ASES over time

Univariate	Number for analysis*	Regression coefficient	95% CI		p value
Female gender	124	-7.1	-12.5	-1.6	0.001
Age (5-year increments)	124	0.11	-0.92	1.14	0.833
RCR versus ASAD	98	-1.59	-7.56	4.14	0.601
WC	120	-12.05	-18.52	-5.58	<0.001
BMI_obese	119	-2.94	-8.92	3.04	0.335
DOS ≥ 1 year	123	-0.22	-5.74	5.29	0.937
Smoker	123	-5.46	-12.25	1.34	0.116
Alcohol (per category increment)	124	3.07	.90	5.24	0.006
Lifting occupation	122	0.47	-5.85	6.78	0.885
Confidence 8 or more (63.3%)	120	9.36	3.88	14.84	0.001
Public versus private	124	-2.21	-9.18	4.76	0.535
Comorbidity 1 or more (31.5%)	124	0.59	-5.17	6.35	0.842
Education level	124				0.656
Tertiary college (versus high or less)		0.23	-5.84	6.31	0.940
University (versus high or less)		3.15	-3.91	10.21	0.382

*Out of 124 for cluster membership

Multilevel mixed model; each variable tested for time interaction; if nonsignificant at $\alpha < 0.1$, results presented pooled for time in absence of time interaction; some ordinal/continuous variables dichotomized (BMI, DOS) for easier interpretation, but presence/pattern of association was checked using continuous variable in the first instance; each variable tested for time interaction; all tests $\alpha > 0.10$. Abbreviations: ASES – American Shoulder and Elbow Surgeons score; CI – confidence interval; RCR – rotator cuff repair; ASAD – arthroscopic subacromial decompression; WC– workers’ compensation claim; BMI – body mass index; DOS – duration of symptoms.

Table C.2 Differences in potential confounding variables between the two psychological clusters

Confounding variable	Measures	Cluster 1 (n = 84 [68%])	Cluster 2 (n = 40 [32%])	p value
ASES_TOTAL [§]	mean (SD)	54.6 (18.0)	39.5 (15.2)	< 0.001*
ASES_Pain subscale	mean (SD)	23.8 (11.9)	16.8 (9.6)	0.002*
ASES_Function subscale [¶]	mean (SD)	30.8 (8.3)	23.1 (7.8)	< 0.001*
Female gender	number (%)	32 (38.1%)	14 (35.0%)	0.739 [†]
Age (years)	mean (SD)	54.5 (14.2)	49.9 (10.7)	0.069*
Surgical procedure ^{§§}				
ASAD	number (%)	30 (44%)	13 (43%)	0.943 [†]
RCR (± SAD)	number (%)	38 (56%)	17 (57%)	
Workers' compensation claim ^{††}	number (%)	10 (12%)	16 (41%)	< 0.001 [†]
BMI ^{**}	mean (SD)	28.5 (4.8)	28.5 (5.1)	0.948*
Duration of symptoms	(median [IQR]) (min, max)	3 (2, 5) (0, 5)	3 (2, 4) (0, 3)	0.998 [‡]
Smoker ^{**}	number (%)	13 (16%)	12 (31%)	0.050 [†]
Alcohol (per category increment)	(median [IQR]) (min, max)	2 (1, 3) (0, 4)	2 (1, 2) (0, 4)	0.148 [‡]
Lifting occupation ^{††}	number (%)	20 (24%)	10 (26%)	0.766 [†]
Confidence that surgery will relieve symptoms (NRS)	mean (SD)	8.2 (1.6)	7.2 (1.7)	0.002*
Private hospital setting	number (%)	67 (80%)	33 (83%)	0.718 [†]
Comorbidity 1 or more (31.5%)	number (%)	29 (35%)	10 (25%)	0.286 [†]
Education level (3 levels)	(median [IQR]) (min, max)	2 (1, 2) (1, 3)	2 (1, 2) (1, 3)	0.540 [‡]

Statistical test used: * t-test; [†] chi square test; [‡] Wilcoxon rank-sum test

[§]missing 8 cases in cluster 1, 2 cases in cluster 2; ^{||}missing 5 cases in cluster 1, 1 case in cluster 2; [¶]missing 4 cases in cluster 1, 1 case in cluster 2; ^{**}missing 1 case in cluster 2; ^{††}missing 3 cases in cluster 1, 1 case in cluster 2; ^{‡‡}missing 2 cases in cluster 2; ^{§§}missing 16 cases in cluster 1, 10 cases in cluster 2.

