Predicting recurrent shoulder instability after a first-time traumatic anterior shoulder dislocation

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Abstract

The optimal management for a person following a first-time traumatic anterior shoulder dislocation (FTASD) is currently unknown. While some have advocated for immediate surgical intervention, others propose a period of conservative management. Failure rates from conservative management leading to recurrent shoulder instability episodes range from between 26 to 100%, with the wide range attributable to the heterogeneity of the population. Decisions regarding clinical management can be aided through the use of decision-making tools. This approach augments patient care to become individualised and the person with the FTASD becomes an active participant in their healthcare.

The number of high quality prospective cohort studies which examine risk factors predisposing or protecting people from recurrent shoulder instability, after a FTASD is limited. The most commonly reported risk factors are age and sex. However, it is widely known that there are other risk factors which predispose a person with a FTASD to recurrent shoulder instability. These factors include pathological lesions, hypermobility, and involvement in collision sport. In order to better understand the relevant risk factors for recurrent instability following a FTASD, a literature search was conducted. As age is one of the most dominant risk factors published in the literature, and children represent differences beyond skeletal immaturity, two separate literature reviews and meta-analyses were undertaken. These publications, along with additional anecdotal risk factors identified by expert clinicians, provided the risk factors to form the basis of a decision-making tool to predict recurrent shoulder instability following a FTASD.

A one-year prospective cohort study was then undertaken in a population of people with FTASD. Data regarding risk factors were collected from participants, at baseline and at 3, 6, 9 and 12 months after the FTASD. Univariate logistic regression was used to establish variables that were significant at $p \leq 0.10$. Backwards stepwise logistic regression was used to establish key variables that were statistically significant in the presence of other risk factors to develop the predictive clinical tool. These variables included the presence of a bony Bankart lesion, immobilisation

status following the FTASD, aged between 16 and 25 years, kinesiophobia (TSK-11), shoulder pain and disability (SPADI), and dislocation to the dominant limb.

The predictive validity and reliability of the tool was established in a second one-year prospective cohort study. Analysis of the receiver operative characteristic (ROC) curve was undertaken to correctly identify the sensitivity and specificity at various cut-points along the curve. The tool was found to have high specificity (94.7%) and a positive likelihood ratio of 7.39, but limited validity (area under the curve (AUC)=0.69) and low sensitivity (38.9%). Analysis of the secondary outcomes revealed a negative relationship between a FTASD and quality of life, kinesiophobia, shoulder pain and disability and shoulder activity level.

The tool developed in this research can predict people who are not going to have recurrent shoulder instability within 12 months following a FTASD. However, clinical implementation of the tool and longer follow-up is required. Further validation of the tool in an international population and in a younger cohort is required to assess its generalisability.

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Attestation of authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent, has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

Signed: ....

Dated: 24/09/2018

Dedication

To you

For your unfaltering support and love,

For that time that you wore the eye mask so I could work in the hotel room early in the morning,

For that time that you passed me coffee when I was flagging,

For the countless other ways you show your love,

Thank you.

I reach higher and further because of you.

x

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Jeepers! What a journey this has been! The germ of an idea for a PhD that took many avenues as it developed over these years. The idea flourished under the supervision of Professor Paula Kersten and Dr Richard Ellis, as have I. This was the PhD I always wanted to write and I thank you for moulding and developing the idea into a piece of work that is academically robust. I cast my mind back now, to that first meeting in Paula's office. Nervous about what was in store, and delicate from previous experiences. Paula, your direct manner, your forthrightness and steadfastly reaching and attaining academic excellence are an inspiration. Richard, your humour, approachability and support have sustained me through this process. I would like to thank you both for your dedication to this project, your patience while I slowly grasped concepts and your support while I traversed this learning journey. Your humour, attention to detail, and belief in both my ability and this project, has made this PhD possible. Thank you for steadfastly keeping me on track and staying the course when I became excited. In your different ways, you both have had a tremendous influence on my development as a critical thinker, and an academic writer. The combination of your approachability and level of academic rigour has provided me with the confidence to rise to the challenge of this PhD and develop my thinking. I couldn't have asked for a better supervisory team. You are both tremendous and important role models for me, as I begin my academic research journey. Thank you for your mentoring. Thanks also to Priya Parmar for her assistance with the statistical analysis and the interpretation of this analysis.

I would also like to acknowledge the role of ACC in facilitating recruitment of participants in this study. In a country where traumatic injuries are documented in a nationwide database, I hope that future studies can be undertaken in collaboration with ACC so we can learn more about traumatic injuries. Thanks for Hayley Bathard, research coordinator at ACC for her work on this project and delivery of participant information in a timely and consistent manner. I would also like to thank Auckland University of Technology (AUT), New Zealand Manipulative Physiotherapy Association (NZMPA), Shoulder Elbow Physiotherapist Australasia (SEPA) and Sports Medicine New Zealand (SMNZ) for assistance with funding this project.

This project would not have been possible without the participants freely and willingly sharing the story and progress of their shoulder dislocation. The numerous hours spent listening to the impact of their shoulder dislocation on their quality of life, their kinesiophobia has taught me a great deal. Now I not only have an understanding of people who present for physiotherapy with a shoulder dislocation, but also those people who do not present for physiotherapy. The knowledge of the barriers to rehabilitation that are currently present in New Zealand society fuels yet more interest to establish an equitable and accessible healthcare system in this country of ours.

To the research assistants who assisted with the blinded follow-up of the participants. Thank you to Nitika, Dave, Ema, Tara and Alicia for the hours you have spent on the phone talking to participants and the careful documentation of their injuries. To my colleague Pradnya, for checking the reliability of participant inclusion. To Nakul for his word proofing. Thank you.

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Finally, to my husband Shane. The answer to the repeated question – “are you done yet?” – will soon be ‘yes’. This thesis has been a part of our lives while we bought property, built a house, travelled to the States and Bali, and got married. I am looking forward to the space that will be created once it is completed. Thanks for sharing my dream. Here’s to our next adventure.

Abbreviation and Glossary

Abbreviations

+LR	Positive likelihood ratio
-LR	Negative likelihood ratio
ACC	Accident Compensation Corporation
ACJ	Acromio-clavicular joint
AMED	Agency for Medical Research and Development
AUC	Area Under the Curve
AUTEC	Auckland University of Technology Ethics Committee
CINAHL	Cumulative Index to Nursing Allied Health Literature
DASH	Disability of Arm Shoulder and Hand
EBM	Evidence Based Medicine
ERIC	Educational Resources Information Center
FABQ	Fear Avoidance Beliefs Questionnaire
FTASD	First-time Traumatic Anterior Shoulder Dislocation
FOI	Fear of Injury
FOP	Fear of Pain
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ICC	Intraclass Correlation Coefficient
MCID	Minimal Clinically Important Difference
MDC	Minimal Detectable Change
MEDLINE	Medical Literature Analysis and Retrieval System Online
MLM	Medium, Large or Multi-tendon
MRA	Magnetic Resonance Arthrogram

MRI	Magnetic Resonance Imaging
NPRS	Numeric Pain Rating Scale
NPV	Negative Predictive Value
NZ	New Zealand
OR	Odds Ratio
PhD	Doctor of Philosophy
PPV	Positive Predictive Value
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RD	Risk Difference
RCT	Randomised Controlled Trial
RIAI	Reinjury Anxiety Index
ROC	Receiver Operative Characteristic
ROM	Range of Motion
RR	Relative Risk
SPSS	Statistical Package for Social Sciences
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
SAS	Shoulder Activity Scale
SEM	Standard Error of the Mean
SF	Somatic Focus
SIGN	Scottish Intercollegiate Guidelines Network
SPADI	Shoulder Pain and Disability Index
SRM	Standard Response Mean
SST	Simple Shoulder Test
TSK	Tampa Scale of Kinesiophobia

US	Ultrasound
URL	Uniform Resource Locator
USA	United States of America
VAS	Visual Analogue Scale
WOSI	Western Ontario Shoulder Instability Index

Glossary of Terms

Construct validity	How well the score measures the different constructs (underlying factors) that it represents. Can be subdivided into convergent, discriminative, and trait validity (Salkind, 2007).
Content validity	How well the test adequately represents the content domain that it is intended to measure (Salkind, 2007).
Criterion validity	How well the scores on a test agree with performance on a task it was meant to predict. Can be divided into two types; concurrent (data are collected at the same time) and predictive validity (when the data is available in the future) (Salkind, 2007).
External validity	Relates to the generalisability of the study to a defined population and presumable the total population (Gordis, 2014).
Glenohumeral dislocation	There is complete dissociation of the articular surfaces of the glenohumeral joint which requires application of external force to restore joint congruity (Owens et al., 2010).
Glenohumeral subluxation	Translation of the humeral head that is beyond the physiologic limits with some amount of glenohumeral contact maintained (Owens et al., 2010).

Incidence rate	The rate of new (or newly diagnosed) cases of the disease that occur during a specific time period in a population at risk of developing the disease (Gordis, 2014).
Internal validity	Refers to the validity within the study population. The study is internally valid if it is free from other biases (Gordis, 2014).
Interrater reliability	Measure of variation that occurs between observation as a result of different observers (also known as inter-observer reliability). Can either be classified as consensus estimates (measure of exact agreement) or consistency estimates (measure of the systematic differences in applying scoring rubric). It allows the test to be generalised from one researcher to another (Salkind, 2007).
Intrarater reliability	Measure of variation that occurs within an observer as a result of multiple exposures to a stimulus (also known as intra-observer reliability or test-retest reliabililty). It allows the test to be generalised from one time period to another (Salkind, 2007).
Kinesiophobia	Kinesiophobia is the fear of movement and reinjury (Parr et al., 2012).
Mediator	The extent to which the variable explains the relationship between the predictor variable and the dependent variable. It explains how or why such effects occur (Baron & Kenny, 1986).
Minimal Clinically Important Difference	The smallest change that represents an important difference for the patient (same unit as the original measurement) (Roy, MacDermid, & Woodhouse, 2009).

Minimal Detectable Change	An estimate of the smallest change that can be detected by patients (in the same unit as the original measurement), based on the standard error of the measure (Roy et al., 2009).
Moderator	A qualitative (e.g. sex or race) or quantitative (e.g. level of a scale) variable that affects the direction and/or strength of the realtionship between the dependent variable and the predictor variable (Baron & Kenny, 1986).
Negative likelihood ratio	Likelihood of a negative test in those with the condition compared to those without the condition (Fritz & Wainner, 2001).
Negative predictive value	Probability that someone with a negative test won't have the condition (Fritz & Wainner, 2001).
Odds ratio	Measure of an association between an exposure and an outcome. The odds ratio represents the probability that an outcome will occur given a particular exposure, compared to the probability of the outcome occurring in the absence of that exposure (Salkind, 2007).
Postive likelihood ratio	Likelihood of a positive test in those with the condition compared to those without the condition (Fritz & Wainner, 2001).
Positive predictive value	Probability that someone with a positive test will have the condition (Fritz & Wainner, 2001).
Prevalence	The number of cases present in the population at a specific time divided by the number of persons in the population at that time (Gordis, 2014).

Reliability	A meaure of subject variability as a component of total variability, calculated by the formula: Subject variability / (Subject variability + Measurement Error) (also known as sensitivity to change) (Salkind, 2007).
Responsiveness	The ability of an instrument to measure a meaningfull or clinically important change in a clinical state (Salkind, 2007).
Risk difference	The excess risk in an exposed versus unexposed group. It is the difference between the observed risks (proportion of the individuals with the outcome of interest) in the two groups (also known as attributable risk) (Salkind, 2007).
Relative Risk	Is the ratio of the risk of an event in the two groups (also known as risk ratio). The ratio of the probability of an event occurring in an exposed group to the probability of the event occurring in a comparison non-exposed group (Salkind, 2007).
Sensitivity	Probability of test being positive when the condition is present (100% sensitivity: negative test will rule-out the condition) (Fritz & Wainner, 2001).
Specificity	Probability of test being negative when the condition is absent (100% specificity: positive test will rule in the condition) (Fritz & Wainner, 2001).
Standard Error of the Measure	A measure of absolute reliability; represented the standard deviation of measures in the same unit as the originial measurement (Roy et al., 2009).
Standardised Response Mean	Mean change in score divided by the standard deviation of the change in score (Roy et al., 2009).

Validity	The ability of a test to distinguish between who has a disease and who does not, and has two components: sensitivity and specificity of a test (Gordis, 2014).
Psychosocial	Umbrella term which encompasses the psychological characteristics of the individual and the structural characteristics of society (Martikainen, Bartley, & Lahelma, 2002).
Psychological	Factors pertaining to an individual's mind or behaviour which operate on and affect the individual (e.g. depression) (Martikainen et al., 2002).
Temporal validity	Evaluation of the performance of the model when the data is split into two groups in a different time period. It can be considered an intermediate level of valdity between internal and external validation because it is external with regards to time (Altman, Vergouwe, Royston, & Moons, 2009).

Co-authored works

All the co-authors on the chapters /papers indicated in the following tables have approved these works for inclusion in Margie Olds' doctoral thesis

Chapter	Publication reference	Percentage contribution
Chapter 2	Olds M., Ellis, R., Donaldson, K., Parmar, P., Kersten, P. Risk factors which predispose first-time traumatic anterior shoulder dislocations to recurrent instability in adults: A systematic review and meta-analysis. *British Journal of Sports Medicine*. 2015; 49: 913-923.	MO80%, RE 7.5%, KD 2.5%, PP 2.5% PK 7.5%
Contribution	*MO – Search and review of the literature, data extraction, analysis and manuscript writing* *RE – Assistance with analysis and review of manuscript* *KD – Assistance with analysis* *PP – assistance with statistical analysis* *PK – Assistance with analysis and review of manuscript*	
Chapter 3	Olds, M., Donaldson, K., Ellis, R., Kersten, P. In children 18 years and under, what promotes recurrent shoulder instability after traumatic anterior shoulder dislocation? A systematic review and meta-analysis of risk factors. *British Journal of Sports Medicine.* 2016; 50: 1135-1141	MO80% RE 7.5% KD 5% PK 7.5%
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Chapter 6	Olds, M., Ellis, R., Parmar, P., Kersten. Predicting recurrent instability following a first-time traumatic anterior shoulder dislocation: A multivariate model. Submitted to *British Journal of Sports and Exercise Medicine Open* 2018.	MO80% RE 8% PP 4% PK 8%
Contribution	*MO – Search and review of the literature, gathering data, data analysis and manuscript writing* *RE – Assistance with analysis, interpretation of findings and review of manuscript* *PP – assistance with statistical modelling, interpretation of findings and review of manuscript* *PK – Assistance with analysis, interpretation of findings and review of manuscript*	

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Research outputs resulting from this thesis

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Olds, M., Ellis, R., Parmar., P. & Kersten, P. (2016). Risk factors for redislocation after a first-time traumatic shoulder dislocation. Oral presentation at the New Zealand Shoulder and Elbow Conference, Rarotonga. July 6th, 2015.

Olds, M, Donaldson, K., Ellis, R., Kersten, P. (2014). The risk factors for recurrent shoulder instability following a first-time traumatic anterior shoulder dislocation in children under the age of 18: a systematic review and meta-analysis. Oral presentation at the American Shoulder and Elbow Therapists Annual Conference, North Carolina, USA, 9th Oct – 14th Oct. 2014.

Olds, M., Ellis, R., Donaldson, K., & Kersten, P. (2014). The risk factors which predispose first-time anterior traumatic shoulder dislocations to recurrent instability in adults: A systematic review. Oral presentation at the Physiotherapy New Zealand Conference 2014: Linking the chain, Auckland, New Zealand. 19th -21st Sept, 2014.

Chapter 1 **Introduction**

1.1 Background

The concept for this work began in a clinical setting and was fuelled by literature which advocated surgical intervention for people following a first-time traumatic shoulder dislocation (FTASD). When working as a physiotherapist, specialising in shoulder injuries, I based my treatment approach for people who had sustained a FTASD on the best available evidence at the time. I discharged patients with maximal strength, endurance, proprioception and coordination. Despite this, some patients following a FTASD continued to reappear at my clinic door with recurrent shoulder instability. Intrigued by why some people fully recovered and why some went on to have recurrent shoulder instability and inspired to improve patient outcomes, the concept for this thesis was born. In embarking on this PhD, I hoped to uncover the factors that could help predict recurrent shoulder instability in people following a FTASD. I proposed that identification of the people with a FTASD who would develop recurrent shoulder instability may allow different, more targeted rehabilitation protocols to be developed and evaluated. This could impact positively on patients' burden, save time and money and assist in the timing of onward referral for more appropriate management and/or alternative rehabilitation strategies.

My doctoral journey began by reviewing the literature. This first chapter will provide a brief overview of the definition of FTASD and recurrent shoulder instability, rates of recurrent shoulder instability, an introduction to risk factors, and predictive tools.

Anterior shoulder dislocations can occur as a result of trauma which forces the humeral head to be displaced from the glenoid fossa. The humeral head is completely separated from the articular surfaces and requires external force to relocate the shoulder (defined as a dislocation), or it spontaneously reduces without the requirement of external force (defined as a subluxation) (Owens et al., 2010; Rockwood, Matsen, & Wirth, 1998). There are over 3,800 new shoulder dislocations in New Zealand that are reported to the Accident Compensation Corporation (ACC) every year which cost the New Zealand tax payer between $7-20 million per year (personal communication, Peter Ng, ACC, 2013). There is a lack of published literature which has documented the incidence rate of FTASD in New Zealand.

The optimal management of people with a FTASD is a contentious topic and there is a lack of published evidence-based guidelines. Some authors have advocated for immediate surgical management following a FTASD, for all people under the age of 30 years (Davy & Drew, 2002), while others advocate surgery for young males (Crall et al., 2012). Yet others advocate immediate surgery only for high risk people (males under the age of 30 years who play contact sport with humeral or glenoid bone loss) (Murray, Ahmed, White, & Robinson, 2013). However, others have reported that immediate surgery is unnecessary and advocate for initial conservative management (Sachs, Stone, Paxton, Kuney, & Lin, 2007). Typical management of people following a FTASD would involve a period of initial conservative treatment (Kiviluoto, Pasila, Jaroma, & Sundholm, 1980) which may comprise of a period of immobilisation (Gibson, Growse, Korda, Wray, & MacDermid, 2004), followed by exercises and modalities to restore range of movement (ROM), strength and neuromuscular control (Ma, Brimmo, Li, & Colbert, 2017; Myers, Wassinger, & Lephart, 2006; Wilk & Macrina, 2013).

As alluded to earlier, while many patients have a successful outcome following conservative management, several studies have shown that many people fail conservative management and present with recurrent shoulder instability (Bottoni et al., 2002; Kirkley, Werstine, Ratjek, & Griffin, 2005). Some authors have defined recurrent shoulder instability as the presence of further additional radiographic evidence confirming an anterior dislocation or symptoms consistent with recurrent anterior subluxation or dislocation accompanied by a positive apprehension test, and an anterior load and shift test (Robinson, Howes, Murdoch, Will, & Graham, 2006). Others have simply defined recurrent shoulder instability following a FTASD as either another dislocation or subluxation (Dickens et al., 2014). Yet other authors have classified solitary dislocations to include another single episode of shoulder instability and classified recurrent instability as two or more shoulder dislocations/subluxations (Hovelius et al., 2008).

Rates of recurrent shoulder instability after a FTASD have been documented from as early as 1950 (McLaughlin & Cavallaro, 1950) and have been shown to range from 26% to 92% (Postacchini, Gumina, & Cinotti, 2000; te Slaa, Wijffels, Brand, & Marti, 2004). This wide variation may be explained by the heterogeneous populations within these studies, differences in methodologies, as well as the difference in recurrence rates between countries (Murray et al., 2013).

McLaughlin and Cavalerro (1950) retrospectively evaluated 103 consecutive patients with a FTASD to assess the rate of recurrent shoulder instability. In patients aged younger than 20 years, the recurrence rate was 90% over a 6 month to 5 year follow-up period. Only descriptive statistics were reported with no statistical analysis in this study. However, the authors noted other factors which may have increased recurrence rates in the entire cohort of people with a FTASD, including; that patients were able to lift their arm overhead within the first two months following injury, only one week of sling and swathe immobilisation and the beginning of pendular exercises within one week of injury.

Rowe (1956) followed 488 patients with 500 shoulder dislocations, over a 20 year period (mean follow-up of 4.8 years), who presented to a single hospital with a shoulder dislocation. Of these, 398 had sustained a first-time shoulder dislocation (in any direction) and 102 were people who presented with a recurrent shoulder dislocation. The recurrence rate in the 398 patients following first-time dislocation was 38% over a mean follow-up period of 4.8 years. However, people under the age of 20 years had a much higher rate of recurrent shoulder instability of 83% when compared with older people. While a younger age was associated with increased risk of recurrence, other factors such as a fracture of the greater tuberosity or the shoulder girdle were associated with decreased risk of recurrent shoulder instability. Handedness and the length of time the limb was immobilised did not affect the rate of recurrence. The above two studies (McLaughlin & Cavallaro, 1950; Rowe, 1956) were case series, were not designed as prospective cohort studies and only recorded people who came to hospital after another shoulder instability event, therefore biasing the sample. The findings are therefore not generalisable, cannot establish a cause and effect relationship, and are not representative of the entire population of people with a FTASD.

Hovelius (1987) undertook a prospective clinical trial to assess the effect of immobilisation on rates of recurrent shoulder instability in those following a first-time anterior shoulder dislocation with a traumatic or atraumatic mechanism. Patients were between 12 and 40 years of age, presented to one of 27 hospitals in Sweden and were randomised to one of two groups, with or without immobilisation. Neither the immobilisation status, nor the immobilisation period affected the rate of recurrence. However, other factors such as a fracture of the greater tuberosity, age at first-time dislocation (50% recurrence in those aged under 22 years), and chip fractures of the glenoid fossa did affect the rate of recurrent shoulder instability. In the 25 year follow-up study of the same population, the authors concluded that in the younger group (people aged 12-25 years) half of the cohort which had been treated conservatively had not experienced recurrent shoulder instability (Hovelius et al., 2008). In the remaining group (people aged 26-40 years), 82% (74 of 90) had no episode of recurrent instability or had episodes of instability but became stable over time (Hovelius et al., 2008). Of interest, these two studies included people with both traumatic and atraumatic shoulder instability (Hovelius, 1987; Hovelius et al., 2008). Traumatic and atraumatic shoulder instability is now known as two distinct entities (Kuhn, 2010), and the inclusion of both of these groups, may have biased the results of these studies.

The next section will briefly describe risk factors for recurrent shoulder instability, following a FTASD, found in the literature. Systematic reviews and meta-analyses of risk factors in adults and children follow in Chapters 2 and 3 respectively, followed by Chapter 4 which is devoted to a review of patient reported risk factors.