Abbreviations: ASES – American Shoulder and Elbow Surgeons score; ASAD – arthroscopic subacromial decompression; RCR – rotator cuff repair; SAD– subacromial decompression; BMI – body mass index; NRS – numeric rating scale.

Appendix D Study Four Supplementary Documents

D.1 Comparison between participants with and without all three aspects of patient-centred outcome

Table D.1 Comparison of descriptive statistics for all variables before surgery for participants with and without measures of all three aspects of patient-centred outcome at 12 months after surgery

Variable	Measures	Participants with all three outcomes (n=104)	Participants missing at least one outcome (n=33)	p value
Psychological factors				
DASS†	mean (SD)	12.4 (18.2)	20.5 (23.7)	0.056 ¹
PSEQ††	mean (SD)	43.8 (12.0)	30.3 (13.9)	<0.001 ^{1*}
PCS ‡	mean (SD)	10.1 (10.7)	16.9 (14.4)	0.008 ^{1*}
TSK ‡‡	mean (SD)	23.4 (6.9)	26.1 (7.9)	0.075 ¹
Expectations (0-5)	mean (SD)	4.4 (0.6)	4.3 (0.7)	0.423 ¹
Confidence that surgery will relieve symptoms (8 or more on NRS)	number (%)	69 (69%)	12 (39%)	0.002 ^{2*}
Age (years)	mean (SD)	51.2 (14.2)	54.3 (12.8)	0.246 ¹
Female gender	number (%)	38 (37%)	12 (36%)	0.985 ²
Surgical procedure [^]				
ASAD	number (%)	33 (40%)	15 (60%)	0.074 ²
RCR	number (%)	50 (60%)	10 (40%)	
Workers' compensation claim	number (%)	14 (14%)	15 (39%)	0.001 ^{2*}
BMI	mean (SD)	28.5 (4.7)	28.3 (5.9)	0.837 ¹

Variable	Measures	Participants with all three	Participants missing at least one	p value
		outcomes (n=104)	outcome (n=33)	
Duration of symptoms (1 yr or more)	number (%)	45 (44%)	12 (36%)	0.458 ²
Smoker	number (%)	14 (13%)	14 (44%)	<0.001 ^{2*}
Alcohol	(median [IQR])	2 (1,3)	2 (1,3)	0.162 ³
Lifting occupation	number (%)	80 (77%)	21 (68%)	0.301 ²
Private hospital setting	number (%)	86 (83%)	21 (64%)	0.021 ^{2*}
Comorbidity 1 or more	number (%)	36 (37%)	9 (27%)	0.434 ²
Education level (3 levels)				0.012 ^{3*}
Secondary school	number (%)	42 (40%)	23 (70%)	0.012 ^{3*}
Technical college	number (%)	38 (37%)	7 (21%)	
University	number (%)	24 (23%)	3 (9%)	
Sport level	number (%)	55 (53%)	9 (29%)	0.020 ^{2*}

Statistical test used: ¹ t-test; ² chi-squared test; ³ Wilcoxon rank-sum

Abbreviations: ASAD – Arthroscopic subacromial decompression; RCR – Rotator cuff repair; BMI – Body mass index; NRS – numerical rating scale (11 point scale); DASS – Depression Anxiety Stress Scale; possible range: 0-126 (higher score = greater psychological distress); PSEQ – Pain Self-Efficacy Questionnaire: possible range: 0-60 (higher score = higher pain self efficacy); PCS – Pain Catastrophizing Scale; possible range: 0-52 (higher score = greater pain catastrophizing); TSK – Tampa Scale for Kinesiophobia: possible range: 1-44 (higher score = greater pain related fear of movement)

^missing 29 cases †missing 5 cases; ††missing 7 cases ‡missing 6 cases; ‡‡missing 4 cases

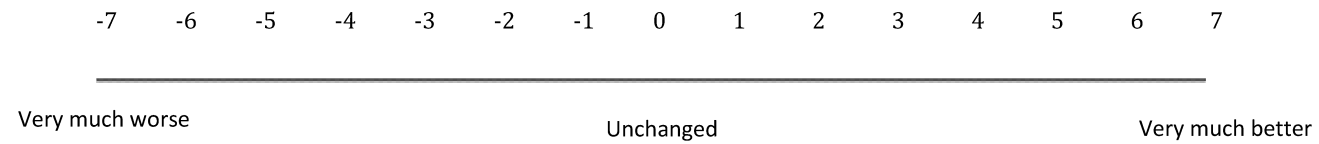
*denotes statistical significance <0.05

D.2 Global Rating of Change Scale

Global rating of change

Please mark on the scale your rating of change following shoulder surgery.

1. With respect to your degree of shoulder pain, how would you describe your pain level now compared to immediately before your surgery?



2. With respect to your shoulder function, how would you describe your shoulder function now compared to immediately before your surgery?



Global rating of change scales (Kamper, 2009)

D.3 Satisfaction Scale

Patient Satisfaction

Please mark on the scale your level of satisfaction for the following two questions.

1. How satisfied are you at the outcome of your shoulder surgery?

1 2 3 4 5 6 7 8 9 10

Very unsatisfied

Neutral

Very satisfied

2. How satisfied are you with the process of your surgery?

1 2 3 4 5 6 7 8 9 10

Very unsatisfied

Neutral

Very satisfied

Patent satisfaction with outcome after rotator cuff surgery (O'Holleran, 2005)

Appendix E Descriptive Statistics for Withdrawn Participants

Descriptive statistics for participants recruited for study who then withdrew consent (n=16). All data analysis was undertaken using STATA Version 14.1 (StataCorp, College Station, TX, USA).

Table E.1 Descriptive statistics for demographic data for the participants who consented to participate in study then withdrew

Demographic variable	Summary statistic
Age, years*	
median (IQR)	54 (36,57)
(min, max)	(28,62)
Female** n (%)	5 (42%)
Reason for withdrawing from study	
Surgery cancelled n (%)	4 (25%)
Opted for conservative management n (%)	4 (25%)
Changed mind about participation in study n (%)	8 (50%)

* missing 8 cases

** missing 4 cases

Appendix F Participant Questionnaire Booklet Before Surgery

Pre-operative participant questionnaire

Participant code:

Date:

Participant characteristics

1. What is your age in years? _____ yrs
2. What is your gender?
 - Male (go to question 4)
 - Female (go to question 3)
3. What is your current hormonal status?
 - Pre-menopause
 - Menopausal
 - Post menopause
4. What is the natural colour of your hair? (Please mark only one response)
 - Fair/blonde
 - Light brown
 - Light red or ginger
 - Dark red or auburn
 - Dark brown
 - Black
 - Other - please specify _____
5. What is the highest level of education you have completed? (Please mark only one response)
 - Primary school
 - Secondary school (high school)
 - TAFE/college
 - University
 - Other (eg personal training course) _____
6. What is the highest year of school you have completed? (Please mark only one response)
 - Year 12 (or equivalent)
 - Year 11 (or equivalent)
 - Year 10 (or equivalent)
 - Year 9 (or equivalent)
 - Other - please specify _____
7. What is your ethnic background?
8. Which is your dominant hand?
 - Right
 - Left
 - Equal dominance
9. Which shoulder is booked for surgery?
 - Right
 - Left
10. At which hospital is your surgery scheduled?
 - Bethesda Hospital
 - Sir Charles Gairdner Hospital
 - Osborne Park Hospital
11. How long have you been waiting for shoulder surgery? _____ months

Social Factors

1. Do you currently smoke cigarettes/cigars?

- No (go to question 4)
- Yes (go to question 2)

2. How many cigarettes/cigars do you smoke per day?

- Less than one
- 1-5
- 6-10
- 11-15
- 16-20
- more than 20

3. At what age did you start smoking regularly?

_____ yrs

4. How often do you have a drink containing alcohol?

- Never (go to question 6)
- Monthly or less
- 2-4 times a month
- 2-3 times a week
- 4 or more times a week

5. How many drinks (one drink is half a pint of beer, a small glass of wine or one shot of spirits) containing alcohol do you have on a typical day when you are drinking?