1.2 Introduction to physical and demographic risk factors for recurrent shoulder instability following a FTASD

The most documented risk factor for recurrent shoulder instability after a FTASD is the age of a person at the time of injury. Increased rates of recurrent shoulder instability in those who are aged between 15 and 30 years are well documented

(Hoelen, Burgess, Rozing, Burgers, & Rozing, 1990; Kralinger, Golser, Wischatta, Wambacher, & Sperner, 2002; Robinson et al., 2006; Safran, Milgrom, Radeva-Petrova, Jaber, & Finestone, 2010; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993). Others have shown increased rates of recurrent shoulder instability in even younger groups (younger than 16 years) (Lampert, Baumgartner, Slongo, Kohler, & Horst, 2003; Marans, Angel, Schemitsch, & Wedge, 1992). It has been postulated that younger people may have increased susceptibility to recurrent shoulder instability because of age-related skeletal anatomy or differences in level of shoulder activity (Buckwalter & Woo, 1996; Lee, Dettling, Sandusky, McMahon, & Lee, 1999; Rowe, 1956). Therefore, detailed examination of age as a risk factor for recurrent shoulder instability, after a FTASD, is necessary and requires separate analysis of children and adults.

The geographical location of research, along with the respective healthcare system, can also affect the reported rates of recurrent instability. Countries with over medicalised, commercialised healthcare systems may report higher rates of surgical intervention, when compared with countries with less commercial health care systems (Jain, 2015). Some countries also demonstrate an increased propensity for certain activities that can result in shoulder dislocations. For example, in New Zealand, participation in contact and collision sport is very popular, mainly for males, but increasingly also for females (Sport New Zealand, 2015). Involvement in collision sports has been purported to be a risk factor for recurrent shoulder instability (Robinson et al., 2006). Increased and repeated exposure to situations, which may involve traumatic contact, could increase the rate of recurrent shoulder instability.

There have been several trials and a systematic review, which have found conservative management to be associated with a higher rate of recurrent shoulder instability when compared with surgical intervention (Bottoni et al., 2002; Handoll & Al-Maiyah, 2004; Kirkley et al., 2005; Wheeler, Ryan, Arciero, & Milinari, 1989). However, a major limitation of any randomised controlled trial (RCT) is that the exclusion criteria necessary for homogenous groups result in many people being excluded from these trials (Kersten, Ellis-Hill, McPherson, & Harrington, 2010). This prevents establishing rates of occurrence within a trial. A systematic review of cohort studies of recurrent instability following a FTASD had not been conducted upon inception of this doctoral study and this work encompassed such reviews in adults and children. These will be discussed in Chapters 2 and 3. The role of psychosocial and other risk factors will now be discussed.

1.3 Introduction to psychosocial risk factors for recurrent shoulder instability

For the purpose of this thesis, psychosocial factors are defined as those which incorporate both the individual factors, as well as those factors which are a result of the structure of society (Martikainen et al., 2002). These societal structures may be macro-structures (such as interactions between nations and governments), meso-structures (such as interactions between communities, schools and workplaces) or micro-structures (such as personal interactions between individuals) (Martikainen et al., 2002).

Psychosocial factors of people with shoulder instability were first studied by Rowe et al. (1973) in the form of 26 case studies of people with voluntary shoulder instability managed both surgically and non-surgically. They were classified into two groups according to psychiatric and emotional states. Group 1 had revealed severe psychiatric and emotional disturbances after psychiatric evaluation and Group 2 had no psychiatric disorder other than the normal emotional disturbances of the adolescent. The results of this study were categorised as excellent, good fair or poor based on an outcome score that recorded stability, function, pain and motion. In those treated conservatively, two of the three patients (66%) in Group 1 had poor outcomes, while one of the three had a good outcome. In comparison, the people in Group 2 with no psychiatric disorder had excellent results in 11 of 15 (73%), good results in 9 of 15 (60%) and fair results in 4 of 15 (27%). In those treated surgically, 31 of the 37 operations (84%) in Group 1 were unsuccessful, with four eventually resulting in arthrodesis. Surgical management of the three people in Group 2 resulted in two excellent and one good outcome. The authors concluded that underlying psychiatric problems negatively influenced the outcomes of both surgical and non-surgical management in people with voluntary shoulder instability (Rowe et al., 1973).

The assessment of psychiatric disorders in people with shoulder instability represents an extreme point in an array of psychosocial factors that may be associated with injury. A more contemporary view of psychosocial variables that may impact on wellbeing include concepts such as quality of life, and fear of movement or reinjury.

Apprehension has been defined as a fear of dislocation and/or resistance in people with a history of anterior glenohumeral instability (Lädermann et al., 2016). Clinical tests to measure 'apprehension' of the shoulder when placed in abduction and external rotation are commonly used (Bahr, Craig, & Engebretsen, 1995; I. K. Y. Lo, Nonweiler, Woolfrey, Litchfield, & Kirkley, 2004). These tests have become standard practice based upon the biomechanical principles of loading the anterior shoulder capsule, using movements that mimic those frequently involved during a dislocation or subluxation. However, there is little substantiation of the psychological concept of 'apprehension', or how it affects people with shoulder instability (Perez, 2008). Recent research has reported altered cortical activation in people with anterior shoulder instability with a positive apprehension test, when compared with a control group with no apprehension (a negative apprehension test) (Cunningham et al., 2015; Shitara et al., 2015). Cunningham et al. (2015) found that Rowe scores (which measures shoulder stability, motion and function), Western Ontario Shoulder Instability Index (WOSI) (which measures quality of life) and pain visual analogue scale (VAS) scores were correlated with altered cortical activation in patients with anterior shoulder instability. Thus, symptoms reported by people with a history of anterior shoulder instability, may be due to not only the local shoulder pathology, but also the cortical changes that result from an episode of shoulder instability.

Shitara et al. (2015) measured brain activity in people with recurrent shoulder instability and healthy controls and reported decreased activity in pre-motor and primary motor/somatosensory areas of the brain in people with recurrent shoulder instability compared to the control participants. Furthermore, a correlation with the intensity of apprehension was found with areas of the brain associated with affect, fear, anxiety and motor control. These two studies investigating cortical changes associated with shoulder instability represent a new area for shoulder instability research. However, both had small sample sizes and therefore may not be representative of the wider population of people with shoulder instability. Further validation of the cortical changes associated with shoulder instability is required before definitive interpretation can be drawn from these studies (e.g. change across time following a shoulder dislocation).

Constructs such as fear of movement and injury (kinesiophobia) have been widely studied in people with low back pain and upper limb dysfunction (Asmundson, Norton, & Allerdings, 1997; Vincent et al., 2011). Kinesiophobia has been defined as the irrational and excessive fear of movement or injury (Das De, Vranceanu, & Ring, 2013). Kinesiophobia and fear of redislocation are common following a shoulder dislocation and were the most prevalent themes in a qualitative study which investigated return to sport after shoulder stabilisation surgery (Tjong, Devitt, Murnaghan, Ogilvie-Harris, & Theodoropoulos, 2015). Fear of reinjury has not been previously studied following a FTASD and may influence rates of recurrent shoulder instability as people may hesitate when playing sport, or hold back and not give maximum effort (Ardern, Taylor, Feller, & Webster, 2012; Ardern, Taylor, Feller, Whitehead, & Webster, 2013; Johnston & Carroll, 1998).

The influence of psychosocial factors of returning to sport following an injury has been examined in the literature (Ardern et al., 2012, 2013; Tjong et al., 2015). Recently, a scale which measured psychosocial readiness to return to sport after an episode of shoulder instability was developed in a population of rugby players who had an episode of shoulder instability (Gerometta, Klouche, Herman, Lefevre, & Bohu, 2018). Despite reporting that fear was the most common negative emotion when returning to sport (Gerometta et al., 2018), fear of reinjury was not recorded, only readiness to return.

In summary, momentum is gathering in the research community to provide a deeper understanding of the psychosocial factors that are associated with shoulder injuries. Further evaluation of the role of psychosocial factors in recurrent shoulder instability is worthy of further investigation.

1.4 Evidence-based tools and algorithms in clinical practice

Current clinical practice is transitioning from an evidence-based era to one which incorporates the evidence to personalise and customise care (Federer, Taylor, & Mather, 2013). Customised care has been defined as healthcare which is individually tailored on a patient-by-patient basis (Frank & Zeckhauser, 2007), whereas personalised care relies upon genetic and other information of an individual patient to select a medical intervention (Cortese, 2007; Schilsky, 2010). A growth in the amount of health information available on the internet, a narrowing gap between traditional paternalistic medical values and a model of consumerism/business, has resulted in people who are increasingly more active and engaged in their own healthcare (Benning, Kimman, Dirksen, Boersma, & Dellaert, 2012).

The customisation of healthcare has associated costs of additional communication, cognition, co-ordination and capability (Benning et al., 2012; Federer et al., 2013). These additional costs stem from the increased time that the clinician requires to explain treatment options, facilitate shared decision-making, ensure that the patient comprehends the choices available, and is adequately informed to make choices which affect their healthcare. However, these costs can be decreased through the use of decision-making tools to enable people to make informed choices regarding their healthcare (Arterburn et al., 2012; Spatz & Spertus, 2012).

Decision-making tools are interventions which have been designed to support patients' decision making through the provision of information about expected outcomes of a particular condition (Stacey et al., 2014). They incorporate current evidence-based factors of the natural history of the health state. Decision-making tools make the decision explicit, describe the available options and help people understand these options as well as the potential risks and harms (Elwyn et al., 2012; Stacey et al., 2014), thus enabling patients to make decisions regarding their healthcare (Spatz & Spertus, 2012).

Detailed decision-making tools are better than simple decision-making tools in improving knowledge and result in people feeling more informed and clear about their personal values (Stacey et al., 2014). The use of decision-making tools has been shown to reduce rates of elective joint replacement surgery and lower treatment costs for people with hip and knee osteoarthritis (Arterburn et al., 2012). Predictive tools and predictive algorithms are examples of decision-making tools and those that are in use with people with first-time and recurrent shoulder instability will now be discussed.

1.5 Predictive tools in shoulder instability

Predictive tools and predictive algorithms have been used for people experiencing shoulder instability to decide the type of surgical intervention, aiming to result in reduced recurrent shoulder instability (Balg & Boileau, 2007; Piasecki et al., 2009), predict the presence of fracture with a dislocation (Emond et al., 2004), compare cost effectiveness of surgical and non-surgical management (Bishop, Crall, & Kocher, 2011; Crall et al., 2012), predict recurrent instability after a FTASD (Mather, Orlando, Henderson, Lawrence, & Taylor, 2011) or an arthroscopic stabilisation (Ahmed, Ashton, & Robinson, 2012; Calvo, Granizo, & Fernández-Yruegas, 2005), diagnose traumatic anterior shoulder instability (van Kampen et al., 2013), or decide on clinical management (Murray et al., 2013). Since this doctoral work was specifically concerned with recurrent shoulder instability following a FTASD, this section will focus on tools that predict recurrent shoulder instability in this group of people.

The predictive model of Mather et al. (2011) was based upon data from Robinson et al. (2006) who undertook a prospective study of the natural history following a FTASD in those aged between 15 and 40 years. Robinson et al. (2006) found that age and sex were significantly related to the rate of recurrent shoulder instability. Mather et al. (2011) used a Monte-Carlo Markov decision-making tree in their study. Markov modelling considers the transition through various health states during a series of short intervals or cycles (Naimark, Krahn, Naglie, Redelmeier, & Detsky, 1997). Monte-Carlo Markov models are a subset of Markov models which incorporate the patient history into the model (Amiri & Kelishadi, 2012). Mather et al. (2011) used the Monte-Carlo Markov model process to predict the probability of a patient experiencing the health states of recurrent instability, surgical stabilisation or having a stable shoulder at 10 years following a FTASD. The predictive model also allowed for other variables such as time lost from work or sport following surgery.

The model, as developed by Mather et al. (2011), was externally validated using the data sets of two other published studies (Bottoni et al., 2002; Hovelius et al., 2008). When the model was adjusted to account for the sex difference in the study of Hovelius et al. (2008), the tool could predict recurrent shoulder instability within one percentage point. However, when data from Bottoni et al. (2002) were used to validate the model it was found to underestimate recurrence by 3-9%. Mather et al. (2011) proposed that with age and sex information, it would be possible for this model to be used by decision makers and researchers to predict further episodes of shoulder instability following a FTASD. In order the examine patient preferences for surgical or non-surgical management after a FTASD, this model was subsequently shown to people with and without shoulder instability (Streufert et al., 2017). Out of pocket costs associated with surgery were allotted $1000USD compared with $0 that was allotted for non-surgical treatment. These authors reported that 55% of males and 23% of females chose surgery after a FTASD (Streufert et al., 2017). This study was conducted after this PhD had commenced and is based upon a computer derived model rather than generalised linear model of logistic regression.

There are several limitations in the model proposed by Mather et al. (2011). The two studies used to validate the model (Bottoni et al., 2002; Hovelius et al., 2008) were limited to two significant variables (age and sex). Additionally, the use of only one intervention study and one non-operative arm of a RCT may limit the external validity of the model developed by Mather et al. (2011). Furthermore, the population in an intervention study may not be representative of the wider population, for example Bottoni et al. (2002) excluded all people with neurologic injuries or fractures associated with their dislocation.

Other risk factors for an unsuccessful outcome (recurrent shoulder instability) following a FTASD (such as Hill Sachs lesions, hyper-laxity and glenoid bone loss) were not included in the model of Mather et al. (2011). Finally, Hovelius et al. (2008) have shown that up to 30% of people with a FTASD will become stable over time without surgical intervention, yet this Monte-Carlo Markov model does not allow for people with recurrent shoulder instability to develop a stable shoulder in the Monte-Carlo Markov tree structure.

An algorithm which outlined the investigation and management of athletes following a FTASD was proposed by Murray et al. (2013). In this algorithm, patients who had a history, examination and plain radiographs consistent with a FTASD and who were considered as ‘low risk’ of recurrent shoulder instability (defined as over the age of 30 years, female and involved in non-contact sport) were immobilised and managed with physiotherapy. For people who were considered as ‘high risk’ of recurrent shoulder instability (defined as under the age of 30, male, and involved in contact sport with bone loss from plain radiographs) surgical intervention was advocated. This approach offered clinicians a guide in the management of those with a FTASD. However, some authors have reported similar rates of recurrent instability in men and women (te Slaa, Wijffels, Brand, & Marti, 2003). The algorithm developed by Murray et al. (2013) has not been validated retrospectively or prospectively in the population of those with a FTASD. Further, the definition of ‘low risk’ and high risk’ appears to be a classification decided upon by the authors with little substantive rationale. Robinson et al. (2008) had previously classified high risk people as males, 27 years and younger and females, aged 16 years and under; while low risk people were males aged over 27 years and females over the age of 16 years. Clearly there is a lack of consistency in the definition of high and low risk in the above studies.

Another prediction model combining patient characteristics, history and clinical tests to diagnose traumatic anterior instability, in patients presenting with shoulder complaints, was developed by van Kampen et al. (2013). This model included the following variables: age, previous dislocation, sudden onset of complaints, high scores on the WOSI question five (*clicking, cracking or snapping*), and WOSI question eight (*feeling of instability or looseness*) and the Anterior Release clinical test. The WOSI questions did not demonstrate linearity and were therefore excluded from the final model. Magnetic resonance arthrogram (MRA) was used as the gold standard to confirm the diagnosis. This model demonstrated a high degree of accuracy (95%) in diagnosing traumatic anterior shoulder instability. However, this study provided a prediction model for the diagnosis of shoulder instability in people with shoulder problems, rather than for people with a FTASD and therefore the findings cannot be generalised to this population.

1.6 Summary

The literature shows varied and high rates of recurrent instability for people following conservative management of a FTASD, a range of studies that have examined risk factors but which have not been synthesised systematically, and an absence of validated tools to predict who will go on to develop recurrent shoulder instability following a FTASD.

Chapter 2 will systematically examine the risk factors which predispose adults to recurrent shoulder instability following a FTASD. As alluded to in Chapter 1, children who suffer from a FTASD may present with different risk factors due to different anatomical entities such as the presence of growth plates and an immature skeletal system (Buckwalter & Woo, 1996; Rowe, 1956). Therefore, the risk factors which predispose or protect children from recurrent instability following a FTASD will be examined separately in Chapter 3. While physical risk factors which predispose people to recurrent instability following a FTASD have been highlighted, little attention has been paid to the psychosocial factors, such as kinesiophobia, which may predispose or protect people to recurrent shoulder instability. Chapter 4 reviews the impact of a shoulder dislocation on quality of life, kinesiophobia and pain scores in people with a shoulder dislocation and discusses the potential for these factors to predispose or protect people to recurrent instability.

1.7 Thesis aims and objectives

The aims and objectives of the current thesis are:

Aim 1: to identify risk factors which predispose those with a FTASD to further episodes of shoulder instability.

OBJECTIVES

To conduct a systematic review of risk factors which predispose adults with a FTASD to further episodes of shoulder instability, including meta-analysis where appropriate (Chapter 2).

To conduct a systematic review of risk factors which predispose children with a FTASD to further episodes of shoulder instability, including meta-analysis where appropriate (Chapter 3).

Aim 2: to develop and pilot a predictive tool which can differentiate between those who will have recurrent shoulder instability and those who will not develop recurrent shoulder instability, in a population of people with a FTASD.

OBJECTIVE

To develop and pilot the tool in a New Zealand based cohort study of adults who have sustained a FTASD (Chapters 5-6).

Aim 3: to examine the validity of a predictive tool in differentiating between those who will have recurrent shoulder instability and those who will not develop recurrent shoulder instability, in a population of people with FTASD who are managed conservatively.

OBJECTIVE

To validate the tool in a New Zealand based cohort study of adults who have sustained a FTASD (Chapters 5 and 7).

Aim 4: to evaluate the impact of a FTASD on patient perceived pain, function, kinesiophobia, activity level and quality of life and examine the association between these variables and recurrent shoulder instability.

OBJECTIVES

To review the literature concerning patient perceived pain, function, kinesiophobia and quality of life after a FTASD (Chapter 4).

To examine the level of quality of life, pain and disability, kinesiophobia within 12 weeks following a FTASD (Chapters 5 and 8).

To assess whether quality of life, pain and disability, kinesiophobia and shoulder activity level were different in people with and without recurrent shoulder instability (Chapters 5 and 8).

To assess how quality of life, pain and disability, kinesiophobia and shoulder activity level changed from the time of FTASD over the following 12 months (Chapters 5 and 8).

1.8 Significance of the research

Conservative management of people with a FTASD has been poorly explored in the literature with a lack of robust longitudinal follow-up and clinical trials (Gibson et al., 2004; Hanchard, Goodchild, & Kottam, 2014; Handoll, Hanchard, Goodchild, & Feary, 2009). Following a FTASD, people will either have successful conservative management or develop recurrent shoulder instability (i.e. unsuccessful management). Accurate identification of the members of these two groups is essential to enhance and further the current management of people with a FTASD. This doctoral research aims to develop a valid tool that can be used to predict the likelihood of recurrent shoulder instability following a FTASD. The aim is that this tool will allow accurate identification of people with FTASD that have successful or unsuccessful outcomes following conservative management and may be used by clinicians to decide on treatment alternatives. Used in the context of shared decision-making, this tool will also assist in setting realistic expectations for both patients and clinicians regarding the likelihood for further shoulder instability.

1.9 Thesis organisation

The organisation for this thesis was designed around discrete manuscripts (published and submitted) that comprise this body of work, along with connecting chapters (Figure 1.1).

The background and general overview of the thesis as well as the aims and objectives of this thesis have been presented in Chapter 1. The literature review comprises two separate systematic reviews with meta-analyses. Both reviews examined risk factors which predispose people with a FTASD to recurrent shoulder instability, the first focused on adults and the second focused on children. These reviews are presented in Chapters 2 and 3. They were published as two manuscripts in peer reviewed journals. A detailed review of psychosocial and patient reported risk factors is undertaken in Chapter 4. Chapter 5 provides details of the methodology of the prospective cohort study. Chapters 6 and 7 detail the development and assessment of the predictive validity of the tool respectively (these papers are under review with peer reviewed journals). Associations between FTASD and recurrent instability with quality of life, kinesiophobia, shoulder pain and disability and shoulder activity level are presented in Chapter 8 (this paper is under development for submission for publication). A summary of the overall thesis is presented in Chapter 9, along with discussion of the research findings and implications for further research.

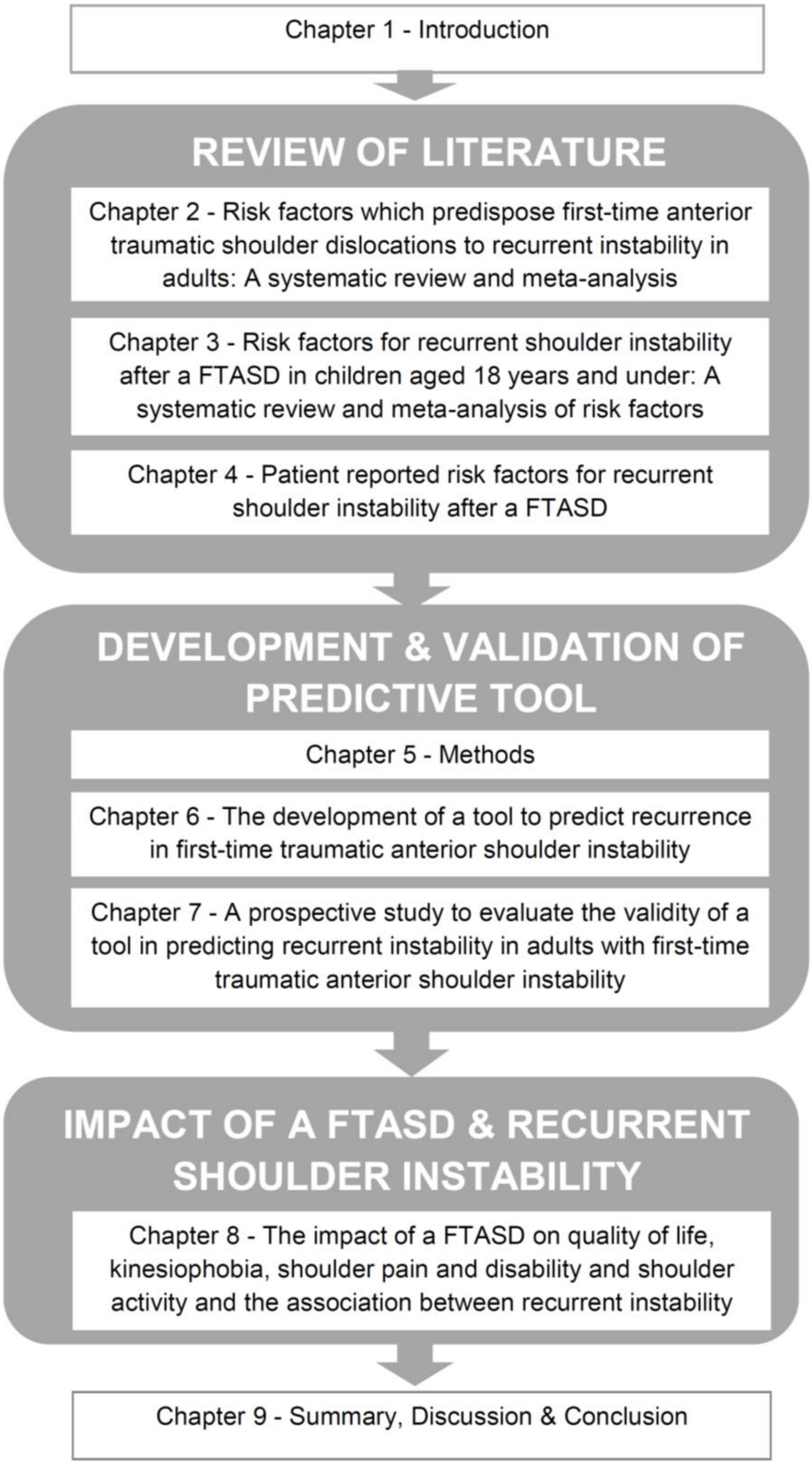

Figure 1.1 Thesis structure

Chapter 2 **Risk factors which predispose FTASD to recurrent instability in adults: A systematic review and meta-analysis**

2.1 Preface

This chapter relates to Aim 1 of the thesis: to identify risk factors which predispose those with a FTASD to further episodes of shoulder instability by undertaking a systematic review of the literature (see 1.7).