- 1-2
- 3-4
- 5-6
- 7-9
- 10 or more

6. What is your marital status?

- Single
- Married/de facto
- Divorced
- Widowed

7. What is your current residential status?

- Living with another family member who does not require care
- Living alone
- In residential care

8. How would you describe your pre-operative activity level?

- Minimal daily activity
- Walks 3 x per week
- Daily moderate exercise
- Daily intense exercise

Work History

1. **What is your occupation?** _____
2. **Which of the following best describes the activities in your current occupation? (choose one only)**
 - Office work
 - Manual lifting (below shoulder height)
 - Overhead lifting (above shoulder height)
 - Sustained overhead activity
 - Physical with minimal lifting or overhead activity
 - Home duties
 - Retired
 - Other (please specify) _____
3. **What is your current work status?**
 - Full time - normal duties
 - Part time - normal duties
 - Full time - modified due to shoulder problem
 - Part time - modified due to shoulder problem
 - Workers compensation
 - Not working - unrelated to shoulder problem
4. **How much satisfaction do you have in your current job?**
 - Not satisfied at all
 - Minimally satisfied
 - Neutral
 - Moderately satisfied
 - Extremely satisfied
5. **How motivated are you to return to your previous job after your shoulder surgery?**
 - Not motivated at all
 - Minimally motivated
 - Neutral
 - Moderately motivated
 - Extremely motivated

Sport History

1. **In what level of sport do you currently participate?**
 - None
 - Recreational overhead sport (eg tennis, squash 1-2 x per week)
 - Recreational lower limb sport (eg running, walking 1-2 x per week)
 - Competitive overhead sport (eg tennis more than 3 x per week)
 - Competitive lower limb sport (eg running, football more than 3 x per week)
 - Elite sport (eg state or national level athlete)
2. **In what level of sport have you previously participated?**
 - None
 - Recreational overhead sport (eg tennis, squash 1-2 x per week)
 - Recreational lower limb sport (eg running, walking 1-2 x per week)
 - Competitive overhead sport (eg tennis more than 3 x per week)
 - Competitive lower limb sport (eg running, football more than 3 x per week)
 - Elite sport (eg state or national level athlete)
3. **How many years of competitive or elite sports training and competition do you have?**
_____ yrs

History of shoulder problem

1. **How did your shoulder problem start?**
 - Recent traumatic injury
 - Gradual onset
 - Past history of traumatic injury

2. **How long have you had shoulder symptoms prior to surgery?**
 - Less than one month
 - 1-3 months
 - 3-6 months
 - 6-12 months
 - 12-24 months
 - Longer than 2 years

3. **Have you been diagnosed with any of the following conditions? (Tick all appropriate)**
 - Diabetes
 - Rheumatoid arthritis or polyarthritis
 - Fibromyalgia
 - Osteoarthritis of the shoulder joint
 - Osteoarthritis of the acromioclavicular joint
 - Past fracture of the collarbone
 - Carpal tunnel syndrome
 - Local cancer in the shoulder region
 - Malignant cancer
 - Dislocation of the same shoulder

4. **Have you undergone previous surgery for any of the following conditions? (Tick all appropriate)**
 - Carpal tunnel surgery on the same side as your shoulder problem
 - Breast surgery on the same side as your shoulder problem
 - Previous surgery on the same shoulder - for rotator cuff repair
 - Previous surgery on the same shoulder - for unstable shoulder
 - Previous surgery on the opposite shoulder - for rotator cuff repair
 - Previous neck surgery

5. **Have you undertaken long-term use of oral corticosteroid medication (more than 5 years)?**
 - Yes
 - No

6. **Have you received one or more injections for your shoulder symptoms? (Tick all appropriate)**
 - No (please go to question 8)
 - Cortisone injection by GP
 - Cortisone injection by surgeon
 - Cortisone injection by radiologist under ultrasound guidance
 - Plasma rich protein injection
 - Other (please specify) _____
 - Unsure

7. **If yes, how many injections have you received for your current shoulder problem?**
 - _____ cortisone injections
 - _____ plasma rich protein injection
 - _____ other injection

8. **Have you received any other forms of treatment prior to surgery? (Tick all appropriate)**
 - No
 - Medication
 - Physiotherapy - manual therapy
 - Physiotherapy instructed exercise program
 - Gym based exercise program - self-instructed
 - Other (please specify) _____

9. How long have you received this treatment?

Medication _____ months
Physiotherapy – manual therapy _____ months
Physiotherapy instructed exercise program _____ months
Gym based exercise program – self-instructed _____ months
Other (please specify) _____ months

10. How confident are you that your shoulder symptoms will improve after surgery?

0	1	2	3	4	5	6	7	8	9	10
Not confident			unsure				Completely confident			

11. We are interested in what patients see as a successful outcome after shoulder surgery. From your perspective what would you consider a successful outcome of your shoulder surgery?

(eg I can sleep on my shoulder pain-free, I can play tennis without shoulder pain, I can reach into an overhead cupboard without pain)

Appendix G Participant Information Sheet



BETHESDA HOSPITAL



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School of Physiotherapy

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Title:
**Which pre-operative factors are predictive
of shoulder surgery outcomes?**

Participant Information Sheet

Investigator: Alison Thorpe
Primary Supervisor: Assoc Prof Anne Smith
Co-Supervisors: Prof Peter O'Sullivan, Dr Tim Mitchell
Participating surgeons: Mark Hurworth, Paul Khoo, Jonathon Spencer, Aaron Tay, Grant Booth, Sven Goebel

Purpose of this research

Shoulder pain and poor shoulder function are common in people of different ages and occupations. Surgery is frequently recommended for people who experience persistent shoulder pain. This study will look at a range of different factors in people that are already scheduled for shoulder surgery by their surgeon.

We are interested to know if there are factors before the shoulder surgery is performed, that will help us to determine which people are likely to do well 12 months after their shoulder surgery.

We are interested how your pain, ability to do daily tasks with your arm, your quality of life, your expectation of the surgery and your overall satisfaction is affected by your shoulder surgery, over the course of one year. We are also interested to know which of these factors are important to you after your shoulder surgery.

As there are many shoulder questionnaires available to use, we are also interested to know, of the three most commonly used, if there is one which is the best to use for your type of shoulder surgery.

Our Investigation aims to:

- Identify what factors assessed before surgery might predict which people will have better outcomes.
- Determine what factors are important to you after your shoulder surgery at 3 and 12 months.
- Determine what questionnaires are the best ones to use for your shoulder surgery.

Your role in this research

This study will involve your participation by completion of questionnaires and clinical tests. Participation is completely voluntary. Once you have had the chance to read the information sheet and discuss any queries you may have, you will be requested to sign a consent form to participate in the study.

Before your surgery

- Completion of a pre-operative questionnaire booklet asking about your history of shoulder problem, other medical conditions, lifestyle, sport and work-related history. It is anticipated that this will take about 30 minutes to complete at home and bring in with you to admission.

Alison Thorpe 2014

- Before surgery physical assessment by a physiotherapist to assess range of movement, strength, function in your affected shoulder and your sensitivity to pressure.
- Any scans your surgeon has ordered as part of routine preoperative investigations (such as ultrasound or MRI) will be reviewed and reported.

During surgery

- The surgeon will complete a survey to identify exactly what was observed at the time of surgery, what procedure was performed and the type of pain cover used.

At 6 weeks after your surgery

- You will be asked to complete a brief weekly logbook of your sling use and activity level during the first 3 months after your surgery.
- The physiotherapist will telephone you at 6 weeks to remind you to continue completing the logbook and to ask how easy it is for you to move comfortably.

At 3 months after your surgery

- You will be asked to complete another questionnaire booklet (your choice of an on-line or paper copy) which includes some of the questionnaires you completed before your surgery and some new questions which help to determine how satisfied you are with the surgery and how much change you feel has occurred since before your surgery. It is anticipated that this will take about 15 minutes to complete.
- You will be asked to attend an appointment at the hospital where you had your surgery, where the physiotherapist will repeat the physical tests that were done before your surgery. We will try and do this at the time of your 3-month surgeon review.
- You will be asked to give the physiotherapist the logbook that records your activity level during the first 3 months since your surgery.