A systematic review and meta-analysis of risk factors which predispose or protect people with a FTASD to recurrent shoulder instability enabled an objective appraisal of the existing evidence and was used to explain the heterogeneity between studies. Furthermore, graphical representation of odds ratios allowed analysis of the overall effect of the risk factors identified (Egger, Smith, & Phillips, 1997). Restriction of included studies to that of cohort study design allowed analysis of multiple risk factors from a population representative of the general population of people who have a FTASD. Exclusion of intervention studies allowed comparison of the natural history of a FTASD and removed bias that may have resulted from limiting the population to a clearly defined homogenous group (Gordis, 2014). Therefore, this chapter reports the risk factors for recurrent instability in adults aged 15 years of age and older, including details of the systematic review and meta-analysis. The contents of this chapter have also been published in the *British Journal of Sports Medicine* in 2015 (Olds, Ellis, Donaldson, Parmar, & Kersten, 2015) and the Version of Record can be accessed online at http://dx.doi.org/10.1136/bjsports-2014-094342. Some editorial changes have been made, to the text seen in the published article, in accordance with presenting this formal thesis. Literature published after the publication date of this manuscript will be included in the thesis discussion (Chapter 9).

2.2 Risk factors which predispose FTASD to recurrent instability in adults: A systematic review and meta-analysis.

Olds, M., Ellis, R., Donaldson, K., Parmar, P., & Kersten, P. (2015). Risk factors which predispose first-time traumatic anterior shoulder dislocations to recurrent instability in adults: A systematic review and meta-analysis. *British Journal of Sports Medicine, 49*, 913-923. http://dx.doi.org/10.1136/bjsports-2014-094342

2.2.1 Abstract

2.2.1.1 Background

Recurrent instability following a first-time anterior traumatic shoulder dislocation (FTASD) may exceed 26%. We systematically reviewed risk factors which predispose this population to events of recurrence.

2.2.1.2 Methods

A systematic review of studies published before July 1, 2014. Risk factors which predispose recurrence following a FTASD were documented and rates of recurrence were compared. Pooled odds ratios (OR) were analysed using random effects meta-analysis.

2.2.1.3 Results

Ten studies comprising 1,324 subjects met the criteria for inclusion. Recurrent shoulder instability following a FTASD was 39%. Increased risk of recurrent shoulder instability was reported in people aged 40 years and under (OR=13.46), in men (OR=3.18) and in people with hyperlaxity (OR=2.68). Decreased risk of recurrent shoulder instability was reported in people with a greater tuberosity fracture (OR=0.13). The rate of recurrent shoulder instability decreased as time from the initial dislocation increased. Other factors such as a bony Bankart lesion, nerve palsy, and occupation influenced rates of recurrent shoulder instability.

2.2.1.4 Conclusion

Sex, age at initial dislocation, time from initial dislocation, hyperlaxity and greater tuberosity fractures were key risk factors in at least two good quality cohort studies

resulting in strong evidence as concluded in the GRADE criteria. Although bony Bankart lesions, Hill Sachs lesions, occupation, physiotherapy treatment and nerve palsy were risk factors for recurrent shoulder instability, the evidence was weak using the GRADE criteria – these findings relied on poorer quality studies or were inconsistent among studies.

2.2.1.5 Keywords

Recurrence, shoulder instability, first-time, anterior shoulder dislocation, risk factors

2.2.2 Introduction

Shoulder dislocations are a significant and costly problem. Overall incidence rates of shoulder dislocations varies between 23.9 (Zacchilli & Owens, 2010) and 23.1 (Leroux et al., 2014) per 100,000 person years with a higher incidence rate in young men (98.3 per 100,000 person-years) (Leroux et al., 2014). Traumatic shoulder dislocations in males under the age of 30 years cost New Zealand approximately five million dollars per year, with 3,886 new injuries reported from April 2012 to March 2013 (Personal Communication, ACC Statistics, 2013). The total cost to the health service of these claims over this period was almost NZD $8 million. Real additional costs include time off work/school and impact on family members for care. When a first-time traumatic anterior shoulder dislocation (FTSAD) develops into recurrent instability, additional emotional and financial costs can be substantial. Reported rates of recurrent shoulder instability vary between 26% (te Slaa et al., 2003) and 100% (Rowe, 1956).

Some authors have proposed immediate stabilisation for young athletes following a dislocation (Boone, Arciero, & Boone, 2010; Davy & Drew, 2002; Kirkley et al., 2005). Others have proposed that this will result in unnecessary surgical intervention for those that are not at risk of developing further instability (Sachs et al., 2007). Consequently, better decision making regarding immediate surgical stabilisation at the time of first dislocation is a desirable goal for both patients and the wider society.

It has also been argued that there is a need to identify modifiable risk factors for recurrent shoulder instability following a FTASD (Cameron et al., 2013). Extrinsic risk factors of recurrent shoulder instability include occupations which involve using the upper limb above chest height (Sachs et al., 2007), collision sport (Robinson et al., 2006), or sports' playing surface (Cheng et al., 2012). Intrinsic risk factors include hypermobility (Chahal, Leiter, McKee, & Whelan, 2010; Cheng et al., 2012; Ranalletta, Bongiovanni, Suarez, Manuel, & Ovenza, 2012; Wasserstein et al., 2016) and age (Kralinger et al., 2002). Some intrinsic risk factors may be the result of pathological damage which had occurred during a dislocation. A FTASD may also predispose patients to recurrent instability (De Smedt, Hoogmartens, Milier, Mulier, & Milier, 1975; Robinson et al., 2006; Simonet & Cofield, 1984). However, much of the evidence which supports these risk factors is based on clinical opinion or cross-sectional studies (Gordis, 2014).

Therefore, we aimed to identify the risk factors which predict the development of recurrent shoulder instability in adults within one or more years following a FTASD. Data from this review were used in a later study to develop and validate a predictive tool of recurrence after FTASD (Chapters 6 and 7 respectively).

2.2.3 Methods

The systematic review was carried out in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) protocol and registered with the PROSPERO database (registration number: CRD42013005900), which can be accessed at
https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=5556

2.2.3.1 Literature search

A search strategy (Table 2.1) was developed, combined with the Boolean term 'AND', and then used by one reviewer (MO) to search the following databases: Biomedical Reference Collection, CINAHL, Medline, Sports Discus, AMED, EBM Reviews, ERIC, Health and Psychosocial instruments, Proquest, Web of Science and Scopus. Potential articles were identified by screening titles and abstracts and if these met the inclusion criteria, the full text of the articles were obtained. Reference lists of these articles were cross-referenced for other articles of interest and used to help refine the inclusion and exclusion criteria. To exclude the possibility of publication bias, such as the publication of only positive findings, grey literature was searched for theses and other trials.

Table 2.1 Keywords used in search strategy

1	(shoulder* ADJ5 instabil*) OR (shoulder* ADJ5 dislocat*) OR (shoulder* ADJ5 stabil*) OR (shoulder* ADJ5 sublux*) OR (shoulder* ADJ5 unstab*) OR (glenohumeral ADJ5 instabil*) OR (glenohumeral ADJ5 dislocat*) OR (glenohumeral ADJ5 stabil*) OR (glenohumeral ADJ5 sublux*) OR (glenohumeral ADJ5 unstab*) OR (GHJ ADJ5 instabil*) OR (GHJ ADJ5 dislocat*) OR (GHJ ADJ5 stabil*) OR (GHJ ADJ5 sublux*) OR (GHJ ADJ5 unstab*)
2	Recurr* OR reocurr* OR redislocat* OR repeat*
3	Risk* OR factor* OR prevalen* OR predict* OR incidence OR "odds ratio"

2.2.3.2 Inclusion and Exclusion Criteria

Studies were included if they were prospective and retrospective cohort studies, which investigated risk factors for developing recurrent instability following a FTASD. Cohort designs were chosen because of the ability to infer causation and the ability to examine multiple risk factors. For the purpose of this review, recurrent shoulder instability was defined as a repeated instability event of either a subluxation or a dislocation. Studies were included if the subluxation or dislocation was confirmed by either radiological evidence or clinical testing and rate of recurrence was documented as an outcome measure. Studies were also included if they had a follow-up of one year or more as Robinson et al. (2006) have shown a decrease in the incidence of shoulder instability events after 12 months. Studies were included if they were published before July 1, 2014.

Studies were excluded if the follow-up period was less than 12 months; they reported posterior, multi-directional or atraumatic shoulder instability; or if all patients were under the age of 15 years (Cordischi, Li, & Busconi, 2009; Robinson & Aderinto, 2005; Rowe, 1956). Age restrictions were applied in this review as children with open physes may present with different pathoanatomy following a dislocation (Cordischi et al., 2009). Additionally, the open physes themselves may also represent a specific risk factor (Cordischi et al., 2009). Studies with mixed age populations were included if data on those over 15 were presented separately. Studies which investigated risk factors of recurrent instability following surgical intervention or compared alternative surgical interventions were also excluded, as this population is different from those with FTASD that have not undergone surgical intervention.

2.2.3.3 Assessment of study quality

The methodological quality of each of the included studies was evaluated by two reviewers (MO and KD), using the SIGN (Scottish Intercollegiate Guidelines Network) checklist for cohort studies. The SIGN checklist examines the internal validity of the study and includes factors such as subject selection, confounding and assessment. The overall methodological quality of each article is graded as high quality (++), acceptable (+) or low quality (0) (SIGN., 2012). The SIGN checklist is reported to be the most appropriate and valid tool for assessing the methodological quality of observational studies (Perestelo-Perez, 2013). One question (1.4) examines the likelihood that some subjects might already have the outcome of interest at the time of enrolment. This question was excluded as studies were only included if they studied people with a first-time dislocation. Disagreements between reviewers were resolved in a single consensus meeting. If consensus could not be reached, a separate independent author (PK) was used to reach a decision of the methodological quality as recommended by the SIGN50 handbook (SIGN., 2011). No articles were excluded from analysis based on quality scores. This is because scales have been shown to provide unreliable assessments of validity (Jüni, Witschi, Bloch, & Egger, 1999) and have been explicitly discouraged in the Cochrane handbook as they tend to assign a ‘weight’ to particular items in the scale which are difficult to justify (Higgins & Green, 2011).

2.2.3.4 Data extraction and synthesis

Data from included studies were extracted, including patient demographics, rate of recurrent instability, mechanism of injury, pathological factors associated with recurrent instability, and any other factors associated with recurrent shoulder instability. If these data were not available, or the methods required clarification, the authors were contacted. Articles were excluded from further analysis when these authors could not be contacted, did not respond or when they were unable to provide the information on request. Data were pooled and recurrent instability was reported as a percentage across all studies which reported the variable.

A meta-analysis was performed to compare the rates of recurrent shoulder instability of patients in the included studies using Comprehensive Meta-Analysis Software (Borenstein, Hedges, & Higgins, 2005). Studies were included in the meta-analysis if their data allowed calculation of an odds ratio. For each available variable, pooled dichotomous data were analysed using random-effects meta-analyses and odds ratios. Heterogeneity was reported using the I^2 index, where a larger score indicates a greater proportion of the variability that could be attributed to heterogeneity (Higgins, Thompson, Deeks, & Altman, 2003). Significance was set at $p<0.05$.

2.2.4 Results

The initial search resulted in 1,195 citations. An additional three studies were found by cross-referencing the bibliographies of full-text articles. Most of the studies (99%) were excluded as they did not meet the inclusion criteria outlined above. For example, many did not use a cohort study design, did not provide sufficient details of the first dislocation or followed patients for a short duration. Ten studies comprising 1,324 participants were included in the review and data extraction (Figure 2.1). There were more male than female patients in the studies (966 vs. 358) and ages ranged from 15 to 96 years (Table 2.2).

Two studies (Robinson et al., 2006; Sachs et al., 2007) were rated as high quality, three studies (Salomonsson et al., 2010; Simonet & Cofield, 1984; te Slaa et al., 2004) as acceptable and five (Hoelen et al., 1990; Kralinger et al., 2002; Pevny, Hunter, & Freeman, 1998; Safran et al., 2010; Vermeiren, Handelbery, Casteleyn, & Opdecam, 1993) as low (Table 2.3). Seven studies were of retrospective design (Hoelen et al., 1990; Kralinger et al., 2002; Pevny et al., 1998; Salomonsson et al., 2010; Simonet & Cofield, 1984; te Slaa et al., 2004; Vermeiren, Handelbery, Casteleyn, & Opdecam, 1993). The remaining three studies were of prospective design (Robinson et al., 2006; Sachs et al., 2007; Safran et al., 2010). Common strengths of the studies were the representative nature of the sample to the wider population, and follow-up of participants. Weaknesses across the studies included a lack of an explicit definition of recurrence, lack of reported confounding factors or analysis of these factors and lack of blinding to risk factors in the follow-up. Studies that reported arm dominance (Hoelen et al., 1990; Sachs et al., 2007; Salomonsson et al., 2010; Vermeiren, Handelbery, Casteleyn, & Opdecam, 1993) or affected side (Simonet & Cofield, 1984) failed to find an association between these variables and recurrent instability.

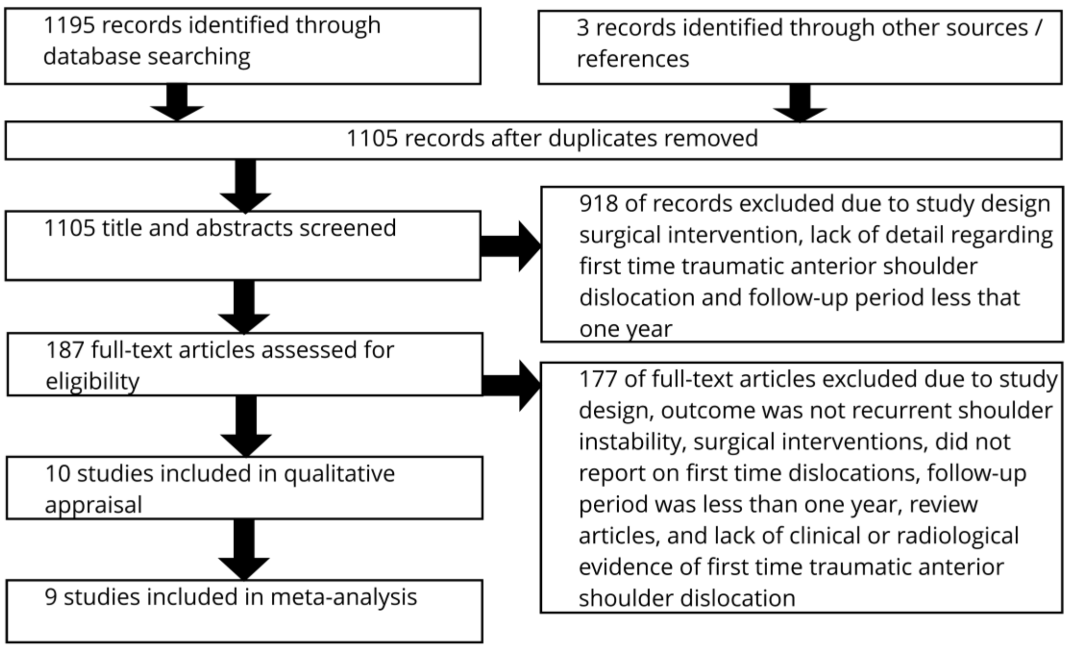

Figure 2.1 Flow diagram of article selection according to PRISMA

Table 2.2 Demographic data of the ten studies which reported risk factors for recurrent shoulder instability after a FTASD in adults

	Total subjects	**Total recurrence**	**Age; yrs* (range)**	**Dominant Dislocation (side)**	**Male**	**Female**	**Male recurrence**	**Female recurrence**	**Study Design**
Robinson et al. (2006)	252	60%	15-35	NR	225	27	39%	7%	Prospective
Salomonsson et al. (2009)	51	52%	17-69	57%	42	9	NR	NR	Prospective
Simonet & Cofield (1984)	116	33%	20-96	58 (R), 66 (L)	82	34	NR	NR	Retrospective
Sachs et al. (2007)	131	33%	20-82	40%	102	29	NR	NR	Prospective
te Slaa et al. (2003)	107	74%	20-88	NR	69	38	71%	79%	Retrospective
Vermeiren et al. (1993)	154	25%	15-85	NR	82	72	32%	18%	Retrospective
Kralinger et al. (2002)	241	23%	13-86	42%	176	65	NR	NR	Retrospective
Hoelen et al. (1990)	168	26%	15-94	53%	96	72	40%	8%	Retrospective
Pevny et al. (1998)	52	4%	40-79	NR	40	12	5%	0%	Retrospective
Safran et al. (2010)	52	46%	17-27	NR	52	0	46%	0%	Prospective
Total	1324	39%	15-96		966	358	47.30%	25.50%	

* patients younger than 20 years were excluded from analysis as data were grouped to include patients younger than 15 years

NR = not reported; yrs*=participants younger than 20 as details not provided to exclude those younger than 15 years

Table 2.3 Quality rating of studies which reported risk factors for recurrent shoulder instability after a FTASD in adults

SIGN (2004)	**Clear Focused question**	**Selection Bias**	**Selection Bias**	**Performance Bias**	**Attrition Bias**	**Attrition Bias**	**Detection Bias**	**Detection Bias**	**Detection Bias**	**Detection Bias**	**Detection Bias**	**Detection Bias**	**Confounding**	**Confidence Interval**	**Limitation of Bias**		
Author	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	1.1	1.11	1.12	1.13	1.14	2	Rating**	TOTAL***
te Slaa et al. (2003)	1	1					0	1	1	0	0		1	N	+	Acceptable	5
Simonet & Cofield (1984)	1	1					1	1	0	0	0		1	N	+	Acceptable	5
Safran et al. (2010)	1	1	0		1	1	1	0	0	1	0	1	0	Y	-	Low	7
Sachs et al. (2007)	1	1	1		1	0	1	1	1	0	0	1	1	Y	+	High	9
Robinson et al. (2006)	1	1	1		1	1	1	0	0	1	1	1	1	Y	+	High	10
Kralinger et al. (2002)	1	0					0	0	0	1	1		1	N	-	Low	4
Vermeiren et al. (1993)	1	1					0	0	0	0	0		0	N	-	Low	2
Hoelen et al. (1990)	1	1					1	0	0	0	0		0	N	-	Low	3
Salomonsson et al. (2009)	1	1					1	1	1	1	0		1	N	+	Acceptable	7
Pevny et al. (1998)	1	1					1	1	0	1	0		0	N	-	Low	5

*Grey shading indicates retrospective studies where it was not possible to evaluate criteria

** Rating scales refer to how well the study has minimised the risk of bias or confounding and establish a causal relationship between the risk factor and recurrent instability. High quality studies have little or no risk of bias, and the results from these studies are unlikely to change with further research. Acceptable quality studies have some associate risk of bias and the conclusions may change in light of further studies. Low quality studies have significant flaws related to study design and the conclusions drawn from these studies are likely to change in the light of further studies.

***Total scores can range from zero to 13 with lower number representing increased risk of bias and higher numbers representing prospective cohort studies with minimal risk of bias

2.2.4.1 Age

All ten studies examined age as a risk factor for recurrent instability (Table 2.4) and found an association between age and instability. Some studies had previously grouped data for those 40 years and younger, and they were unable to provide raw data. Therefore, these data were grouped into two age brackets 15-40 years and greater than 40 years. This shows increased rates of recurrence in those 40 years and less (44%) compared with those over the age of 40 (11%). There is increased risk of recurrence for those aged 40 or below, compared with those aged over the age of 40 (OR=13.46, 95% CI (5.25, 34.49), Z=5.41, $p<0.001$, $I^2=63.18$) (Figure 2.2). Further analysis of the association between age at first dislocation and rate of recurrent instability is presented in Table 2.5. This table shows that the rate of recurrent instability in those aged between 15-20 years and 15-30 years is approximately 50%. Lower rates of recurrence are seen in people aged between 41 and 60 years and those aged over 61 years and the rate does not vary greatly between these two groups.

Study name	Statistics for each study				
	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Hoelen et al., 1990	26.471	8.803	79.597	5.832	0.000
Kralinger et al., 2002	3.913	1.900	8.057	3.702	0.000
te Slaa et al., 2003	9.284	2.478	34.783	3.307	0.001
Simonet and Cofield, 1984	54.811	3.161	950.471	2.751	0.006
Vermeiren et al., 1993	244.574	14.398	4154.638	3.805	0.000
Salomonnsson et al., 2009	5.760	1.605	20.670	2.686	0.007
Pevny et al., 1998	22.000	0.978	494.760	1.946	0.052
	13.459	5.252	34.492	5.414	0.000

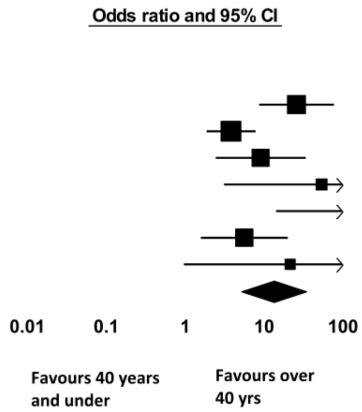

Figure 2.2 Age as a predictor for recurrent shoulder instability after a FTASD in adults aged over 40 years compared with those aged 15-40 years

Table 2.4 Age as a predictor for recurrent shoulder instability after a FTASD in adults

	Hoelen et al. (1990)		**Kralinger et al. (2002)**		**Robinson et al. (2006)**		**te Slaa et al. (2003)**		**Sachs et al. (2007)**		**Simonet & Cofield (1984)**		**Vermeiren et al. (1993)**		**Safran et al. (2010)**		**Pevny et al. (1998)**		**Salomonsson et al. (2009)**		**Total**	
Age	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode	No Recurrence	≥ 1 recurrent episode
15-20	35%	65%	13-20 yrs		51%	49%	11-20yrs		12-20 yrs		14-20 yrs		46%	54%	54%	46%			17%	83%	337	266
21-30	37%	63&	39%	61%	71%	29%	63%	37%			60%	40%	88%	12%								
31-40	74%	26%	65%	35%	79%	21%							88%	12%								
41-50	100%	0%	89%	11%													100%	0%				
51-60	95%	5%	73%	27%													100%	0%	55%	45%	361	45
61-70	90%	10%	86%	14%			94%	6%	90%	10%	100%	0%					91%	33%				
71-80	100%	0%	78%	22%													100%	0%				
80-100	100%	0%	73%	27%																		
Total	74%	26%	76%	30%	65%	35%	80%	20%	90%	10%	70%	20%	75%	25%	54%	46%	96%	4%	47%	53%	698	311

Yrs = years, *Grey shading indicates that age groups were not examined in the study

Table 2.5 Percentage of recurrent shoulder instability after a FTASD across age in adults aged 15 years and greater

Age Range (years)	Number of studies	Total Number Recurrence	Total Recurrence	Total Number	Percentage Recurrence
15-20	2 studies (Hoelen et al., 1990; Robinson et al., 2006)	53	56	109	51%
15-30	6 studies (Robinson et al., 2006; Kralinger et al., 2002; Salomonnson et al., 2009; Hoelen et al., 1990; Vermeiren et al., 1993; Safran et al., 2010)	224	211	435	49%
21-40	7 studies (Hoelen et al., 1990; Kralinger et al., 2002; Pevny et al., 1998; Robinson et al., 2006; Simonet & Cofield, 1984; te Slaa et al., 2003; Vermeiren et al., 1993)	319	147	413	36%
41+	7 studies (Hoelen et al., 1990; Kralinger et al., 2002; Pevny et al., 1998; Sachs et al., 2007; Salomonsson et al., 2010; Simonet & Cofield, 1984; te Slaa et al., 2003)	737	41	389	11%
41-60	3 studies (Hoelen et al., 1990; Kralinger et al., 2002; Pevny et al., 1998)	109	13	122	11%
61+	3 studies (Hoelen et al., 1990; Kralinger et al., 2002; Pevny et al., 1998)	102	11	113	10%

2.2.4.2 Sex

Seven studies reported the effect of sex on recurrent shoulder instability with an overall rate of recurrence of 46.84% in men compared with 27.22% in women (Table 2.6) (Hoelen et al., 1990; Pevny et al., 1998; Robinson et al., 2006; Safran et al., 2010; Simonet & Cofield, 1984; te Slaa et al., 2003; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993). Six studies compared rates of recurrent instability in men with women, and men were found to be over three times more at risk of recurrent instability (OR=3.18, 95% CI (1.28, 7.89), Z=2.49, p=0.01, I^2=75.53) (Figure 2.3). One study included only men and so did not compare recurrence between sexes (Safran et al., 2010).