At 12 months after your surgery

- You will again be asked to complete the same questionnaire booklet (your choice of an on-line or paper copy) which you completed at 3 months after you surgery.
- The physiotherapist will telephone you also to remind you to complete the questionnaire booklet and to ask you a few extra questions about your return to work (if relevant), problems you may have experienced with your shoulder since your surgery and exercise level.

Risks and discomforts

It is unlikely that there will be any risk or discomfort involved. Most of the physical assessment tests are routinely done before surgery to help decide whether surgery is the best option for you. One of the tests (which is not routinely done before surgery) involves testing how sensitive you are to pressure at two points; one at your affected shoulder and the other on your lower leg. You will be asked to indicate the first onset of pain, when increasing pressure is gradually applied to the shoulder or leg. These tests will take approximately 20 minutes to complete and will stop as soon as you feel any pain.

However, the study does take some of your time for questionnaire completion and telephone surveys. You will be asked to complete the questionnaires before your surgery (approximately 30 minutes), 3 months and 12 months (approximately 15 minutes) after your surgery. You will also be asked to complete a weekly logbook of your activity level for the first 3 months after your surgery. The physiotherapist will telephone you at 6 weeks after your surgery and 12 months after your surgery. Each telephone call should be no more than 10 minutes to answer a few questions.

You may be asked to attend a physiotherapy assessment before or 3 months after your surgery at a different time to your surgeon review. If this is necessary, reimbursement of travelling and parking costs will be made.

Benefits

By taking part in this study, you will be helping us to better understand which people are likely to do well with your type of shoulder surgery and which questionnaires are the best ones to use. In this way, it will assist surgeons and other health professionals to give the best individualized advice and treatment to patients with regards to surgery for their shoulder problem.

Confidentiality

The information we collect will be kept private and confidential. All your information will be coded with a number so that your identity remains confidential. The master file with the number given to your data will be stored in a secure filing cabinet at the study supervisor's (Dr Anne Smith) office at Curtin University. All information collected will be kept in a secure location in the School of Physiotherapy and Exercise Science, Curtin University for 5 years before being destroyed. In accordance with ethical procedures, data collected may be used in scientific presentations and articles but will be presented collectively, so that individual participants cannot be identified. No information will be released to any third party.

Refusal or Withdrawal

You have the right to refuse to take part in this study and withdraw from the study at any time without prejudice or negative consequences. Whatever your decision, it will not lead to any penalty or affect your regular medical care or any benefit to which you are otherwise entitled. All information relating to you will be destroyed if you choose to withdraw.

For any queries about the study please contact Alison Thorpe on a.thorpe@curtin.edu.au or 9266 9227 (office) 0412 093 715 (mobile).

This study has been approved by the Curtin University Human Research Ethics Committee (Approval number HR 178/2013). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 9223 or by emailing hrec@curtin.edu.au.

Thank you for considering participating in this study.

Appendix H Consent Form



Curtin University

Faculty of Health Science
School of Physiotherapy

Telephone +61 8 9266 4644
Facsimile +61 8 9266 3699
Web www.physiotherapy.curtin.edu.au

CONSENT SHEET

Project title: **Multidimensional factors as predictors of outcome following shoulder surgery**

Investigator: **Alison Thorpe**
Primary Supervisor: **Dr Anne Smith**
Co-Supervisors: **Mr Mark Hurworth, Prof Peter O'Sullivan, Dr Tim Mitchell**

This study has been approved by the Curtin University Human Research Ethics Committee (Approval number xxx) and the Bethesda Hospital Medical Advisory Committee (Approval number xxx) and SCGH Human Research Ethics Committee (Approval number xxx)

I, _____
(Given names) (Family name)

- I understand the purpose and procedures of the study.
- I have been provided with the participant information sheet.
- I understand that the study itself may not benefit me.
- I understand that my involvement is voluntary and I can withdraw at any time without prejudice.
- I understand that no personal identifying information like our names and address will be used and that all information will be securely stored for 5 years before being destroyed.
- I have been given the opportunity to ask questions.
- I agree and consent to my participation in the study outlined to me.

I am willing to be contacted in the future for a possible follow-up study: Yes / No
(Please circle)

Signature _____ Date _____

I have explained the research procedures to which the subject has consented to participate and answered all questions to his/her satisfaction.

Investigator's name _____

Signature _____ Date _____

Alison Thorpe - 2013

Appendix I Ethics Approval Letters



Memorandum

To	Dr Anne Smith, Physiotherapy
From	Professor Stephan Millett, Chair, Human Research Ethics Committee
Subject	Protocol Approval HR 178/2013
Date	18 November 2013
Copy	Mrs Alison Thorpe Physiotherapy Prof Peter O'Sullivan Physiotherapy Dr Tim Mitchell Physiotherapy Mr Mark Hurworth Physiotherapy

Office of Research and Development
Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for providing the additional information for the project titled "*Multidimensional factors as predictors of outcome following shoulder surgery*". The information you have provided has satisfactorily addressed the queries raised by the Committee. Your application is now **approved**.

condition; (see #5)

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 178/2013**. Please quote this number in any future correspondence.
- Approval of this project is for a period of four years **19-11-2013 to 19-11-2017**.
- Your approval has the following conditions:
 - i) Annual progress reports on the project must be submitted to the Ethics Office.
- **It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.**

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **Progress Report** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development annually.

Our website https://research.curtin.edu.au/guides/ethics/non_low_risk_hrec_forms.cfm contains all other relevant forms including:

- Completion Report (to be completed when a project has ceased)
- Amendment Request (to be completed at any time changes/amendments occur)
- Adverse Event Notification Form (If a serious or unexpected adverse event occurs)

Yours sincerely

Professor Stephan Millett
Chair Human Research Ethics Committee

Memorandum

To	Dr Anne Smith, Physiotherapy
From	Professor Stephan Millett, Chair, Human Research Ethics Committee
Subject	Protocol Approval Application 4563
Date	13 November 2013
Copy	Mrs Alison Thorpe, Physiotherapy Prof Peter O'Sullivan, Physiotherapy Dr Tim Mitchell, Physiotherapy Mr Mark Hurworth, Physiotherapy

Office of Research and Development
Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "*Multidimensional factors as predictors of outcome following shoulder surgery*". Your application has been reviewed by the HREC will be **approved subject to** the conditions detailed below:


1. Please simplify the project title on the participant information sheet.
2. Please advise if permission has been granted from SCGH for this project.
3. Please clarify the consent process in the participation information sheet.
4. Please amend the data storage section of the application to be in line with section 14 of the Western Australian University Sector Disposal Authority.
5. Ethics approval will be conditional to ethics approval from participating hospitals Bethesda and SCGH.
6. Please amend the participant information sheet and consent forms as per the attached suggestions from a reviewer.

Please do not commence your research until your response to the above conditions has been approved and final clearance has been granted by the Human Research Ethics Committee.

Please note the following:

- Reference Number: 4563. *Please quote this number in any future correspondence.*
- The following standard statement **must be included** in the information sheet to participants:
This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HRxxxx). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 9223 or by emailing hrec@curtin.edu.au.
- It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

Yours sincerely



Professor Stephan Millett
Chair Human Research Ethics Committee



Government of **Western Australia**
Department of Health

Our Ref: 2013-202 approval HREC

7 April 2014



Sir Charles
Gairdner Hospital

Mrs Alison Thorpe
School of Physiotherapy and Exercise Science
Curtin University
GPO Box U1987
PERTH WA 6845

Dear Mrs Thorpe

HREC No: 2013-202

Project Title: Multidimensional factors as predictors of outcome following shoulder surgery.

The ethics application for the project referenced above was reviewed by the Sir Charles Gairdner Group (SCGG) Human Research Ethics Committee (HREC) at its meeting on 20 February 2014. It has been approved and the following documents have been approved for use in this project.

Document
Study Protocol, version 1 dated 16 December 2013
Participant Information and Consent Form, version 2 dated 20 March 2014
Participant Flyer, version 1 dated 16 December 2013
Participant Checklist
Pre-Operative Physiotherapy Physical Assessment
Post-Operative Physiotherapy Physical Assessment
Quality Orthopaedic Indicator Interview Template
Pre-Operative Questionnaire Booklet
Peri Surgical Data Collection Questionnaire Booklet
3 Month Post Sugery Questionnaire Booklet
12 Month Post Sugery Questionnaire Booklet
Follow Up Consent Telephone Script
6 Week Post op telephone script
12 Month Post op Telephone Script

Approval of this project from the Sir Charles Gairdner Group Human Research Ethics Committee EC00271 is valid to 7 April 2017 and on the basis of compliance with the 'Conditions of HREC Approval for a Research Project' (attached).