Five studies reported rates of recurrent instability across sexes in people aged under 40 years and found the rates of recurrence to be similar to the total recurrence (Hoelen et al., 1990; Robinson et al., 2006; Safran et al., 2010; Simonet & Cofield, 1984; te Slaa et al., 2003). Three studies reported that there were more women with an initial dislocation aged over 40 years compared with the number of women aged 40 years and under (Hoelen et al., 1990; Simonet & Cofield, 1984; te Slaa et al., 2003). te Slaa et al. (2003) reported that rates of recurrent instability in those aged over 40 years were similar in men and women (22% and 25% respectively). No further analysis of recurrent instability in men compared with women over the age of 40 was undertaken.

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
	Statistics for each study				
Hoelen et al., 1990	7.526	2.970	19.070	4.255	0.000
Pevny et al., 1998	1.364	0.061	30.638	0.195	0.845
Robinson et al., 2006	7.880	1.821	34.105	2.762	0.006
Simonet & Cofield, 1984	7.143	2.308	22.102	3.412	0.001
te Slaa et al., 2003	0.653	0.256	1.668	-0.890	0.373
Vermeiren et al., 1993	2.107	0.986	4.504	1.923	0.054
	3.181	1.281	7.896	2.495	0.013

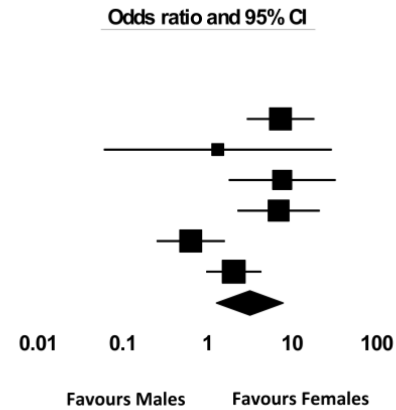

Figure 2.3 Sex as a predictor for recurrent instability after a FTASD in adults

Table 2.6 Sex as a predictor for recurrent shoulder instability after a FTASD in adults

	Total subjects	Total recurrence	Number of Men	Number of Women	Total recurrence in men	Total recurrence in women	Recurrence in men <40Yrs	Recurrence in women <40Yrs
Robinson et al. (2006)	252	60%	225	27	39%	7%	39%	7%
Salomonsson et al. (2009)	51	52%	42	9				
Simonet & Cofield (1984)	116	33%	82	34	49%	12%	49%	40%
Sachs et al. (2007)	131	33%	102	29				
te Slaa et al. (2003)	107	74%	69	38	71%	79%	91%	36%
Vermeiren et al. (1993)	154	25%	82	72	30%	18%		
Kralinger et al. (2002)	241	23%	176	65				
Hoelen et al. (1990)	168	26%	96	72	40%	8%	65%	57%
Pevny et al. (1998)	52	4%	40	12	5%	0%		
Safran et al. (2010)	52	46%	52	0	46%	0%	46%	0%
Total Values & Mean Percentage	657	39%	966	358	47.30%	25.50%	46.84%	22.22%

Grey shading indicates that data was not available for sex

2.2.4.3 Mechanism of injury

Mechanism of injury was reported in nine studies (Hoelen et al., 1990; Kralinger et al., 2002; Pevny et al., 1998; Robinson et al., 2006; Sachs et al., 2007; Safran et al., 2010; Simonet & Cofield, 1984; te Slaa et al., 2003; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993). Many authors reported a direct blow or fall as a mechanism of initial dislocation. Other mechanisms of injury included assaults and seizures or motor vehicle accidents (Robinson et al., 2006; Simonet & Cofield, 1984). Meta-analysis was not possible due to large variation in the definition of mechanism of injury.

Many authors reported the initial dislocation to occur during an athletic activity, particularly in the younger age group. Simonet & Cofield (1984) reported that 77% of those younger than 30 years of age suffered a recurrent instability event due to a sporting activity. Two low quality studies reported no significant difference in the rate of recurrent instability in the type of sport played following the FTASD (Hoelen et al., 1990; Kralinger et al., 2002). A high quality study found a non-significant relationship between recurrent instability and those involved in contact or collision sports despite a trend towards significance and more requests for surgery in those involved in contact or collision sports (OR=7.846, p=0.105) (Sachs et al., 2007). There was a trend between return to sport or full activities of daily living within 6 weeks of a FTASD (p=0.082) and a return to sport within the first year after a FTASD (p=0.095) with respect to recurrent shoulder instability (Robinson et al., 2006). Simonet and Cofield (1984) also reported that 56% of those who returned to sport or full activity within six weeks and were under the age of 30 years suffered from recurrent shoulder instability.

2.2.4.4 Pathological features

Six studies (Hoelen et al., 1990; Kralinger et al., 2002; Robinson et al., 2006; Salomonsson et al., 2010; te Slaa et al., 2003; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993) examined the effect of concomitant pathology on recurrent shoulder instability and five studies found the presence of a greater tubercle fracture decreased the risk of recurrence (Hoelen et al., 1990; Kralinger et al., 2002; Robinson et al., 2006; te Slaa et al., 2003; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993). The data showed that people with a greater tuberosity fracture were over seven times less likely to suffer from recurrent shoulder instability compared to those without a fracture (OR=0.13, 95% CI (0.06, 0.30), Z=-4.99, $p<0.0001$, $I^2=0.00$) (Figure 2.4). The presence of a bony Bankart lesion was also found to have a protective effect against recurrent shoulder instability although this was not statistically significant (OR=0.51, 95% CI (0.17, 1.52), Z=-1.2, p=0.23, $I^2=19.6$) (Figure 2.5). Three studies (Hoelen et al., 1990; Kralinger et al., 2002; Salomonsson et al., 2010) examined Hill Sachs lesions, although one low quality study (Kralinger et al., 2002) reported Hill Sachs lesions in all participants, preventing the calculation of an odds ratio. Data from the remaining two studies show that people are 1.55 times more likely to have recurrent shoulder instability in the presence of a Hill Sachs lesions compared to people who do not have a Hills Sachs lesion (OR=1.55, 95% CI (0.14, 17.63), Z=0.356, p=0.72, $I^2=61.51$) (Hoelen et al., 1990; Salomonsson et al., 2010). These results were not statistically significant and there was a large degree of variability between the studies. Two studies compared the effect of a nerve palsy on recurrent shoulder instability with no nerve palsy and data showed that people with a nerve palsy were 2.49 times less likely to suffer from recurrent instability in the presence of a nerve palsy (OR=0.40, 95% CI (0.043, 3.762), Z=-0.80, p=0.42, $I^2=45.57$) (Figure 2.6) (Pevny et al., 1998; Robinson et al., 2006).

Study name	Statistics for each study				
	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Salomonsson et al., 2009	0.164	0.007	3.586	-1.149	0.250
Robinson et al., 2006	0.194	0.024	1.560	-1.541	0.123
Pevny et al., 1998	0.771	0.034	17.319	-0.163	0.870
Krallinger et al., 2002	0.124	0.037	0.413	-3.399	0.001
Vermeiren et al., 1993	0.112	0.015	0.864	-2.100	0.036
te Slaa et al., 2003	0.124	0.007	2.162	-1.432	0.152
Hoelen et al., 1990	0.035	0.002	0.582	-2.336	0.019
	0.135	0.061	0.296	-4.992	0.000

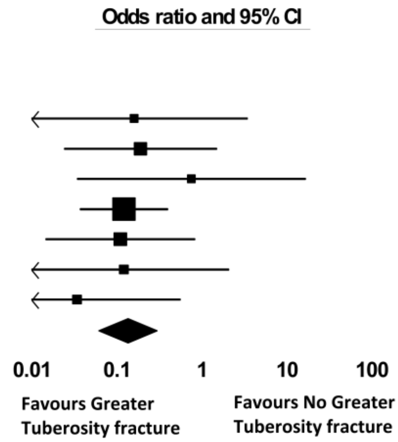

Figure 2.4 Greater tuberosity fractures as a predictor for recurrent shoulder instability after a FTASD in adults

Study name	Statistics for each study				
	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Salomonsson et al., 2009	0.163	0.034	0.792	-2.250	0.024
Veimeren et al., 1993	0.730	0.079	6.738	-0.277	0.782
Pevny et al., 1998	3.880	0.144	104.328	0.807	0.419
Hoelen et al., 1990	0.718	0.150	3.432	-0.415	0.678
	0.512	0.172	1.527	-1.201	0.230

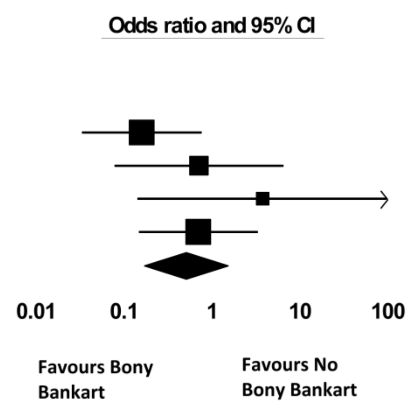

Figure 2.5 Bony Bankart lesions as a predictor for recurrent shoulder instability after a FTASD in adults

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Robinson et al., 2006	0.181	0.040	0.811	-2.233	0.026
Pevny et al., 1998	2.067	0.085	50.036	0.446	0.655
	0.401	0.043	3.762	-0.800	0.424

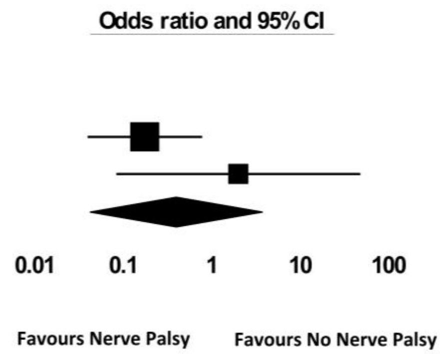

Figure 2.6 Nerve palsy as a predictor for recurrent shoulder instability after a FTASD in adults

2.2.4.5 Other risk factors for recurrent instability

Four studies examined treatment options following a FTASD (Hoelen et al., 1990; Kralinger et al., 2002; Simonet & Cofield, 1984; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993). No statistically significant difference in the rate of recurrent shoulder instability was found related to the reduction method or type of immobilisation (Simonet & Cofield, 1984) or the period of immobilisation (Hoelen et al., 1990). Two studies examined the effect of physical therapy of recurrent shoulder instability. Vermeiren et al. (1993) reported that those with recurrent instability reported an average of 15 daily sessions of intensive exercises with a physiotherapist, which was considerably less than those in the non-recurrent group (47 daily sessions). In contrast, Kralinger et al. (2002) found that the age adjusted rate of participation in physical therapy showed no association with recurrent shoulder instability. Time from the initial dislocation appeared to affect recurrent shoulder instability as most subsequent episodes occurred within two years of the initial dislocation (Robinson et al., 2006; Sachs et al., 2007; Simonet & Cofield, 1984; te Slaa et al., 2003). One high quality (Robinson et al., 2006) and one acceptable quality study (Salomonsson et al., 2010) examined hyperlaxity and the data showed that people with hyperlaxity were 2.68 times more likely to experience recurrent shoulder instability compared to those without hyperlaxity (OR=2.68, 95% CI (1.33, 5.39), Z=2.76, p=0.0057, I^2=0.00) (Figure 2.7). Occupation was a factor in recurrent instability as Sachs et al. (2007) reported that those who worked with their arms above chest height were more likely to suffer from recurrent shoulder instability (p=0.006, OR=5.762). Vermeiren et al. (1993) similarly examined occupation and reported that manual labourers had a recurrence rate of 31% compared to other professions (students, retired people and housewives 24%). Kralinger et al. (2002) reported that those who had recurrent shoulder instability had 0.44 degrees of loss of external rotation at 90 degrees of abduction compared with those without recurrence (p=0.044). Finally, Safran et al. (2010) examined the predictive ability of the apprehension test at 6 weeks following a shoulder dislocation and found that a negative test was statistically significantly related to recurrent instability (OR=4.286, 95% CI (1.129-16.266), p=0.03). However, the test was not statistically significant in predicting the length of time to dislocation.

Study name	Statistics for each study				
	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Robinson et al., 2006	2.680	1.261	5.694	2.564	0.010
Salomonsson et al., 2009	2.667	0.414	17.169	1.032	0.302
	2.678	1.332	5.385	2.764	0.006

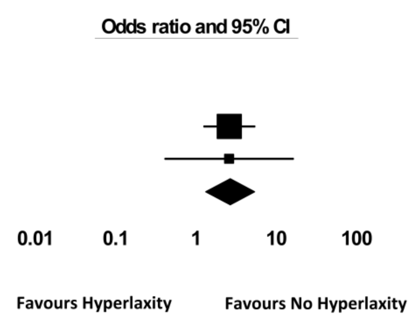

Figure 2.7 Hyperlaxity as a predictor for recurrent shoulder instability after a FTASD in adults

2.2.5 Discussion

Many studies have reported the rate of recurrent instability following a FTASD to be over 75% (Bottoni et al., 2002; Wheeler et al., 1989). Many variables influence recurrent shoulder instability such as sex, age, laxity and other pathological lesions. Across all these variables, our study showed the rate of recurrent instability one year after a FTASD was 39%.

2.2.5.1 What is the true rate of recurrence after first-time shoulder dislocation?

The rate of 39% is a great deal lower than other studies, which have compared patients treated non-surgically compared with those treated surgically (Jakobsen, Johannsen, Suder, & Søjbjerg, 2007; Wheeler et al., 1989). These clinical studies excluded a large proportion of subjects due to poor recruitment methods (e.g. only including the subjects that present for medical treatment and ignoring those that do not contact medical professionals) (Jakobsen et al., 2007; Kirkley et al., 2005; Wheeler et al., 1989). The strict inclusion and exclusion criteria necessary for rigorous RCTs can result in study populations which are not representative of the general population as only those participants with pathological lesions are entered into the trial and therefore data may be skewed in favour of surgical stabilisation. Prospective cohort studies are ideal to accurately identify risk factors for recurrent instability (Doll & Hill, 1956). These study designs do not exclude any subject who has had a FTASD and consequently provide a more complete picture of the risk factors for this population. Three other seminal papers have reported similar results in regard to rates of recurrent shoulder instability as found in this review (Hovelius et al., 2008; McLaughlin & Cavallaro, 1950; Rowe, 1956). However, one was a prospective intervention study (Hovelius et al., 2008), one included both traumatic and atraumatic dislocations (Rowe, 1956), and one did not have an adequate follow-up period (McLaughlin & Cavallaro, 1950). These studies therefore did not reach the inclusion criteria required to examine this topic and were excluded from the review.

2.2.5.2 Key risk factors – age, sex, and mechanism of injury

Men were found to have increased risk of recurrence compared with women. There may be an interaction between sex and other risk factors such as neuromuscular factors (Owens, Agel, Mountcastle, Cameron, & Nelson, 2009) or mechanism of injury. For example, men may be more likely to sustain an instability event during contact with a sporting opponent (Owens, Agel, et al., 2009). Furthermore, studies in collision sports may have a sex bias and many traditional collision sports have modified rules in the women's version (Keeler, 2007). Further examination is required to understand the effect of confounding variables such as contact sports, before alteration in clinical practice is advocated.

All studies included in this review found that age was associated with recurrent shoulder instability with people aged 40 years and under 13.46 times more likely to suffer from recurrent instability, compared with those over the age of 40 years. This may be due to differences in biomechanical properties (Lee et al., 1999), collagen fibre type (Lin, James, Spitzer, & Fabricant, 2018), elasticity of the glenohumeral joint capsule (Hovelius et al., 1983), or changes in activity level as a function of age (Rowe, 1956).

The effect of mechanism of injury was difficult to quantify as authors grouped the mechanisms differently. Some authors grouped sporting activity as a mechanism of injury when perhaps it would have been more accurate to have described the actual mechanism itself, for example imposed force from another person (Robinson et al., 2006; Sachs et al., 2007; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993). Sporting injuries may have also encompassed falls under two metres (Robinson et al., 2006), creating confusion regarding categorisation. There was a lack of statistically significant findings to show an association between participation in contact sport or early return to sport following a FTASD. It is possible that the number of people involved in contact or collision sports in this study, compared with other or no sports, prevented these results reaching significance.

2.2.5.3 Risk factors related to the injury itself

Of interest is the protective effect that some pathological variables had on recurrent shoulder instability. The presence of a greater tuberosity fracture was found to decrease the rate of recurrent instability by over seven times. Kralinger et al. (2002) postulated that this was due to decreased range of external rotation in abduction as those with a loss of external rotation in neutral had decreased risk of recurrence. An axillary nerve palsy similarly does not affect the structural integrity of the joint and this lesion was also found to decrease the risk of recurrent instability. Furthermore, both tubercle fractures and axillary nerve palsies resulted in decreased movement of the limb for a significant period of time, which may have increased the strength of the anatomical repair and limited exposure to high risk dislocation positions such as abduction/external rotation (Kralinger et al., 2002). Other authors (Baker, Uribe, & Whitman, 1990) have proposed that lesions which involve the glenoid labrum result in increased rates of recurrent instability. There was a trend towards increased risk of recurrent shoulder instability in people with a Hill Sachs lesion. Further prospective investigation is required to investigate whether the size of a Hill Sachs lesion has an impact on recurrent instability (Kralinger et al., 2002).

The finding of decreased recurrent shoulder instability in the presence of a bony Bankart was surprising. Robinson et al. (2002) followed subjects for six weeks following a FTASD and reported increased risk of recurrence in the presence of a glenoid rim fracture (Relative Risk (RR)=7.0) and in the presence of both a Hill Sachs lesion and glenoid rim fracture (RR=33.5). However, a one year follow-up of the same cohort reported no analysis related to glenoid rim fractures and the ten people who underwent surgical stabilisation as a results of a glenoid rim fracture associated with subluxation were excluded from the cohort. Similarly, Salomonsson et al. (2010) excluded people with large bony Bankart lesions who had difficulty maintaining stability following a closed reduction. Further examination of the bony Bankart size, location and interaction with Hill Sachs lesions (e.g. glenoid track) (Di Giacomo, Itoi, & Burkhart, 2014) is required in a prospective cohort study.

2.2.5.4 Study limitations

Cohort studies are required to examine risk factors as they encapsulate a representative sample of the population and allow analysis of multiple variables. However, a limitation of these types of studies is the degree of bias present. Retrospective studies are limited by historical accuracy due to recall bias, imperfect information within medical records, and loss to follow-up (Gordis, 2009). Limitations of prospective studies include a difficulty in controlling for bias and a loss to follow-up (Gordis, 2009).

Although all studies in this review were appraised for methodological quality, no subjects were excluded based upon methodological quality as per recommendations of the Cochrane review (Higgins & Green, 2011). The inclusion of lower quality studies in this meta-analysis may have affected the results of this study. However, the calculation of the heterogeneity of variables highlights the variability amongst the studies. Where the results of lower quality studies differ from higher quality studies, this has been documented. The use of the GRADE system to categorise the quality of agreement and strength of evidence across all qualities of studies, adds to the strength of this paper (Guyatt et al., 2008).

2.2.6 Clinical summary & conclusion

We report that the average rate of recurrent shoulder instability one year following a FTASD is 39% (minimum=4%, maximum=60%). People aged between 15 and 40 years of age were 13 times more likely to experience recurrent shoulder instability and men were three times more likely to than women to experience this. People with a greater tuberosity fracture were seven times less likely to experience recurrence when compared to those without a greater tuberosity fracture. People with hyperlaxity were nearly three times more likely to experience recurrent instability compared to those without hyperlaxity (Table 2.7).

Table 2.7 Summary of risk factors and relationship with recurrent instability.

Risk Factor	Rate of recurrence
Aged 15 to 40 years	13 times more likely
Men	3 times more likely
Greater tuberosity fracture	7 times less likely
Hyperlaxity	3 times more likely

The rate of recurrent shoulder instability decreased as time from the initial dislocation increased. Other factors such as a bony Bankart lesion, nerve palsy, and occupation were shown to influence rates of recurrent instability. Further evidence is required to investigate the influence of large Hill Sachs lesions, hyperlaxity and physiotherapy treatment on recurrent shoulder instability and the combined effect of these variables.

A range of variables may predict recurrent instability following a FTASD. Further research is required to establish a valid and reliable predictive tool weighted according to the strength of evidence of each variable. This tool could then be used by health care professionals to predict risk rates for groups of people depending on their profile.

It would be premature to conclude that those people who are at increased risk of recurrent shoulder instability are necessarily good candidates for surgical intervention, given the presence of confounders such as hypermobility in this group. The next step is to develop a predictive algorithm as outlined above. If the algorithm proves useful, it may then be time for an RCT of surgery and conservative management in those who are deemed at high risk of recurrence. In complex clinical scenarios such as after first-time shoulder dislocation, shared decision making with appropriate patient decision-making aids, must be part of patient management (Hoffmann, Montori, & Del Mar, 2014).

Competing Interest: none of the authors have any competing interests

Chapter 3 **Risk factors for recurrent shoulder instability after a FTASD in children aged 18 years and under: A systematic review and meta-analysis of risk factors**

3.1 Preface

This chapter relates to Aim 1 of the thesis: to identify risk factors which predispose those with a FTASD to further episodes of shoulder instability by undertaking a systematic review of the literature (see 1.7).