The nominated participating site/s in this project is/are:

Sir Charles Gairdner Hospital
Osborne Park Hospital

[Note: If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.]

Sir Charles Gairdner Group Human Research Ethics Committee, Level 2 A Block, Hospital Ave, Nedlands, WA 6009
Telephone (08) 9346 2999 Fax (08) 9346 3307 ABN: 13 993 250 709
email HREC.SCGH@health.wa.gov.au Website www.scgh.health.wa.gov.au

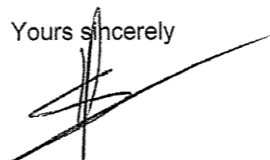
A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate site authorisation has been obtained from the CE, or delegate, of the site under whose auspices the research will be conducted at that site.

The SCGGHREC is registered with the Australian Health Ethics Committee and operates according to the NHMRC National Statement on Ethical Conduct in Human Research and International Conference on Harmonisation – Good Clinical Practice.

Should you have any queries about the HREC's consideration of your project, please contact me. The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <http://www.scgh.health.wa.gov.au/Research/AboutUs.html> or from the HREC Office.

Yours sincerely



Sean Howarth
Delegate of the Chair
for
Hal Jackson
Chair
Sir Charles Gairdner Group
Human Research Ethics Committee



Your health, comfort and wellbeing. Our passion.

06 December 2013

Alison Thorpe FACP
Specialist Sports Physiotherapist
Lecturer | School of Physiotherapy and Exercise Science | Faculty of Health Sciences
Curtin University
GPO Box U1987
PERTH WA 6000

Via email a.thorpe@curtin.edu.au

Dear Alison

RE: RESEARCH AT BETHESDA HOSPITAL: MULTIDIMENSIONAL FACTORS AS PREDICTORS OF OUTCOME FOLLOWING SHOULDER SURGERY

Thank you for your research submission that has been considered by the Hospital's Medical Advisory Committee and has been given approval to proceed.

I note that the initial contact, determination of interest and obtaining of consent will be made with patients directly through Mark Hurworth's rooms and I request that you confirm this for me? I am interested to determine whether you will require access to that patient's notes following surgery at Bethesda, as this will require a confirmation of consent to be sighted by our Health Information staff.

Other than these 2 questions, the MAC showed interest in eventually hearing of the results.

I wish you all the best with your research and I am very pleased that Bethesda is one of the host hospitals.

Yours sincerely



Yasmin Naglazas
Chief Executive Officer

Copy to: Maria Pasich, Manager, Health Information
Christine Phillips, Manager Safety and Quality
Marie Murphy, Manager, Learning and Development

W:\Executive\Research\2013\Shoulder Surgery Study\131206 Bethesda CEO to A Thorpe re Research.docx

Appendix J Copyright for Publications

Tuesday, June 12, 2018 at 4:39:00 PM Australian Western Standard Time

Subject: RE: copyright query for thesis submission

Date: Tuesday, June 5, 2018 at 11:29:46 PM Australian Western Standard Time

From: Wiley Global Permissions

To: Alison Thorpe

CC: Dawkins, Kumie

RE: Thorpe, A. , Hurworth, M. , O'Sullivan, P. , Mitchell, T. and Smith, A. (2016), Rising trends in surgery for rotator cuff disease in Western Australia. *ANZ Journal of Surgery*, 86: 801-804

Thorpe, A. , Hurworth, M. , O'Sullivan, P. , Mitchell, T. and Smith, A. (2017), Rotator cuff disease: opinion regarding surgical criteria and likely outcome. *ANZ Journal of Surgery*, 87: 291-295.

Dear Alison,

Thank you for your email.

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Best wishes,

Kelly Hoff

Permissions Coordinator

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From: Dawkins, Kumie



Title: Are Psychologic Factors Associated With Shoulder Scores After Rotator Cuff Surgery?

Author: Alison Thorpe, Peter O'Sullivan, Tim Mitchell, et al

Publication: Clinical Orthopaedics and Related Research

Publisher: Wolters Kluwer Health, Inc.

Date: Oct 1, 2018

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