Following on from the systematic review and meta-analysis in adults, a systematic review and meta-analysis was undertaken of prospective cohort studies which examined the risk factors which predisposed children under the age of 18 years with a FTASD to recurrent shoulder instability. Across many studies, age is a significant risk factor for predicting recurrent shoulder instability (see 2.2.4.1). Furthermore, rates of recurrent shoulder instability differ significantly between children, adolescents and adults. Some authors have proposed that this may be due to differences in skeletal anatomy, skeletal maturity, or tissue biomechanics. Examples of these include the open humeral physis in the growing child and labral disruption with a dislocation in children compared with capsular disruption in the adult (Cordischi et al., 2009; Deitch, Mehlman, Foad, Obbehat, & Mallory, 2003; Lee et al., 1999; Reeves, 1968). Shoulder activity levels also changes as people age and may influence the rate of recurrent shoulder instability (Hepper, Smith, Steger-May, & Brophy, 2013; Rowe, 1956). Knowledge of these predisposing risk factors specific to children and adolescents necessitated further analysis of this subset of the population with a FTASD. Therefore, this chapter reports the risk factors for recurrent shoulder instability in children aged 18 years and under, including details of the systematic review and meta-analysis. The contents of this chapter has been written as a formal manuscript which was published in the *British Journal of Sports Medicine* in December 2016 following peer review (Olds, Donaldson, Ellis, & Kersten, 2016) and the Version of Record can be accessed online at http://dx.doi.org/10.1136/bjsports-2015-095149. Some editorial changes have been made to the published article, in accordance with presenting this formal thesis. Literature published following acceptance of this manuscript will be included in the discussion (Chapter 9).

3.2 In children 18 years and under, what promotes recurrent shoulder instability after traumatic anterior shoulder dislocation? A systematic review and meta-analysis of risk factors.

Olds, M., Donaldson, K., Ellis, R., & Kersten. (2016). In children 18 years and under, what promotes recurrent shoulder instability after traumatic anterior shoulder dislocation? A systematic review and meta-analysis of risk factors. *British Journal of Sports Medicine, 50*(18), 1135-1141. http://dx.doi.org/10.1136/bjsports-2015-095149

3.2.1 Abstract

4.2.1.1 *Background*

Skeletal maturity and age-related changes in the composition of the glenoid labrum and joint capsule may influence rates of recurrent shoulder instability in children. We systematically reviewed risk factors which predispose children to recurrent shoulder instability following a first-time traumatic anterior shoulder dislocation (FTASD).

3.2.1.1 Methods

The systematic review concerned studies published before May 2015. Statistical analysis was undertaken to compare rates of recurrence for each extracted risk factor. Pooled odds ratios were analysed using random effects meta-analysis.

3.2.1.2 Results

Six retrospective cohort studies met the inclusion criteria. Eight risk factors were identified across the studies including age, sex, shoulder dominance and injury side, mechanism of injury, state of physis closure, and Hill Sachs and Bankart lesions. The rate of recurrent instability was 73%. Children aged 14 to 18 years were 24 times more likely to experience recurrent instability than children aged 13 years and

less (93% versus 40%) (OR=24.14, 95% CI (3.71, 156.99), Z=3.33, p=0.001, I^2=6.83%). There was a non-significant trend indicating males were 3.4 times more likely to experience recurrent instability, (OR=3.44, 95% CI (0.98, 12.06), Z=1.93, p=0.053, I^2=0%). Analysis of one study found that children with a closed physis were 14 times more likely to experience recurrent instability compared to those with an open physis (OR=14.0, 95% CI (1.46, 134.25), Z=2.29, p=0.02, I^2=0%).

3.2.1.3 Conclusion

Male children aged between 14 and 18 years had the greatest risk of recurrent shoulder instability following a FTASD. This meta-analysis summarised a mix of six acceptable and low quality Level III retrospective cohort studies. Further examination of this population with blinded prospective cohort studies will assist clinicians in the appropriate management of FTASD.

3.2.2 Introduction

Many studies which examine recurrent shoulder instability following a first-time traumatic anterior shoulder dislocation (FTASD) do not differentiate skeletally immature children from adult populations, despite the presence of unique pathoanatomical entities such as open physes (Cordischi et al., 2009) which can be present until 18 years of age (Postacchini et al., 2000). Rates of recurrent shoulder instability following a FTASD have been reported to be as high as 100% in the skeletally immature (Marans et al., 1992) and 96% in adolescents (Deitch et al., 2003). Further analysis of the specific risk factors which predispose this subgroup of the population to recurrent shoulder instability following a FTASD is warranted.

Factors reported to influence the high rates of recurrent shoulder instability following a dislocation in children include anatomical age-related variances of the shoulder joint, such as a more lateral insertion of the joint capsule on the glenoid (Matsen, Lippitt, Bertlesen, Rockwood, & Wirth, 2009), and a higher composition of type three collagen fibres (J. Walton et al., 2002). Other proposed factors relating to recurrent shoulder instability in both adults and children include the severity of initial injury, presence of a labral Bankart lesion, lack of rehabilitation compliance and premature return to high-level activity (Cil & Kocher, 2010; Lee et al., 1999). While several systematic reviews have investigated the effects of surgical intervention on shoulder instability (Cil & Kocher, 2010; Godin & Sekiya, 2010; Grument, Bach, & Provencher, 2010; Hobby, Griffin, Dunbar, & Boileau, 2007; Lenters, Franta, Wolf, Leopold, & Matsen, 2007), none have identified the risk factors of recurrent shoulder instability in a non-operative, skeletally immature population.

The aim of this systematic review was to identify the risk factors associated with recurrent shoulder instability following a FTASD in children aged 18 years and under. For the purposes of this systematic review, a recurrent shoulder instability event was defined as either a subluxation or dislocation.

3.2.3 Methods

The development of this systematic review was carried out in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol (Moher, Liberati, Tetzlaff, & Altman, 2009) and was registered with the PROSPERO database which can be accessed at http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42013005900#.Uyj7BKiSySo. A systematic review and meta-analysis was conducted of the available literature in November 2014 and updated in May 2015 using the following databases; MEDLINE, CINAHL, SPORTDiscus, Scopus, Web of Science, Biomedical Reference Collection, Health and Psychosocial Instruments, AMED, ERIC and Proquest Health and Medical. Five key concepts were used in determining the keywords used in the database search (Table 3.1). Where keywords returned greater than 100,000 titles, the keywords which referred to the shoulder (i.e. ‘shoulder’, ‘glenohumeral’ and ‘GHJ’) were contained to search within the ‘title’ field only. Screening of the literature was initially done by title and abstract followed by a screening of the full text. The reference lists from the included articles were then analysed to identify any additional articles (Figure 3.1). Literature not published in English was sent to an external source for translating. Two authors (KD & MO) reviewed potential articles and a consensus was reached regarding included and excluded articles. Inclusion and exclusion criteria for articles are listed in Table 3.2.

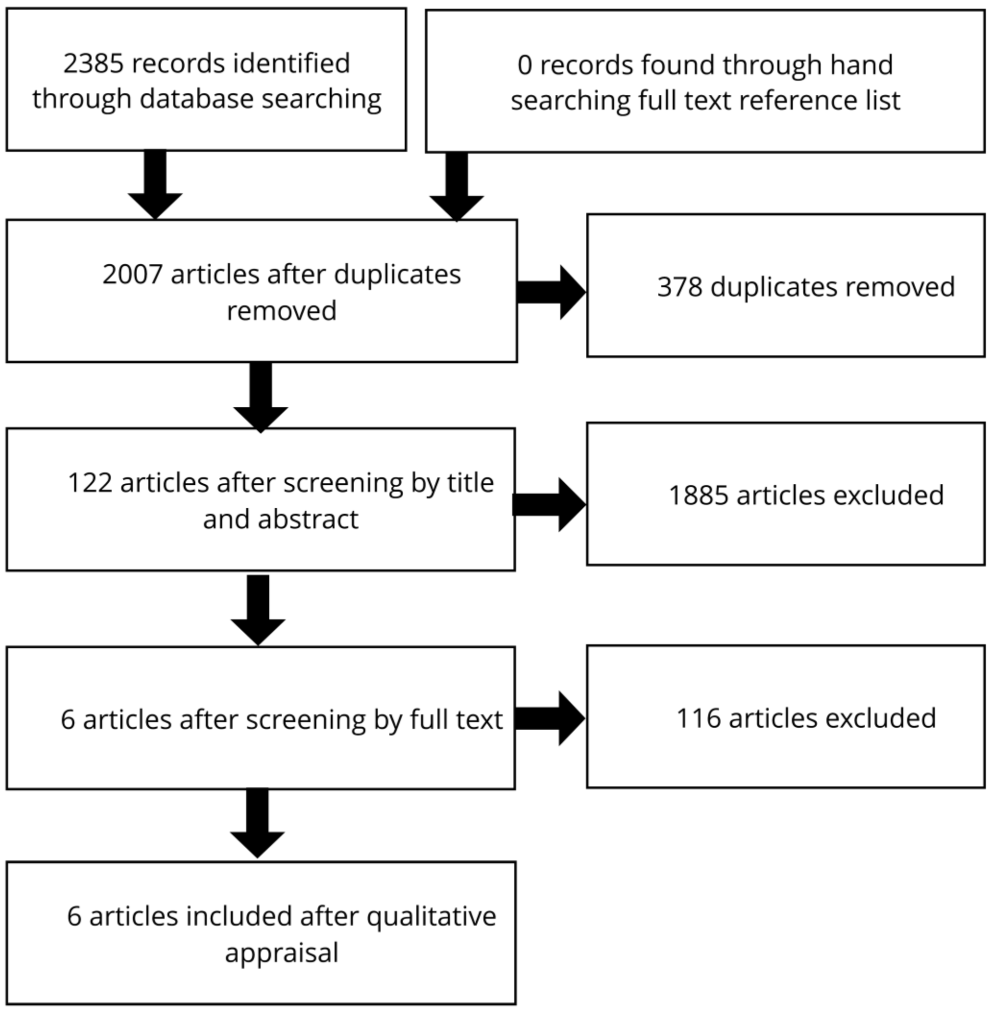

Figure 3.1 Flow diagram of article selection according to PRISMA

Table 3.1 Search strategy keywords

Concept	Keywords used in search strategy
Shoulder	Shoulder* OR glenohumeral* OR GHJ*
Dislocation and instability	Instabilit* OR unstable OR subluxat* OR stabil* OR stabl* OR luxat* OR disarticulat* OR detach* OR disassociat* disengage* OR sublux* OR dislocat*
Recurrent	Recurr* OR repeat* OR repetit* OR intermit* OR frequen*
Children (0-18 years old)	Child* OR adolescen* OR youth* OR juvenil* OR teen* OR student* OR pubescen* OR pubert*
Risk	Risk* OR factor* OR prevalen* OR predict* OR incidence* OR “odds ratio” OR “relative risk”

Table 3.2 Study inclusion and exclusion criteria

Inclusion criteria
1. Participants 18 years of age or less
2. Participants had a first-time traumatic anterior shoulder dislocation or subluxation confirmed by radiographic or clinical testing(Dumont, Russell, & Robertson, 2011; Lo, Nonweiler, Woolfrey, Litchfield, & Kirkley, 2004; Murray et al., 2013)
3. Case control, prospective or retrospective cohorts study designs
4. Recurrence of glenohumeral instability was used as an outcome
5. Studies had a follow-up of one year or more - Studies have shown that the majority of anterior instability events following a first-time traumatic dislocation occur within a year(Kazár & Relovszky, 1969; Kiviluoto, Pasila, Jaroma, & Sundholm, 1980b; Marans, Angel, Schemitsch, & Wedgl, 1992b; Postacchini et al., 2000)
6. Studies were published before May, 2015
Exclusion criteria
1. Studies which reported multi-directional or posterior shoulder instability
2. Studies which reported participants with atraumatic shoulder instability
3. Studies available in abstract only
4. Chapters from a book
5. Grey literature
6. Studies investigating risk factors of instability following surgical intervention or when comparing alternative surgical interventions

The methodological quality of the articles was evaluated using the Scottish Intercollegiate Guidelines Network (SIGN) checklist (Scottish Intercollegiate Guidelines Network, 2004). While other tools are available for assessing the methodological quality of observational studies, the SIGN checklist is reported to be the most appropriate and valid tool (Perestelo-Perez, 2013). This assessment tool for cohort study designs covers areas of subject selection, assessment, confounding factors, statistical analysis and overall assessment of the study. The overall methodological quality of each article was graded as being either high quality (++) (addressed 7 or more of the nine SIGN quality appraisal questions), acceptable (+) (addressed 5-6 of the nine SIGN quality appraisal questions) or low quality (-) (addressed 4 or less of the nine SIGN quality appraisal questions) (Scottish Intercollegiate Guidelines Network, 2004). Methodological quality appraisal was carried out independently by two authors (MO and KD). If a consensus on methodological quality could not be made, a separate independent author (PK) was used to arbitrate to reach an agreement on the methodological quality results as recommended by the SIGN50 handbook (Scottish Intercollegiate Guidelines Network, 2004).

Data pertaining to the recurrence rates of shoulder instability was extracted from the included references. These data were pooled to provide an overall instability recurrence rate specific to each risk factor/exposure. Where there was sufficient data to calculate an odds ratio, statistical analyses were performed using the Comprehensive Meta-Analysis programme (Version 2.2.064) (Borenstein et al., 2005). Statistical significance was set at 0.05. Statistical heterogeneity between studies was assessed using I^2. I^2 is a measure of the heterogeneity of the data, where a value of 0% represents no heterogeneity while values above 75% indicate that high heterogeneity exists (Higgins et al., 2003).

3.2.4 Results

3.2.4.1 General study characteristics/demographics

A total of 2,385 abstracts were identified following an initial database search, of which 122 articles were potentially suitable after title and abstract screening (Figure 3.1). Six articles met the criteria for inclusion and exclusion following a full text screen (Table 3.3). These studies reported on a total of 137 participants, with an age from 4 to 18 years (Table 3.3). The mean follow-up period was 8.8 years (s.d. 4.86). The minimum follow-up period was 1 year.

The methodological quality of four articles was rated as acceptable (+) and two articles were low quality (-) (Table 3.3). All articles followed a retrospective cohort study design which prevented completion of analysis related to selection or attrition bias. Furthermore, all articles failed to mention or attempted blinding of the assessment of recurrent instability from the exposure status. Finally, the two papers deemed low quality (Marans et al., 1992; Wagner & Lyne, 1983), either poorly addressed or did not address the definition of the primary outcome measure of recurrent instability (SIGN Q1.7).

Eight common risk factors for recurrent shoulder instability following a FTASD in children 18 years or younger were identified in the six included articles. These included: age, sex, mechanism of initial injury, state of physis closure, shoulder dominance and side of the affected shoulder, Hill Sachs lesion and Bankart lesion.

Table 3.3 Article Summaries

Author	Number of participants	Participants age range (years)	Follow-up period (years)	Risk factors/exposure	Outcome measures	SIGN ratings
Cordischi et al. (2009)	14	10.9-13.1	2-4	Age, Sex, Shoulder dominance, Open physis, Greater tuberosity fracture, HAGL*** lesion	Recurrence rate, WOSI****	**+**
Deitch et al. (2003)	32	11-18	1-14	Age, Sex, Mechanism of injury, Open/close physis	Recurrence rate	**+**
Lampert et al. (2003)	40*	4-18	1	Age; <14 years and ≥14 years	Recurrence rate	**+**
Marans et al. (1992)	20*	4-16	2-13.8	Age, Sex, Mechanism of injury, Shoulder dominance, Open/Closed physis, Immobilisation/No immobilisation	Recurrence rate	**-**
Postacchini et al. (2000)	21*	12-17	5.5-8.9	Age, Sex, Hill Sachs lesion, Bankart lesion	Recurrence rate	**+**
Wagner & Lyne (1983)	10**	12-16	2.2-11.3	Age, Sex, Mechanism of injury, Open physis	Recurrence rate	**-**

**Note.* Numbers relate to participants of the study that were applicable to this systematic review.

***Note.* 9 participants in study, 10 shoulders dislocated

*** Humeral Avulsion of Glenohumeral Ligament

****Western Ontario Shoulder Instability Index

3.2.4.2 Age

All six studies reported an association between age and recurrent shoulder instability (Table 3.4) (Cordischi et al., 2009; Deitch et al., 2003; Lampert et al., 2003; Marans et al., 1992; Postacchini et al., 2000; Wagner & Lyne, 1983). Pooled data revealed that 92.9% (79/85) of children aged 14 years and older experienced an instability event following a FTASD and 40.4% (21/52) of children aged 13 years and younger experienced recurrent instability (Table 3.4). A meta-analysis revealed that children aged 14 to 18 years were 24.14 times more likely to experience recurrent instability compared with those aged 13 years and under (OR=24.14, 95% CI (3.71, 156.99), Z=3.33, p=0.001, I^2=6.83%) (Figure 3.2). This odds ratio is heavily influenced by the one study of Lampert et al. (2003), which reported a large number of recurrent instability episodes in children aged over 14 years (27/28) compared with no episodes of recurrence in children aged under 14 years (0/12). The large confidence interval was due to small numbers in the study by Wagner et al. (1983) (Figure 3.2).

Study name	Statistics for each study				
	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Deitch et al., 2003	11.000	1.483	81.606	2.345	0.019
Postachini et al., 2000	34.000	1.479	781.787	2.204	0.027
Wagner et al., 1983	3.182	0.115	87.919	0.684	0.494
Lampert et al., 2003	458.333	17.425	12055.670	3.673	0.000
	24.136	3.711	156.993	3.332	0.001

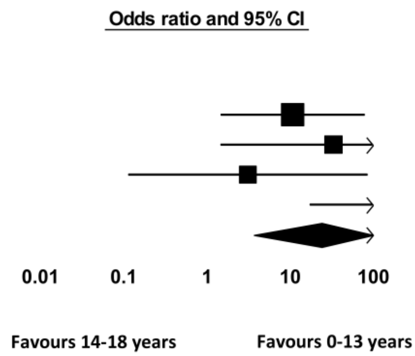

Figure 3.2 Recurrent shoulder instability following a FTASD in children aged 14-18 years compared with those aged 0-13 years

3.2.4.3 Sex

Five articles reported the association between sex and recurrent shoulder instability (Cordischi et al., 2009; Deitch et al., 2003; Marans et al., 1992; Postacchini et al., 2000; Wagner & Lyne, 1983). Pooled data revealed that 83.4% (57/66) of males had at least one recurrent episode of shoulder instability while 51.6% (16/31) of females experienced a recurrent instability event following a FTASD (Table 3.5). Analysis showed that male children were 3.44 times more likely to experience recurrent instability when compared to female children. While this result was not statistically significant, it was homogenous (i.e. all studies reported a similar result) (Higgins et al., 2003) (OR=3.44, 95% CI (0.98, 12.06), Z=1.93, p=0.053, I^2=0%) (Figure 3.3).

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
	Statistics for each study				
Cordischi et al.,	5.000	0.212	117.894	0.998	0.318
Deitch et al., 2003	3.000	0.501	17.954	1.203	0.229
Postachini et al., 2000	4.000	0.240	66.758	0.965	0.334
Wagner et al., 1983	3.000	0.122	73.642	0.673	0.501
	3.442	0.983	12.057	1.933	0.053

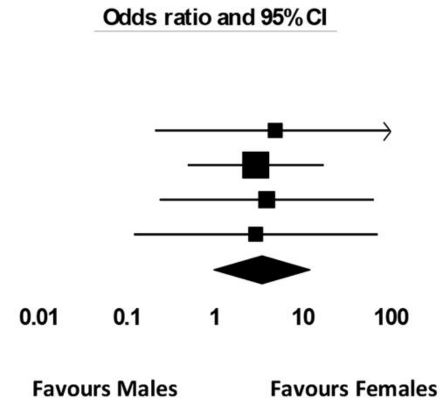

Figure 3.3 Recurrent shoulder instability following a FTASD in male children compared with female children

3.2.4.4 Mechanism of primary shoulder dislocation

The mechanism of injury for FTASD was typically divided into two groups; sporting and non-sporting related. Three articles provided results on instability recurrence rates with regards to sporting and non-sporting injuries as an initial mechanism of injury (Deitch et al., 2003; Marans et al., 1992; Wagner & Lyne, 1983). Pooled data showed that 89.2% (33/37) of participants whose primary mechanism of injury was sporting related had a recurrent instability event while 76% (19/25) of the non-sporting related group experienced recurrent instability (Table 3.6). In cases where the mechanism of injury was sporting activity, children were 2.85 times more likely to experience recurrence, compared to when the mechanism of injury was not during sporting activity. This result was not statistically significant but was homogeneous (Higgins et al., 2003) (OR=2.85, 95% CI (0.64, 12.62), Z=1.38, p=0.17, I^2=0%).

Table 3.4 Recurrent shoulder instability in children aged under 14 years, compared with those aged 14 -18 years

Age	**Cordischi et al. (2009)**		**Deitch et al. (2003)**		**Lampert et al. (2003)**		**Marans et al. (1992)**		**Postachinni et al. (2000)**		**Wagner & Lyne (1983)**		**Total**	
	Rec*	Non*	Rec	Non	Rec	Non	Rec	Non	Rec	Non	Rec	Non	Rec	Non
<14 years	3/14	11/14	2/ 6	4/6	0/12	12/12	10/10	0/ 10	1/ 3	2/ 3	5/ 7	2/ 7	40.4% (21/52)	59.6% (31/52)
≥14 years			22/26	4/26	27/28	1/28	10/10	0/ 10	17/ 18	1/ 18	3/ 3	0/ 3	92.9% (79/85)	7.1% (6/85)
Total	3/14	11/14	24/32	8/ 32	27/ 40	13/40	20/20	0/ 20	18/21	3/ 21	8/ 10	2/ 10	73.0% (100/137)	27% (37/137)

*Note. Rec = recurrent shoulder instability; Non = no shoulder instability.

Results indicate number of children with recurrent instability of a total number of children in the study

Table 3.5 Sex of children aged 18 years and under as a predictor for recurrent shoulder instability after a FTASD

Sex	**Cordischi et al. (2009)**		**Deitch et al. (2003)**		**Marans et al. (1992)**		**Postachinni et al. (2000)**		**Wagner & Lyne (1983)**		**Total**		**Percentage**	
	Rec*	Non*	Rec	Non	Rec	Non	Rec	Non	Rec	Non	Rec	Non	Rec	Non
Male	1/2	1/2	20/25	5/25	14/14	0/14	16/18	2/18	6/7	1/7	57/66	9/66	83.4%	13.6%
Female	2/12	10/12	4/7	3/7	6/6	0/6	2/3	1/3	2/3	1/3	16/31	15/31	51.6%	48.4%
Total	3/14	11/14	24/32	8/32	20/20	0/20	18/21	3/21	8/10	2/10	73/97	24/97		

*Note. Rec = recurrent shoulder instability; Non = no shoulder instability.

Results indicate number of children with recurrent instability of a total number of children in the study

Table 3.6 Sporting vs. non-sporting mechanism of injury in children aged 18 years and under as a predictor for recurrent shoulder instability after a FTASD

	Deitch et al. (2003)		**Marans et al. (1992)**		**Wagner & Lyne (1983)**		**Total**		**Percentage**	
	Rec*	Non*	Rec	Non	Rec	Non	Rec	Non	Rec	Non
Sporting	14/17	3/17	12/12	0/12	7/8	1/8	33/37	4/37	89.2%	10.8%
Non-sport	10/15	5/15	8/8	0/8	1/2	1/2	19/25	6/25	76%	24%
Total	24/32	8/32	20/20	20/20	8/10	2/10	52/62	10/62	83.9%	16.1%

*Note. Rec = recurrent shoulder instability; Non = no shoulder instability.

Results indicate number of children with recurrent instability of a total number of children in the study

3.2.4.5 Open/closed proximal humeral physis

Four articles provided information on the state (open or closed) of the proximal humeral physis of the affected shoulder at the time of primary anterior shoulder dislocation (Cordischi et al., 2009; Deitch et al., 2003; Marans et al., 1992; Wagner & Lyne, 1983). Pooled data revealed that 61.1% (39/59) of subjects with an open proximal humeral physis at the time of the initial dislocation, had a recurrent episode of shoulder instability, compared with 94.1% (16/17) of participants with a radiographically confirmed closed proximal humeral physis (Table 3.7). One study (Deitch et al., 2003) of the four identified, compared open and closed physes. Further analysis of this study indicated children with a closed physis were 14 times more likely to experience recurrent instability compared to those with an open physis (OR=14.0, 95% CI (1.46, 134.25), Z=2.29, p=0.02, I^2=0%). Again, the large variation in confidence intervals reflects the small subject numbers in these studies.

Table 3.7 Open/closed physis at time of injury in children aged 18 years and under as a predictor for recurrent instability after a FTASD

	Cordischi et al. (2009)		**Deitch et al. (2003)**		**Marans et al. (1992)**		**Wagner & Lyne (1983)**		**Total**		**Percentage**	
	Rec*	Non*	Rec	Non	Rec	Non	Rec	Non	Rec	Non	Rec	Non
Open	3/14	11/14	8/15	7/15	20/20	0/20	8/10	2/10	39/59	20/59	66.1%	33.9%
Closed			16/17	1/17					16/17	1/17	94.1%	5.9%
Total	3/14	11/14	24/32	8/32	20/20	0/20	8/10	2/10	55/76	21/76	72.4%	27.6%

*Note. Rec = recurrent shoulder instability; Non = no shoulder instability.

Results indicate number of children with recurrent instability of a total number of children in the study

3.2.4.6 Shoulder dominance

Two of the six eligible articles presented information regarding the side-dominance of the shoulder that was initially dislocated (Cordischi et al., 2009; Marans et al., 1992). Pooled data illustrated that 83.3% (15/18) of participants whose initial dislocation was on their dominant shoulder experienced recurrent shoulder instability. Of those participants who initially dislocated their non-dominant side, 50% (8/16) experienced a recurrent episode of instability (Table 3.8). Calculation of an odds ratio was possible in one study (Cordischi et al., 2009) indicating children who have a FTASD in their dominant shoulder were 65% less likely to experience recurrence (OR=0.35, 95%CI (0.01, 8.63), Z=-065, p=0.52, I^2=0%).

Table 3.8 Dominance of dislocated shoulder and recurrent shoulder instability in children aged 18 years and under

	Cordischi et al. (2009)		**Marans et al. (1992)**		**Total**		**Percentage**	
	Rec*	Non*	Rec	Non	Rec	Non	Rec	Non
Dominant	0/3	3/3	15/15	0/15	15/18	3/18	83.3%	16.7%
Non-dominant	3/11	8/11	5/5	0/5	8/16	8/16	50.0%	50.0%
Total	3/14	11/14	20/20	0/20	23/34	11/34	67.6%	32.4%

*Note. Rec = recurrent shoulder instability; Non = no shoulder instability.

Results indicate number of children with recurrent instability of a total number of children in the study

3.2.4.7 Side of shoulder that was initially dislocated

Three of the six included articles did not report arm dominance but presented information on the side of the shoulder that was initially dislocated (Cordischi et al., 2009; Postacchini et al., 2000; Wagner & Lyne, 1983). Pooled data showed that 66.7% (14/21) of participants with right shoulder dislocations and 62.5% (15/24) of participants with left shoulder dislocations experienced recurrent instability (Table

3.9). The data show that children who experienced a FTASD on the right side were 61% less likely to experience recurrent instability. The result was not statistically significant but was homogeneous (Higgins et al., 2003) (OR=0.39, 95%CI (0.065, 2.42), Z=-1.00, p=0.31, I^2=0%).

Table 3.9 Side of shoulder initially dislocation as a predictor for recurrent shoulder instability after a FTASD in children aged 18 years and under

	Cordischi et al. (2009)		**Postachinni et al. (2000)**		**Wagner & Lyne (1983)**		**Total**		**Percentage**	
	Rec*	Non*	Rec	Non	Rec	Non	Rec	Non	Rec	Non
Right	0/3	3/3	10/13	3/13	4/5	1/5	14/21	7/21	66.7%	33.3%
Left	3/11	8/11	8/8	0/8	4/5	1/5	15/24	9/24	62.5%	37.5%
Total	3/14	11/14	18/21	3/21	8/10	2/10	29/45	16/45	64.4%	35.6%

*Note. Rec = recurrent shoulder instability; Non = no shoulder instability.

Results indicate number of children with recurrent instability of a total number of children in the study

3.2.4.8 Hill Sachs lesion

Radiographic evidence (X-Rays and magnetic resonance imaging (MRI)) of the presence of a Hill Sachs lesion was reported by two studies (Postacchini et al., 2000; Wagner & Lyne, 1983). Combined data from the two articles illustrated that 100% (13/13) of participants who had radiographic evidence of a Hill Sachs lesion on their affected shoulder experienced a recurrent instability event. For participants who had no evidence of a Hill Sachs lesion, 72% (13/18) had a recurrent instability episode (Table 3.10). Odds ratio calculations were possible using the data of Postacchini et al. (2000) indicating that people aged under 18 years with Hill Sachs lesions were 17.18 times more likely to experience recurrent instability compared to those without a Hill Sachs lesion (OR=17.18, 95% CI (0.76, 390.92), Z=1.78, p= 0.07, I^2=0%).

Table 3.10 Hill-Sachs lesions as a predictor for recurrent shoulder instability after a FTASD in children aged 18 years and under

	Postachinni et al. (2000)		**Wagner & Lyne (1983)**		**Total**		**Percentage**	
	Rec*	Non*	Rec	Non	Rec	Non	Rec	Non
HSL#	13/13	0/13			13/13	0/13	100%	0%
No HSL#	5/8	3/8	8/10	2/10	13/18	5/18	72.2%	27.8%
Total	18/21	3/21	8/10	2/10	26/31	5/31	83.9%	16.1%

*Note. Rec = recurrent shoulder instability; Non = no shoulder instability.

Results indicate number of children with recurrent instability of a total number of children in the study

#HSL = Hill Sachs lesion

3.2.4.9 Labral Bankart lesions

Two studies reported the presence of a labral Bankart lesion (Cordischi et al., 2009; Postacchini et al., 2000). Cordischi et al. (2009) reported that no participants (0/14) had evidence of a discrete labral tear as determined by either MRI or MRA evaluation. Postacchini et al. (2000) evaluated 12 of the 18 people who had experienced recurrent shoulder instability for the presence of a labral Bankart lesion. All twelve participants had evidence of a labral Bankart lesion (Table 3.11). Odds ratio calculations were not possible with this data as neither paper made comparisons between children with and without a labral Bankart lesion.

Table 3.11 Labral Bankart lesions as a predictor for recurrent shoulder instability after a FTASD in children aged 18 years and under

	Cordischi et al. (2009)		**Postachinni et al. 2000**		**Total**		**Percentage**	
	Rec*	Non*	Rec	Non	Rec	Non	Rec	Non
Bankart			12/12	0/12	12/12	0/12	100%	0%
No lesion	3/14	11/14			3/14	11/14	21.4%	78.6%

*Note. Rec = recurrent shoulder instability; Non = no shoulder instability.

Results indicate number of children with recurrent instability of a total number of children in the study

3.2.5 Discussion

Across the included studies, age has been identified as the primary prognostic factor for recurrent shoulder instability (Hoelen et al., 1990; Kralinger et al., 2002; Simonet, Melton, Cofield, & Ilstrup, 1984; te Slaa et al., 2003; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993). The majority of studies appeared to group the paediatric populations as one cohort thus making it difficult to distinguish those who were skeletally immature. Some studies (Deitch et al., 2003; Postacchini et al., 2000) have suggested that the 13 and under age group have lower rates of shoulder instability following a FTASD than children 14 years and older. This review supported these findings and found the 14 to 18 year age group were 24.14 times more likely to experience recurrent instability than the 13 and under year age group. There are many reasons why this may occur including a more lateral glenohumeral joint capsule insertion at a younger age (Rockwood, Matsen, Lipitt, & Wirth, 2009), greater joint capsule elasticity in children younger than 13 years (Walton et al., 2002), healing potential, capsular versus labral lesions (Reeves, 1969) and level of activity (Rowe, 1956). It is beyond the scope of this review to hypothesise further regarding the presence of increased recurrence in the younger age group.

The state of closure of the proximal humeral physis may relate to the lower recurrence rates found in younger children. Some authors have shown rates of recurrent shoulder instability to be as high as 100% in children with an open proximal humeral physis (Marans et al., 1992; Rowe, 1956; Rowe & Sakellarides, 1961). In contrast, the results of this systematic review revealed a 66.1% recurrence rate in children with an open physis and 91.4% rate in the closed humeral physis group. However, data presented in this systematic review must be interpreted carefully as there were significantly more subjects within the closed physis group (n=59) compared to the open physis group (n=17). In addition, rates of recurrence in people aged between 15 and 40 have been reported to be 44% (Olds et al., 2015) and therefore the presence of variables other than a closed physis must be considered.

A person’s sex has also been proposed to be an important recurrent instability; however, there is discrepancy in the literature. Robinson et al. (2006) used a Cox regression model to predict sex-specific risk factors for recurrent shoulder instability and found males to be at higher risk in all reported ages (15-35 years). Data from Owens et al. (2009) supported these results and found significantly higher shoulder instability rates in males. However, some studies have suggested that sex has no significant effect on recurrent shoulder instability (Deitch et al., 2003; Hoelen et al., 1990; Hovelius et al., 1996; Simonet et al., 1984). This meta-analysis showed an association (p=0.053) between sex and risk of glenohumeral instability with males 3.44 times more likely to experience recurrent shoulder instability.

There is controversy in the literature regarding sporting related dislocations and recurrence rates. Simonet et al. (1984) found that 82% of people of all ages who initially dislocated their shoulder during athletic activity experienced recurrent shoulder instability, which was significantly higher than the non-athletic dislocation cohort (30%) (p=0.001). Sachs et al. (2007) reported that people of all ages with sporting related shoulder dislocations were more prone to recurrent instability; however this trend did not reach a level of significance in the current study. In contrast, Kralinger et al. (2002) and Hovelius et al. (1987) concluded that sporting related dislocations in people of all ages were not associated with recurrent instability. This systematic review found an 89.2% recurrence rate in sporting related dislocations and 76% recurrence rate in the non-sporting group. However, these results were not significantly different (p=0.17).

While the relationship between shoulder dominance and instability recurrence has been mentioned in several studies, there appears to be no relationship (Cordischi et al., 2009; Hoelen et al., 1990; Marans et al., 1992; te Slaa et al., 2004). te Slaa et al. (2004) and Hoelen et al. (1990) found no differences in recurrence rates for people of all ages following a FTASD between dominant and non-dominant shoulders. Cordischi et al. (2009), Postachinni et al. (2000) and Wagner & Lyne (1983) also compared recurrence rates between left and right shoulders in children aged 18 years and under and found no significant difference. These results support the findings of this systematic review. Recurrence rates were similar between left and right shoulders, 62.5% and 66.7% respectively. The rates between dominant and non-dominant shoulders were 83.3% and 50% respectively, however, only two articles assessed the relationship between shoulder dominance and recurrent shoulder instability (Cordischi et al., 2009; Marans et al., 1992).

Our study was limited by the number of studies which reported pathological lesions. Only two studies (Postacchini et al., 2000; Wagner & Lyne, 1983) reported the presence of a Hill Sachs lesions following a FTASD. Postacchini et al. (2000) reported that all children had a Hill Sachs lesion and 100% rate of recurrence in these children, Wagner and Lyne (1983) found no Hill Sachs lesions in the nine children who underwent radiological investigations. Adults with Hill Sachs lesions were 1.55 times more likely to have recurrent instability following a FTASD, although this finding was non-significant (p>0.05) with moderate heterogeneity (Olds et al., 2015). Further investigations are required into the presence of Hill Sachs lesions and rates of recurrent instability in children following a FTASD. With regards to a labral Bankart lesion, this systematic review found a 100% rate of recurrent instability in children with a labral Bankart lesion based from one study of acceptable quality which reported labral Bankart lesions in all participants (Postacchini et al., 2000). Conversely, Cordischi et al. (2009) reported no labral Bankart lesions were evident on MRI or MRA. Further evidence from prospective studies which use investigations which have high rates of sensitivity and specificity for detecting labral Bankart lesions (such as MRA (Chauvin et al., 2013)) is required to establish the association between labral Bankart lesions and risk of recurrent instability in children aged 18 years and under.

There are some limitations to the findings of this systematic review. The methodological quality of the eligible studies was limited as all were Level III evidence (retrospective cohort studies). There was no mention in any of the six studies on whether the assessment of the outcome was made blind to the exposure status. Consequently, all articles received ‘low quality’ ratings due to increased risk of bias (Cordischi et al., 2009; Deitch et al., 2003; Lampert et al., 2003; Marans et al., 1992; Postacchini et al., 2000; Wagner & Lyne, 1983). A noticeable strength of this systematic review was the homogeneity of participants in the six included studies. All the participants were recruited from hospitals, aged eighteen years and under, had radiographic evidence of anterior shoulder dislocation, and were followed for a minimum of one year. Furthermore, the risk factors/exposures described in the studies were similar throughout, meaning that common risk factors could be clearly identified. However, the effect sizes of the identified risk factors in this systematic review may have been influenced by confounding variables (such as sample size and participant recruitment) reported across the included studies.

3.2.6 Conclusion

This systematic review was carried out to determine the risk factors associated with recurrent shoulder instability in children aged 18 years and under with a diagnosis of a FTASD. The common risk factors identified in the six included articles were age at time of initial dislocation, sex, mechanism of initial injury, side and dominance of injured shoulder, state of the proximal humeral physis, and the presence of labral Bankart and/or Hill Sachs lesions. As with other studies, age and sex appeared to be the most significant predictors of recurrent shoulder instability. Male children aged between 14 and 18 years appeared to be at the greatest risk of recurrent shoulder instability. This evidence is based on studies deemed acceptable and poor Level III evidence, and the strength of evidence in this paper is Level II evidence. Recommendations for future research include carrying out blinded, prospective cohort studies with larger sample sizes in people aged 18 years and under in order to provide higher quality research, thus strengthening the evidence base for predicting recurrent instability.

3.2.6.1 Implications

As evident following this meta-analysis, rates of recurrent instability were high in a population of children aged between 14 and 18 years. This is a topic worthy of further investigation. The decision to approach the topic of recurrent shoulder instability after a FTASD by means of a national cohort study, with the assistance of the Accident Compensation Corporation for recruitment, had already been made prior to conclusion of this systematic review. Recruiting participants nationally required consent and data to be gathered via the telephone. This method of data collection presents several ethical challenges in children, such as being able to explain the study by phone, gaining assent / consent by phone, and accuracy of reporting of a recurrence when relying on recall (Constand, Tanel, & Ryan, 2015). Therefore, this population may be better suited to a cohort study which involves face-to-face interviews where the parent or caregiver of the child can be present in the interview. For this reason, the remainder of this thesis pertains to people who were aged between 16 and 40 years and were able to provide informed consent.

Although children were not to be included in the cohort study, pertinent risk factors gathered from this systematic review and meta-analysis were taken forward to develop the beta-version of the predictive tool (see Chapter 5). These risk factors include side of dislocation, dominant arm as well as age and sex. This systematic review also suggested the presence of Hill Sachs lesions and labral Bankart lesions as risk factors. Since X-Rays are able to provide data with regards to the presence of Hill Sachs lesions this was included in the beta-version of the tool. However, X-Rays have limited diagnostic accuracy in the detection of labral Bankart lesions, with MRA being the preferred method (Chauvin et al., 2013). MRAs are not routinely collected in patients presenting with a FTASD and this risk factor could therefore not be included in the tool. Examination of labral Bankart lesions as a predictor for recurrent shoulder instability is worthy of further investigation and will be further discussed in Chapter 9.

Chapter 4 **Patient reported risk factors for recurrent shoulder instability after a FTASD**

4.1 Preface

This chapter relates to Aim 4 of the thesis: to evaluate the impact of a FTASD on patient perceived pain, function, kinesiophobia, activity level and quality of life and examine the association between these variables and recurrent shoulder instability (see 1.7).

As the preceding chapters have shown, many demographic and physical risk factors have been identified which may predispose both adults and children to recurrent shoulder instability. Additionally, there are other psychosocial factors such as an individual's perception of pain or level of kinesiophobia, which may influence recurrent shoulder instability, and these have not been previously examined.

In the 1970's, Rowe et al. (1973) proposed that an individual's psychiatric state may affect the rate of recurrent shoulder instability following a dislocation. Other authors have since reported that none of the participants in their studies of voluntary and involuntary shoulder instability had a psychiatric condition (Fuchs, Jost, & Gerber, 2000; Huber & Gerber, 1994; Neer, 1980). However, a psychiatric condition may be perceived to be at the extreme end of a spectrum of psychological conditions. Other psychosocial factors (which include the influence of societal structure) may better represent the impact of a FTASD or be modifiable risk factors for recurrent shoulder instability. Therefore, further examination of psychosocial factors may improve clinical outcomes for people following a FTASD.

The ability to predict recurrent shoulder instability is thought to be advantageous to people following a FTASD, clinicians and stakeholders as it decreases uncertainty, and provides the ability to streamline services (Sachs et al., 2007). Several studies have examined the prognostic ability of psychosocial factors and patient reported outcomes for other shoulder pathologies (Cadogan, McNair, Laslett, Hing, & Taylor, 2013; Kraeutler, Aberle, Brown, Ptasinski, & McCarty, 2018; Tokish et al., 2017).

These variables have not been examined as predictive variables in a population of people with a FTASD.

This chapter reviews the impact of a shoulder dislocation on kinesiophobia, quality of life, shoulder pain and disability and shoulder activity and then the predictive nature of such variables upon recurrent shoulder instability. Some general discussion concerning tools which measure these key variables of quality of life, kinesiophobia, activity level, and shoulder pain and disability will also be introduced. The justification for choosing specific outcome measures used in this thesis research are discussed in Chapter 5.

4.2 Shoulder instability and psychosocial risk factors

'Psychosocial risk factors' is an umbrella term which incorporates both individual psychological risk factors, and risk factors which result from the social structure and context in which they exist (Martikainen et al., 2002). Psychosocial risk factors; such as fear of reinjury, fear of movement and anxiety have been shown to be significant predictors of delayed return-to-work or return-to-sport in a variety of musculoskeletal conditions (Åkerström, Grimby-Ekman, & Lundberg, 2017; Kalisch, Müller, & Tüscher, 2014; Walker, Thatcher, & Lavallee, 2010). The impact of a FTASD on these psychosocial variables, and the potential of these variables as predictors for recurrent shoulder instability will now be discussed in more detail.

4.2.1 Kinesiophobia

Kinesiophobia was originally defined by Kori et al. (1990) as a condition in which a person has "an excessive, irrational, and debilitating fear of physical movement and activity resulting from a feeling of vulnerability to painful injury or reinjury" (p. 37). Vlaeyen et al. (1995) further defined kinesiophobia as a specific fear believed to cause injury or reinjury. Parr et al. (2014) defined kinesiophobia as the fear of movement and reinjury. Flanigan et al. (2013) used the term fear of reinjury and kinesiophobia synonymously. However, other authors have differentiated between the constructs of fear of movement and fear of reinjury (Åkerström et al., 2017). For the purposes of the thesis, the definition of kinesiophobia from Parr et al. (2014) was used, in that the constructs of fear of movement and fear of reinjury were both examined.

High levels of fear of reinjury have previously been associated with greater levels of pain and disability and delayed recovery in people following anterior cruciate reconstruction surgery (Chmielewski et al., 2008). Fear of reinjury manifests itself in many different ways including being hesitant, not giving 100% and over-zealous taping of the injured body part (Johnston & Carroll, 1998). Reinjury has been defined as an injury occurring after a previous injury of the same type and location (Hägglund, Waldén, Bahr, & Ekstrand, 2005). Ironically, the fear of reinjury may potentially increase the risk of injury during functional or sporting activities due to decreased attention, decreased efficiency with skilled execution and poor use of energy resources (Heil, 1993; Williams & Andersen, 1998). This can create a self-perpetuating cycle. Taylor and Taylor (1997) suggested that a lack of confidence and trust can influence the onset of reinjury. Some authors have observed fear of reinjury following a sporting injury to the knee (Ardern et al., 2012; Chmielewski et al., 2008), yet fear of reinjury or kinesiophobia has not previously been examined in people following a FTASD. Therefore, examining kinesiophobia may give some insight into the psychosocial state of those affected by a FTASD and provide information regarding psychosocial risk factors.

4.2.2 Stress and anxiety

Williams and Andersen (1998) have proposed a generic stress-injury model which explains an increased likelihood of injury due to stress and anxiety. These authors propose that psychological stress or threat may lead to muscular fatigue, reduced coordination and delayed reaction time that may increase the likelihood of injury. The perception of threat may narrow peripheral vision and increase distractibility which may also increase the risk of injury (Williams & Andersen, 1998).

Debate exists between the definition of fear of reinjury and reinjury anxiety. Fear has been defined as a mechanism that is benign, stimulus-specific and associated with definite danger, while anxiety is connected with uncertainty or an imagined result (Hackfort & Schwenkmezger, 1993). Fear has been thought to typically result in escape behaviours (such as avoiding/escaping the stimulus) (Hackfort & Schwenkmezger, 1993). However, those that are reported to be anxious about returning to sport following an injury, do not discuss escape actions, but rather engage in rehabilitation activities, albeit with some hesitation (Walker et al., 2010). However, not all people with a FTASD engage in rehabilitation, or are involved in sport. Thus, kinesiophobia may better represent the impact of a FTASD in a general population.

4.2.3 The impact of a FTASD on kinesiophobia

Kinesiophobia has previously been found to be an important predictor of upper limb disability in a cross-sectional study of patients with an upper limb condition (Das De et al., 2013). Parr et al. (2014) also reported that higher pain levels are associated with poor recovery, fear of reinjury and longer pain duration in people with shoulder disorders. Fear of reinjury may also influence rates of recurrent shoulder instability due to hesitation during sporting activity, holding back and not giving 100% effort (Ardern et al., 2012, 2013; Johnston & Carroll, 1998).

An example of kinesiophobia following a FTASD is seen with the apprehension test. Apprehension has been defined as a fear of dislocation and/or resistance in patients with a history of anterior glenohumeral instability (Lädermann et al., 2016). Clinical apprehension tests are widely used following shoulder dislocation and involve positioning the arm in abduction and external rotation (Bahr et al., 1995; Lo et al., 2004). Biomechanically, this places tension upon the anterior/inferior glenohumeral ligament which is commonly injured in an anterior shoulder dislocation (Ellis, et al. 2010; Lo et al., 2004).

Haller et al. (2014) considered anxiety and fear as key cognitive processes associated with shoulder apprehension. These authors concluded that apprehension is more complex than an isolated mechanical problem and the neuronal changes associated with shoulder instability may explain why mechanical stabilisation via surgical intervention alone can provide unsatisfactory results.

4.2.4 Kinesiophobia as a predictive variable for recurrent instability after a FTASD

Although there is increasing appreciation of the role of the brain and emotion in predicting outcomes from a shoulder injury, kinesiophobia has not yet been examined in a population of people following a FTASD. Milgrom et al. (2014) investigated a positive apprehension test as a predictive variable for recurrent shoulder instability when administered 6 weeks following a FTASD. The participants were all active soldiers in the Israeli army with a mean age of 20.2 years (range 17-27). Both the shorter term 24 month results (Safran et al., 2010), and the longer term results of 75 month follow-up have been published (Milgrom et al., 2014). After a minimum of 75 months following a FTASD, 11 of 14 subjects with a positive anterior apprehension test had redislocated, compared with 20 of 38 subjects with a negative test result. Follow-up was undertaken yearly, either in a clinic or over a telephone. People who had a positive apprehension test six weeks after a FTASD were found to redislocate earlier and more often compared to those with a negative apprehension test ($p=0.02$) (Milgrom et al., 2014). No difference was found between rate of recurrent shoulder instability and age of participants ($p=0.6$), possibly as the range of age was relatively small (17-27 years).

Positive clinical apprehension tests are associated with increased activity in the areas of the cortex related to fear and anxiety (Cunningham et al., 2015; Shitara et al., 2015). This doctoral study did not seek to undertake clinical tests, however it was possible to include measurement of kinesiophobia. Therefore, further examination of kinesiophobia as a predictive variable for recurrent shoulder instability following a FTASD is required.

4.3 Shoulder instability and health related quality of life

Health related quality of life is an important outcome measure following a FTASD as it develops a greater understanding of the impact of a FTASD, provides a patient-centred outcome as an alternative to the rate of recurrent instability and provides a measurement which can be compared between treatments (Kemp et al., 2012). The impact of a FTASD on quality of life and the predictive nature of this variable will now be discussed.

4.3.1 Impact of a FTASD on health related quality of life

The impact of a FTASD on health related quality of life has been measured with the Western Ontario Shoulder Instability index (WOSI) (Kirkley, Griffin, McLintock, & Ng, 1998). Kirkley et al. (2005) conducted a RCT which compared people who underwent immediate surgical stabilisation following a FTASD with those who were treated non-operatively. Both groups of patients were treated with the same rehabilitation protocol. People who had surgery had better quality of life, as measured by the WOSI, when compared to those who were treated non-operatively. This finding is in contrast to that of Sachs et al. (2007) who prospectively followed people after a FTASD and found no difference in quality of life (WOSI scores) between people who had surgery and those who were treated non-operatively and did not have recurrent shoulder instability ($p=0.48$). However, those people who were treated non-operatively who had recurrent instability had decreased quality of life when compared to both the surgical group and those that did not have recurrent instability ($p=0.004$) (Sachs et al., 2007).

4.3.2 Health related quality of life as a predictive variable for recurrent instability after a FTASD

The WOSI has been used to predict the ability to return to play when administered after an initial instability event (i.e. subluxation or dislocation) (Dickens et al., 2014). Dickens et al. (2014) explored the likelihood of returning to sport and recurrence of instability following an in-season anterior shoulder instability event. The WOSI score administered at the time of initial injury was predictive of return to play within that same season (OR=1.05, 95% CI (1.00-1.09), p=0.037). Time loss from sport following an in-season subluxation or dislocation was inversely related to the initial WOSI score (p=0.039). For every 10 points higher on the WOSI score, the athlete returned to sport 1.3 (95% CI (0.2-2.4)) days sooner (p=0.021). Sixteen percent of the variability in the time to return to sport after an in-season shoulder subluxation or dislocation was accounted for by the WOSI score. However, recurrent shoulder instability was not associated with WOSI scores at the time of injury (p=0.957).

4.4 Shoulder instability and shoulder pain and disability

Although many studies have anecdotally referred to the presence of pain following a FTASD (Hovelius, 1987; Longo et al., 2014; Salomonsson et al., 2010), only one prospective cohort study has reported levels of pain (Sachs et al., 2007). The impact of a FTASD on shoulder pain and disability and the predictive nature of these variables will now be discussed.

4.4.1 Impact of a FTASD on shoulder pain and disability

Sachs et al. (2007) have reported pain following a FTASD to range widely from a minimum of 0 to a maximum of 10 using a VAS. In this prospective cohort study, which investigated predictors for recurrent shoulder instability after a FTASD, people who had associated rotator cuff tears presented with higher levels of pain than those that did not have a tear. People who continued to have pain at 6 weeks after a FTASD, underwent MRI and were treated surgically based on the MRI findings. No other mention of the time taken for pain to resolve was mentioned (Sachs et al., 2007).

Shoulder function was measured in a prospective cohort following a FTASD (Robinson et al., 2002). No difference was shown between people with or without recurrent shoulder instability in Constant-Murley Scores or Disability of Arm, Shoulder and Hand (DASH) scores (both measures of shoulder function) at 12 months following a FTASD. No information was provided regarding shoulder function in the intermediary months between the time of injury and 12 months following

(Robinson et al., 2006). Similarly, Hovelius et al. (1996) reported that people who had a FTASD reported subjectively similar function during interviews whether they had recurrent shoulder instability or not.

4.4.2 Shoulder pain and disability as a predictive variable for recurrent instability after a FTASD

Shoulder pain following a FTASD was measured at baseline in a prospective cohort study using a VAS by Sachs et al. (2007). Shoulder pain was a significant univariate and multivariate predictor of recurrent instability in this prospective cohort study (Sachs et al., 2007). As mentioned, this study showed that levels of shoulder pain of 8 and greater (of a possible 10), were associated with increased rates of recurrent instability (OR=2.841, p=0.098). Those who underwent surgery had higher levels of pain at the initial injury. However, most of these people underwent surgery for rotator cuff repair. Those who had rotator cuff repair had higher levels of pain that those who selected non-operative management (p<0.01) (Sachs et al., 2007).

Baseline Shoulder Pain and Disability Index (SPADI) scores have been shown to predict work status one year after onset of subacromial pain in patients aged 18-70 years (Engebretsen, Grotle, Bautz-Holter, Ekeberg, & Brox, 2010). Cadogan et al. (2013) examined clinical variables which could predict the presence of a medium, large or multi-tendon (MLM) rotator cuff tear. They reported a SPADI Pain score of more than 48% was associated with the presence of a MLM rotator cuff tear (Cadogan et al., 2013).

Shoulder function has not been examined as a predictive variable people following a FTASD, and does not appear to be different in people with recurrent shoulder instability when compared with controls (Robinson et al., 2002). The ability to measure shoulder pain and disability together in a concise patient reported outcome measure may provide useful information, both regarding the impact of a FTASD on these variables and the ability of shoulder pain and disability to predict recurrent shoulder instability. Anecdotally, people have less pain and disability over time, but the time course for recovery is currently unknown (Owens, 2016). Further examination of the effect of a FTASD on pain and disability and the time to recover will allow further appreciation of the impact of a FTASD. This information could then be used to educate people with a FTASD and guide their expectations regarding return to activity.

4.5 Shoulder instability and levels of shoulder activity

Detailed examination of the short term impact of a FTASD on shoulder activity level could provide useful information that can be used when making decisions regarding treatment options (Streufert et al., 2017) as approximately 70% of people who will have recurrent shoulder instability, will do so with 12 months of their FTASD (Robinson et al., 2006). The impact of a FTASD on shoulder activity level and the predictive nature of this variable will now be discussed.

4.5.1 Impact of a FTASD on levels of shoulder activity

The impact of a FTASD on shoulder activity has not been previously reported in a prospective cohort study. A cross-sectional study of people undergoing shoulder stabilisation following a shoulder instability event has shown that activity levels were increased, as measured with the Shoulder Activity Scale (SAS) in this population (mean SAS score = 13) compared with healthy people without a FTASD (mean SAS score = 10) (Brophy, Hettrich, Ortiz, MOON Shoulder Instability Group, & Wolf, 2016). It may be that a population of people following a FTASD who are presenting for surgical intervention have different levels of shoulder demands than a population of all people who have had a FTASD. Additionally, no values are available for the minimal detectable change (MDC) or minimal clinically important difference (MCID) of the SAS. Thus, it is not possible to say if the 3 point difference between these cohorts is clinically meaningful. However, the impact of a FTASD, nor the time to return to activity has been previously examined.

4.5.2 Shoulder activity level as a predictive variable for recurrent instability after a FTASD

Despite Brophy et al. (2009) advocating that shoulder activity can be used as a prognostic variable for shoulder outcomes, a limited number of studies have measured this following a shoulder injury. Shoulder activity level was not found to be a significant predictor of outcome in people with total shoulder arthroplasty (Mahony et al., 2018a), rotator cuff pathology (Woollard et al., 2017) or surgical shoulder stabilisation (Kraeutler, Aberle, et al., 2018).

Some authors have proposed that alteration to a person's level of activity may be responsible for the rate of recurrent instability after a FTASD (Brophy, Hettrich, et al., 2016; Rowe, 1956). Possible explanations for this change in activity level include wanting to protect themselves from further injury, being less likely to engage in the same activities as when they suffered their initial injury, or decreased ability to return to the same levels of strength and ROM as prior to the injury (Rowe, 1956). Shoulder activity level has not been examined as a predictive variable in a cohort of people with a FTASD to predict recurrent instability and was included in this thesis research.

4.6 Key findings

Psychosocial risk factors such as kinesiophobia, quality of life and pain may predispose or protect people from recurrent shoulder instability following a FTASD. Recording baseline and follow-up measures of these variables is therefore warranted following a FTASD. One of the aims of this thesis was to examine whether patient perceived pain, function, kinesiophobia and quality of life played a role in predicting recurrent shoulder instability after a FTASD and this will be further explored in Chapter 8.

Chapter 5 **Methods**

5.1 Preface

This chapter relates to Aim 2: to develop and pilot a predictive tool which can differentiate between those who will have recurrent shoulder instability and those who will not develop recurrent shoulder instability, in a population of people with a FTASD.

The preceding chapters 2-4 have outlined the gathering of pertinent risk factors which were incorporated into the development of the predictive tool. The following chapter outlines the methods undertaken in Phase 1 and Phase 2 of the study. Phase 1 (Chapter 6) aimed to develop a predictive multivariate tool which predicted whether a person was going to have recurrent instability following a FTASD. Phase 2 (Chapter 7) then examined the predictive validity of this tool.

5.2 Methodology

The overarching methodology of this thesis is of quantitative design, couched in a post-positivist paradigm. The post-positivist paradigm depends on the notion that the truth is based on precise observation and measurement and that data is gathered using questionnaires and observations. The strengths of this form of research is that the findings can be described as objective, reliable, valid and generalisable (Krauss, 2005). The aims of the thesis were to examine risk factors for recurrent shoulder instability and develop a tool which can predict recurrent shoulder instability after a FTASD.

Examination of these risk factors in a prospective cohort study was founded in the world view that recurrent shoulder instability is a measurable event which can be documented. Additionally, the presence of pathological risk factors can be documented radiographically. Further, I considered that psychosocial constructs are measurable with scales that have proven reliability and validity. Therefore, a post-positivist approach was considered appropriate for this study.

There are several different methods of modelling clinical outcomes in patients including logistic regression, Cox regression model and simulation models, each with their advantages and disadvantages (Amiri & Kelishadi, 2012). Cohort studies allow inclusion of multiple clinical risk factors and the interactions between these risk factors to be studied. Additionally, risk factors which are specific to the population in which they were developed can be used to formulate a predictive tool. Therefore, it was decided to undertake an examination of risk factors in a New Zealand population-based prospective cohort study.

5.3 Phase 1

Risk factors for recurrent shoulder instability, that were identified in Chapters 2-4, were collated into a beta-version of a predictive tool of recurrent instability. Included variables were then discussed with expert clinicians to ensure that no predictive variables, that they considered to be clinically relevant, were excluded. This approach mitigated the potential presence of publication bias of risk factors reported in existing literature. The inclusion of other variables was also considered necessary as there may have been other variables present in the clinical population which had not previously been reported in published literature, but which had been recognised clinically or anecdotally.

5.3.1 Expert opinion

Expert opinion was sought by discussing with two surgeons, two physiotherapists, and two sports physicians. These health professionals were clinical and academic specialists in their respective fields in regard to shoulder injury assessment and management. This enabled a range of health professions to share their opinions and clinical experience. They reviewed the list of risk factors that had been previously collated (see Chapters 2-4), made comments regarding these and offered suggestions of other risk factors which they felt may be pertinent to the predictive tool. These variables were considered for addition to the beta-tool by the wider supervisory team and resulted in additions to the beta-version of the tool.

The additional risk factors identified by the experts included: body mass index (BMI), ethnicity, and shoulder activity level. These risk factors were added to the tool. No risk factors identified in the systematic reviews (Chapter 2 and 3) were removed in order to preserve the internal validity of the study. Factors identified as risk factors for recurrent shoulder instability after a FTASD in children (such as the side of shoulder dislocation, shoulder dominance and Hills Sachs lesions) were also added to the beta-version of the tool. The list of risk factors was then examined in a prospective cohort study (Phase 1). The study recorded data which pertained to recurrent instability over a one year period following a FTASD in people who had been managed conservatively.

5.3.2 Phase 1 participants

A prospective cohort study was undertaken with people who had suffered a FTASD to examine the risk factors which predispose them to recurrent shoulder instability or protect them from further instability. Participants were included in the study if they:

- were aged between 16 and 40 years
- sustained a FTASD in New Zealand
- had a shoulder X-Ray following their FTASD
- had a New Zealand contact address
- had a shoulder dislocation registered with the Accident Compensation Corporation (ACC) between the dates of May 2nd, 2015 to April 2016
- had not undergone surgical intervention for their shoulder injury within 2 weeks of the injury.

Participants were excluded if they did not speak conversational English as they would be unable to participate in the telephone conversation. People who had a prior instability episode in the affected shoulder but had been erroneously identified as having a FTASD by ACC were also excluded from this study as these people were considered a separate population from those with a FTASD. People older than 40 years of age were not included in this study, as previous literature has shown they are at decreased risk of recurrent shoulder instability after a FTASD (Hoelen et al., 1990; Hovelius et al., 2008; Pevny et al., 1998)

5.3.3 Phase 1 recruitment procedure

New Zealanders who have a traumatic accident present to health professionals who record their details (including injury details) with ACC, a government owned corporation responsible for administering the country's universal no-fault accidental injury scheme. The scheme provides financial support and compensation to citizens, residents and temporary visitors who have suffered personal injuries. The ACC database can be used to accurately identify those people who have a traumatic anterior shoulder dislocation, and who report to a health professional, through the use of an injury coding system called Read codes. Read codes are a hierarchical system for coding injuries organised by body part and diagnosis to give a specific diagnosis of the injury (Accident Compensation Corporation, 2017b).

Initial conversations were undertaken with the ACC Research Committee regarding the ability of ACC to support the identification of potentially eligible participants for this study. ACC agreed to support the study and ethical approval was subsequently sought and approved (see 5.5). The ACC data analyst identified all those with a traumatic anterior shoulder dislocations using the following Read codes, which had been assigned by the treating clinician: *S41.. (*dislocation or subluxation of shoulder), *S410.* (closed traumatic dislocation of shoulder), *S4100* (closed traumatic dislocation shoulder joint, unspecified), *S4101* (closed traumatic dislocation shoulder joint, anterior (sub-coracoid)), *S410z* (closed traumatic dislocation of shoulder not otherwise specified (NOS)), S*41z.* (dislocation of shoulder NOS).

Potentially eligible participants were contacted by letter (Appendix A) within 12 weeks of their dislocation, by ACC, with information about the study and details of how to opt out of the study (Figure 5.1, Number 1). Also included in the envelope was an invitation to take part in the study (Participant Information Sheet (Appendix B), and a consent form (Appendix C). Contact was made by ACC within 12 weeks of the initial injury in order to optimise patient recall and minimise ACC expenditure by limiting the number of times that the data were extracted from the database. Those that did not have sufficient address details to be contacted by mail were excluded from the study (Figure 5.1, Number 2). Those who wanted to opt-out from the study were asked to contact ACC on a free-phone number within two weeks of receiving the letter and they were excluded from the study (Figure 5.1, Number 3).

Each month the names and contact details of those that did not opt-out of the study, within two weeks of the letter dispatch date, were included in a password protected spreadsheet that was emailed to the researcher (Figure 5.1, Number 4). The relatively small number of people for whom there was no record of a phone number were sent a letter by the researcher, inviting them to make direct contact with her (Figure 5.1, Number 6) (Appendix D). People had the option to respond to this invitation by text, email or phone. Those for whom telephone numbers were available, were contacted by telephone to invite them to take part in the study (Figure 5.1, Number 7).

All those who were contacted were informed again about the study and had an opportunity to ask any questions during the phone call. Inclusion criteria were formally confirmed during this phone call, using standard questions. Those who were eligible and who wished to take part in the study were consented into the study, which was audio recorded (with their permission) (Figure 5.1, Number 8). Those who were not eligible were excluded from the study (See Figure 5.1, Number 9). Some people declined to take part in the study (Figure 5.1, Number 5). Others were not able to be contacted by telephone despite 15 separate attempts at different times of the week and day (Figure 5.1, Number 6). They were sent a letter to invite them again to take part in the study with phone and email contact details of the researcher.

In order to confirm that an anterior shoulder dislocation had occurred, potential participants needed to provide consent for access to radiological images pertaining to their shoulder injury. Those that did not provide consent to access radiology records were excluded from the study. When consent was given by the participants to obtain information regarding medical imaging (Figure 5.1, Number 11), radiology companies who had taken the initial X-Ray (and any other imaging such as ultrasound, and/or MRI/MRA) were contacted. Those companies that accepted the recorded verbal consent as proof of consent, emailed or faxed the radiology records to the researcher (Figure 5.1, Number 13). When the radiology companies required written consent to release the radiology records for the injured shoulder (Figure 5.1, Number 13), the participants were sent a self-addressed stamped envelope and written consent form for release of their X-Ray, ultrasounds, and/or MRI/MRA results (see Appendix E) (Figure 5.1, Number 14). Written consent that was returned to the researcher was then sent to these remaining radiology companies and the records were faxed or emailed to the researcher (Figure 5.1, Number 16). When the participant did not return the radiology consent letter, these data were recorded as missing and the participant was excluded from the study (Figure 5.1, Number 15). The initial X-Ray and any other additional radiological imaging were reviewed to confirm the anterior shoulder dislocation and include the person (Figure 5.1, Numbers 17), exclude the person if they had not had a dislocation (Figure 5.1, Number 18), or exclude them because the dislocation had occurred in a posterior or inferior direction (Figure 5.1, Number 19). The recruitment flow of potential participants can be seen in Figure 5.1

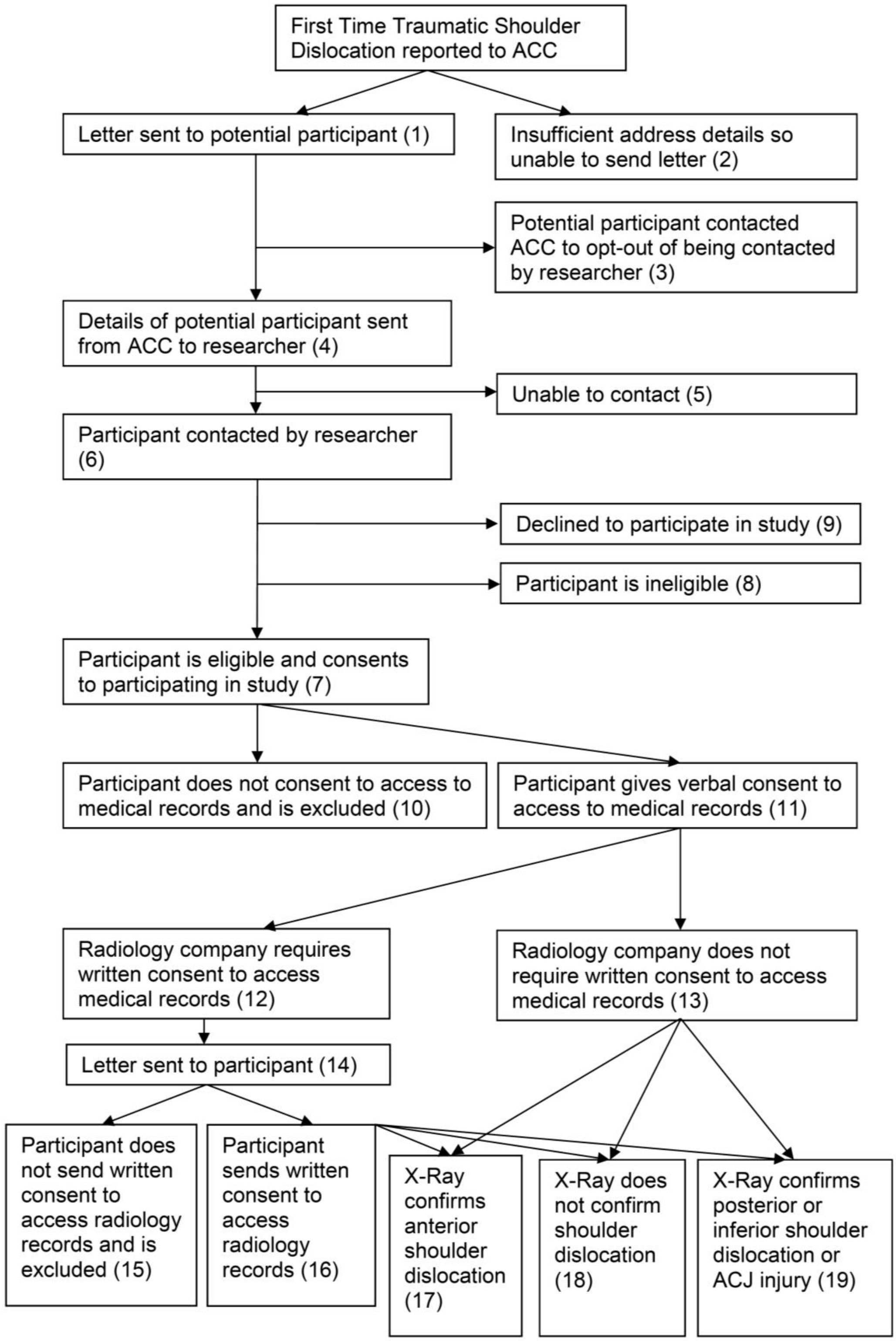

Figure 5.1 The flow of potential participants through the recruitment phase of the study.

5.3.3.1 Reliability of Phase 1 inclusion criteria

Reliability of coding for previous recurrent instability was established using de-identified recordings of the initial interview. A research assistant with a special interest in shoulder injuries listened to and coded a random sample of eight interviews. She coded the transcript to a replica of the excel file as used by the lead researcher to examine the reliability of the coding of previous recurrent shoulder instability. She concluded that all sampled recordings had been correctly classified as having no previous recurrent shoulder instability.

5.3.4 Phase 1 data collection

5.3.4.1 Phase 1 baseline data collection

The baseline phone call made by the lead researcher (MO) was used to record details of the participant's primary predictive variables including age, sex, height, weight, ethnicity, handedness, side of dislocation, occupation, family history of shoulder instability, self-reported hypermobility, period of immobilisation and number of physiotherapy sessions attended (Table 5.1 and Appendix F). Operational definitions of these variables are reported in Table 5.2. Secondary variables including quality of life, level of shoulder activity, shoulder function, and kinesiophobia were collected via the following outcome measures: Western Ontario Stability Instability Index (WOSI) (Appendix G), Shoulder Activity Scale (SAS) (Appendix H), Shoulder Pain and Disability Index (SPADI) (Appendix I) and Tampa Scale of Kinesiophobia (TSK-11) (Appendix J) respectively.

Table 5.1 Data collected at baseline

Personal variables	Clinical	Sport
Age	Mechanism of injury	Level of sport (e.g. club, professional)
Sex	X-Ray	Position of sport
Patient estimated height	Bony Bankart	Type of sport (collision vs. overhead)
Patient estimated weight	Greater tuberosity fracture	Time to return to sport
Hand Dominance	Hill Sachs	Hours per week of playing sport
Occupation	Ultrasound imaging - Bursitis	
Ethnicity	Ultrasound imaging - Rotator cuff tear	
	Ultrasound imaging - Haemarthrosis	
	Side affected	
	Family history of shoulder instability	
	Hypermobility	
	Period of immobilisation	
	Physiotherapy sessions	

Table 5.2 Questions asked to define terms used in the study

Term	Operational definition
FTASD	Did your shoulder come out of its socket?
Previous shoulder instability event	Has your shoulder come out of its socket before? YES/NO
Ethnicity	Categorised as per NZ Statistics (Ministry of Health, 2004) with up to six ethnic categories recorded and the minority ethnicity coded if the alternate was NZ European.
Hand dominance	What hand do you throw with?
Occupation	What do you do during the day?
Family history	Has anybody else in your family also had a shoulder dislocation?
Hypermobility	Do you consider yourself to be hypermobile (for example can you place your hands flat to the floor with your knees straight when standing?)
Period of immobilisation	How long did you wear a sling for?
Number of physiotherapy sessions	How many physiotherapy sessions did you attend?
Recurrent Shoulder Instability	No - no instability event,
	No - feels loose but no instability event,
	Yes - shoulder has come out of its socket but relocated without external force (subluxation),
	Yes - shoulder came out of its socket and was relocated by friend/family member (dislocation),
	Yes - shoulder came out of its socket and was relocated by medical professional (dislocation).

Given that research participants had limited time available to complete the questionnaires, the SPADI was chosen to concisely record both shoulder pain and disability in the present study. The SPADI is a questionnaire which measures shoulder pain and disability and consists of five questions for pain and eight questions to measure the degree of difficulty during functional activity (Roach, Budiman-Mak, Songsiridej, & Lertratanakul, 1991). Patients mark a score on a 100mm VAS for each question (see Appendix I). The mean values of the pain and disability subscales were averaged to produce a total score which ranged from 0 (best) to 100 (worst). An additional reason for choosing the SPADI for this research was it has been shown to have some capacity in predicting outcomes from shoulder injuries (Cadogan et al., 2013). The SPADI has a minimal detectable change of 13 points (90% confidence) when examined in male patients with shoulder pain in the United States of America (USA) (Roach et al., 1991). The SPADI has been shown to demonstrate good internal consistency, criterion and construct validity and test-retest validity in a population of people with shoulder pain in Canada (MacDermid, Solomon, & Prkachin, 2006) and the USA (Roach et al., 1991). Furthermore, the SPADI has been shown to be unbiased based on activity level, age, sex or hand dominance in healthy college age athletes (Brinker, Cuomo, Popham, O’Connor, & Barrack, 2002). The SPADI has also been used in people with shoulder instability (Buteau, Eriksrud, & Hasson, 2007), although it has not previously been used as a predictive variable in a population of people with a shoulder dislocation.

Quality of life measures may be generic (such as the Short Form-36, or Short Form-12) or disease specific (such as the WOSI) (Kirkley & Griffin, 2003). While generic health related quality of life measures allow comparison across medical conditions, they often lack sensitivity to change in specific diseases (Kirkley & Griffin, 2003). The advantage of a disease specific measure is increased responsiveness which may detect small but clinically important change in a person’s health related quality of life (Kirkley & Griffin, 2003). The WOSI was designed to be a primary outcome measure for research studies investigating shoulder instability and has been used as a measure of shoulder-related quality of life since its development in the 1990’s

(Kirkley et al., 1998). Kirkley et al. (1998) argued the necessity of this scale as they believed the most important measure of successful treatment was the patient's perception of their outcome. Therefore, a disease specific measure of quality of life was required to measure the impact of a FTASD.

The WOSI consists of 21 questions, 10 of which examine physical symptoms, 4 examine sports/recreation/work factors, 4 examine lifestyle factors, and the remaining 3 examine emotional factors (see Appendix G). VAS scores are recorded from 0-10 on a 100mm scale for each item for a total score of 2100, with 0 the best possible score and 2100 the worst (Kirkley et al., 1998). The WOSI has been found to be a reliable, valid score which is sensitive to clinically important changes in people with shoulder instability (Kirkley et al., 1998), and has been translated into several languages (French (Gaudelli et al., 2014), Italian (Cacchio et al., 2012), German (Hofstaetter, Hanslik-Schnabel, Hofstaetter, Wurnig, & Huber, 2010), Swedish (Salomonsson, Ahlström, Dalén, & Lillkrona, 2009) and Japanese (Hatta et al., 2011)). The WOSI has been widely used to examine the impact of shoulder instability on quality of life (Cordischi et al., 2009; Garrigues, Warnick, & Busch, 2013; Hovelius, Sandström, Olofsson, Svensson, & Rahme, 2012; Krueger, Kraus, Pauly, Chen, & Scheibel, 2011).

Kinesiophobia was measured with the TSK-11 as it has been widely used within upper limb research (Bot et al., 2005; Lentz, Barabas, Day, Bishop, & George, 2009). The TSK-11 is an 11-item scale with a choice of 4 responses on a Likert scale ranging from 'strongly disagree' to 'strongly agree'. Possible scores range from 11 to 14 (Appendix J). The TSK-11 consists of three subscales; fear of pain (FOP; items 2, 7, 11), fear of reinjury (FOI; items 1, 6, 9, 10) and somatic focus (SF; items 3, 4, 5, 8) (Prugh, Zeppieri, & George, 2012). However, other authors have also shown the TSK-11 to have two separate subscales; a somatic focus (1, 2, 3, 7, 8) and an activity avoidance scale (5, 6, 9, 11) (Tkachuk & Harris, 2012). The TSK-11 has demonstrated similar internal consistency (Cronbach's alpha a=0.79), test-re-test reliability (intraclass correlation coefficient (ICC)=0.81), standard error of the mean (SEM)=2.54), responsiveness (standard response mean (SRM)=-1.11) and concurrent validity (r=0.51) compared to the original version of the TSK (Woby, Roach, Urmston, & Watson, 2005). It has been used previously in adolescents to measure fear avoidance behaviour (Astfalck, O'Sullivan, Straker, & Smith, 2010) and in people aged as young as 15 (Cook, Vowles, & Brawer, 2006).

Although the TSK-11 is not a measure specific to shoulder pathology or dysfunction, it has been previously used in people with upper limb pain. Prugh et al. (2012) used the TSK-11, Fear Avoidance Belief Questionnaire (FABQ), Pain Catastrophising Scale, Quick Dash and Numeric Pain Rating Scale (NPRS) in a group of five competitive throwing athletes aged between 17 and 23 years with elbow pain. For this group of athletes, all TSK-11 subscales (FOI, SF and FOP) were found to have a strong association with the total TSK-11 score (Prugh et al., 2012). Lentz et al. (2009) used the TSK-11 in a population of people with shoulder pain with a mean age of 41.4 (18.5) years to examine the association between measures of fear of pain, pain intensity, physical impairment and disability in this cohort. Pain related fear was found to be a statistically significant variable contributing to decreased function in people with shoulder pain.

Mintken et al. (2010) investigated the reliability and validity of the TSK-11 in patients aged 18-65 years with shoulder pain. Their analysis suggested that the TSK-11 consisted of only one stable factor for patients with shoulder pain: 'activity avoidance due to pain' (items 1, 2, 9, 11). The remaining three of four factors did not meet the reliability criterion (pain indicates injury and activity avoidance because of threat) or reliability could not be assessed (credibility of complaints). These authors concluded that the FABQ provided a better measurement of pain related fear than the TSK-11 (Mintken et al., 2010). However, fear avoidance is a behaviour influenced by the expectation that further activity will result in pain and suffering and is therefore influenced by kinesiophobia (Philips, 1987). Vlaeyen et al. (1995) stated that fear avoidance and kinesiophobia are different constructs. The focus of this thesis was to examine factors immediately following an FTASD that may predispose or protect people to further recurrent instability. As such, fear avoidance behaviour was not the construct to be examined, but rather kinesiophobia. Therefore, a decision was made to use the TSK-11 rather than the FABQ as we believed it would provide more detail in regard to fear of reinjury.

Reinjury anxiety has been measured with the Reinjury Anxiety Index (RIAI) in an athletic population (Walker et al., 2010), but no evidence exists of the use of this tool in a population with shoulder instability. As this doctoral research sought a general population, measurement of kinesiophobia with the short form version of the Tampa Scale of Kinesiophobia (TSK-11), was deemed more appropriate than measurement of reinjury anxiety using the RIAI.

Levels of shoulder activity have been measured using the Shoulder Activity Scale (SAS) which was developed to assess a person's outcome after a shoulder injury (Brophy, Beauvais, Jones, Cordasco, & Marx, 2005). The SAS has been validated in a general population and has been previously used in people with shoulder instability (Brophy, Hettrich, et al., 2016; Brophy, Lin, & Smith, 2014; Olds, McNair, Nordez, & Cornu, 2011). The SAS comprises of 5 questions which examine the frequency of activities such as lifting overhead, lifting weights, and performing a swinging motion e.g. tennis or baseball (see Appendix H). Two questions are included to examine the frequency and level of sporting competition. This score had excellent test-retest reliability and good construct validity when measured in a population of people in the USA with shoulder disorders (Brophy et al., 2005). A maximum score of 20 is indicative of a high level of activity while a score of 0 indicates minimal shoulder activity. Normative data has indicated that men have increased levels of shoulder activity compared with women, and that levels of shoulder activity decline with increasing age (Hepper et al., 2013). Shoulder activity has also been shown to vary across different shoulder pathologies (Brophy et al., 2009) and was increased in people who undergo shoulder stabilisation compared with healthy age matched controls (Brophy, Hettrich, et al., 2016). The direction of shoulder instability (anterior or posterior) does not affect the level of shoulder activity (Kraeutler, Aberle, et al., 2018). More recently, a scale has been developed to measure the degree of shoulder involvement in specific sports (Vascellari et al., 2018), however this was not available at the time of data collection for this thesis research. Furthermore, the current research examined the general population of people in New Zealand and not specific sports people which gave further justification for using a more general measure of shoulder function such as SAS.

Data were entered online at the URL (http://www.shoulderresearch.co.nz/shoulder-dislocation.php) (Appendix J). The secure server was password protected and access was limited by password to the researcher (MO). Data were exported at regular intervals to a .csv file and saved in a secure password protected external hard drive.

5.3.4.2 Reliability of Phase 1 mechanism of injury

Reliability of the coding of mechanism of injury was examined with the supervisory team. Transcriptions regarding the mechanism of injury regarding sports injuries vs. falls from 20 participants were reviewed by MO, RE and PK. Each team member independently categorised whether the mechanism of injury was a fall or a sports injury, and then differences were discussed in an open meeting. This resulted in the categorisation of all falls that occurred during a sporting activity being coded as a ‘sports injury’.

5.3.4.3 Phase 1 follow-up data collection

The primary outcome was recurrent shoulder instability. Recurrent shoulder instability was defined as a repeated event of instability of either a subluxation or dislocation (Figure 5.2) (Olds et al., 2015) as both a subluxation and dislocation may affect clinical decision-making regarding clinical management following shoulder injury (Owens et al., 2010). A dislocation has been defined as complete separation of the humeral head from the articular surface of the glenoid and required external force to relocate the shoulder (Owens et al., 2010; Rockwood et al., 1998). A subluxation has been defined as spontaneous reduction of the humeral head following complete separation of the humeral head from the glenoid without the requirement of external force to relocate the shoulder (Owens et al., 2010; Rockwood et al., 1998).

Research assistants with a health background were instructed in the delivery of the follow-up structured phone interview (Appendix K) and trained to identify recurrent instability events during these interviews. This training included the use of vignettes where the research assistants answered whether there had been recurrent shoulder instability or not. Discussion continued until all research assistants reached 100% accuracy. Further discussion of individual cases was undertaken at regular meetings, scheduled bi-monthly to limit recall bias. In order to ensure clarity and consistency between research assistants, the following categorisation of recurrent shoulder instability was used (Table 5.3).

Table 5.3 Categorisation of recurrent instability

Recurrent shoulder instability event	**Participant response**
No	Participant has had no further episodes of shoulder instability
No	Participant has had pain or felt increased movement in shoulder, but shoulder has not come out of its socket
Yes	Shoulder has come of out its socket and was relocated without the application of external force
Yes	Shoulder has come out of its socket and has required assistance/the application of external force from non-medical personnel (family or friends) to relocate shoulder
Yes	Shoulder has come out of its socket and has required assistance of doctor (or other medical personnel) to relocate shoulder

Secondary outcomes of quality of life (WOSI), level of activity (SAS), function (SPADI) and kinesiophobia (TSK-11) were also recorded during the follow-up phone call (Appendix K). Data were transcribed from the source datasheet by the researcher into a second data sheet that was ordered with respect to the date of follow-up and password-protected in a shared online folder. Data from the follow-up phone call were entered online (http://www.shoulderresearch.co.nz/shoulder-dislocation-followup.php). When the participants preferred to be contacted by email or letter, they were emailed by the researcher with a link to the same questionnaire online or posted a questionnaire with a return self-addressed envelope that was identical to the questionnaire administered over the telephone. Paper copies of the questionnaire were returned to the researcher, who then entered the responses into the database.

Follow-up phone calls/emails were made at three, six, nine and twelve months, following the date of injury, by a research assistant. Regular calls and emails were made to limit recall bias (Pannucci & Wilkins, 2010). Recurrent shoulder instability was recorded at the time of the phone call. If the participant reported recurrent shoulder instability, no further phone calls were made to the participant, and the participant was recorded as having recurrent shoulder instability across future time points to 12 months follow-up. The research assistant was blinded to the responses provided by the participant at the baseline interview in order to limit interviewer bias, which could have resulted from the research assistant inadvertently influencing the data recorded. Interviewer bias is more likely when the disease state is known to the interviewer and refers to the systematic difference regarding how information is solicited, recorded or interpreted (Pannucci & Wilkins, 2010).

As outlined in section 5.3.3., details of potential participants were provided by ACC between three weeks and three months following the date of injury. For the small number of people who were recruited within 14 days from the 3 month post-injury date, baseline data and 3 month data were taken to be the same (and no additional call was made for the 3 month data collection point), and the presentation of a recurrent shoulder instability event was also collected as in the standard 3 month follow-up (Table 5.3).

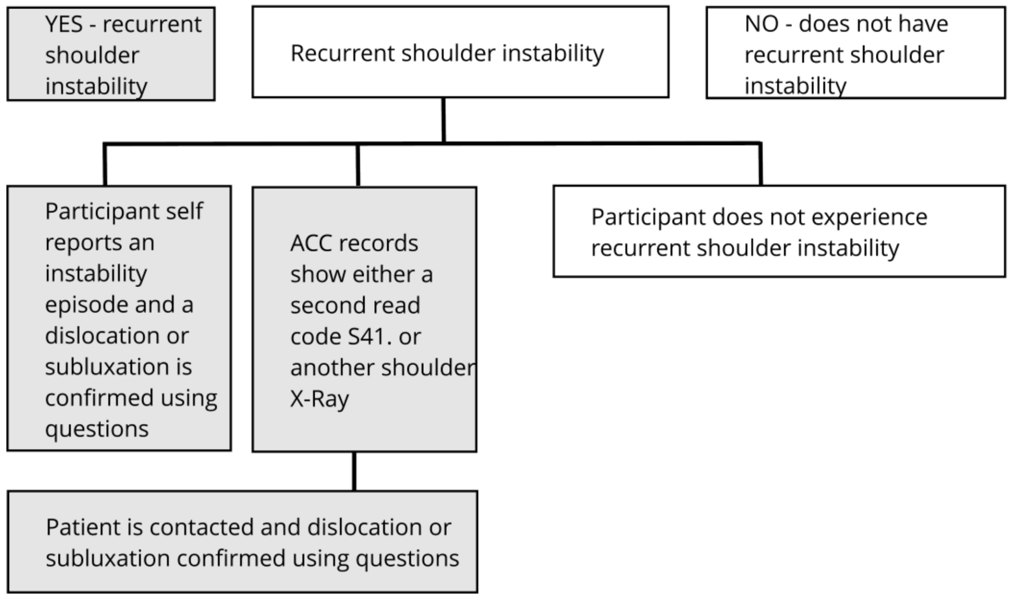

Figure 5.2 The method of assigning recurrent shoulder instability status as used by research assistants in follow-up phone calls.

5.3.4.4 Format and administration of data collection tools

In order to minimise inconvenience to the participant, text messages were sent prior to follow-up phone calls in order to establish a convenient time to call, as recommended in the literature (Ardern et al., 2012). The predictive tool (comprised of baseline predictive variables and outcome questionnaires) was made available to participants in multiple formats as an online, paper-based or verbal format completed over the phone. This approach aimed to maximise both the number of people who agreed to take part in the study and to minimise the drop-out rate of consented participants and was considered appropriate in the New Zealand setting. New Zealanders have high levels of access to internet in the developed world in that 91% of the population has access to the internet (Crothers, Smith, Urale, & Bell, 2016). Furthermore, 84% of the New Zealand population have access to a cell phone. Only 1.6% do not have access to any telecommunications at home (Statistics NZ, 2013). Furthermore, research has exhibited valid and reliable results when comparing electronic with paper based questionnaires (Bot, Menendez, Neuhaus, Mudgal, &

Ring, 2013) and phone with face-to-face recording (Palacín-Marín, Esteban-Moreno, Olea, Herrera-Viedma, & Arroyo-Morales, 2013). The WOSI, TSK, SPADI and SAS have also previously been administered over the telephone (Bouliane, Saliken, Beaupre, & Saraswat, 2014; Hovelius, Vikerfors, Olofsson, Svensson, & Rahme, 2011; Shymon, Roocroft, & Edmonds, 2015). The TSK has exhibited good reliability when used over the phone and compared to face-to-face recording (Cronbach's alpha = 0.977, with a mean difference between methods = -0.20 (95% CI (-0.93, 0.53)) (Palacín-Marín et al., 2013). The SPADI has also shown good internal consistency over the phone (Cronbach's alpha >0.92) (Hill, Lester, Taylor, Shanahan, & Gill, 2011). These authors also showed the SPADI to be a valid measure in a population-based study of people with shoulder pain. While the WOSI has been shown to be one of the most reliable, valid and responsive assessments of shoulder instability (du Plessis et al., 2018), no literature was available to demonstrate reliability between telephone and face-to-face interviewing for the WOSI. The use of electronic shoulder questionnaires has been found to produce valid and reliable results when compared with the paper-based format (Bot et al., 2013).

5.3.5 Phase 1 sample size

Prospective cohort studies investigating recurrent shoulder instability following a FTASD have recruited between 105-250 subjects (Hovelius et al., 2008; Robinson et al., 2006; Sachs et al., 2007). Since recurrence has been shown to vary by age group, the population in the current prospective cohort study were stratified by age in order to ensure appropriate numbers of people at each age strata were recruited into the study (Table 5.4).

The sample size calculation utilised estimates based upon Robinson et al. (2006), who reported mean recurrent shoulder instability following a FTASD to be 37.6% (95% CI (31.4, 43.7)). The current study was powered at 90% with a sample size of 84 participants and alpha at 0.05 to observe a recurrence rate of 50% from ages 15-20 and 21-25, and a 25% recurrence rate for age groups 26-30, 31-35, and 36-40 years respectively. Across the literature, age at the FTASD has been shown to be a consistent predictive variable for recurrent shoulder instability. Therefore, the sample size for this study was based upon the age of the participant, using the previous categories of Robinson et al. (2006). It was anticipated that 50% of people would drop-out of the study as the population in New Zealand is increasingly mobile. Migration in New Zealand also varies by age. Migration rates are high in people in their late teens and twenties as they move home for education or employment opportunities (Statistics New Zealand, 2016). These patterns of migration are long-standing in New Zealand and are also seen internationally (Statistics New Zealand, 2016). Therefore, a minimum of 127 participants were recruited in Phase 1. The incidence of shoulder dislocations in New Zealand was 3,886 for the years 2012-2013 (ACC, Peter Ng personal communication). Therefore, it was expected that if people who have sustained a FTASD made up between 20-25% of all dislocations, recruitment of all participants would take between 12 and 18 months.

Table 5.4 Sample size calculations for Phase 1 with age stratification based upon results of Robinson et al. (2006)

Ages (years)	**Recurrence rate (95% CI)±**	**N**	**Assumed recurrence rate**	**Sample size**	**Assuming a non-response rate of 50%¥**
15-20	52.0 (41.5-62.5)	92	50%	26	39
21-25	40.8 (29.6-52.1)	79	50%	26	39
26-30	15.9 (5.1-26.7)	47	25%	10	15
31-35	21.2 (7.3-35.3)	34	25%	11	17
36-40	Unknown	-	25%	11	17
TOTAL				84	127

N = number of participants. Power = 90%, alpha = 0.05, sides = 2

± Observed recurrence rate from the Robinson et al. (2006) study

¥ Adding 50% more to the sample size± to account for non-response rates

5.3.6 Phase 1 data and statistical analysis

Data were analysed using Statistical Package for the Social Sciences software (SPSS 24.0, IBM Corp., Armonk, NY, USA) and R 3.4.0. (R Core Team, Vienna, Austria). Descriptive data described the population. The aim of the analysis was to identify risk factors to be included in the predictive tool. Univariate risk factors were reported at levels of significance of both $p \leq 0.05$ and $p \leq 0.10$. It is useful to see the outcome of the univariate analysis reported at $p \leq 0.05$ for ease of comparison to other research. However, for the purposes of the development of the predictive tool, risk factors which reached statistical significance ($p \leq 0.10$) with regards to the prediction of recurrent shoulder instability were used to develop the multivariate tool. A p-value of 0.10 was chosen as the threshold for inclusion to enable to the tool to include all potential variables. Logistic regression was used to examine the association between the risk factor and recurrent shoulder instability at 12 months. Logistic regression was also used to plot the association between quality of life, function and kinesiophobia scales and factors within these scales. The coefficients of the regression were used to weight each variable in the tool (Courville & Thompson, 2001; Kraha, Turner, Nimon, Zientek, & Henson, 2012). The predictive tool was compiled with variables and weights, which were entered into a table. Collinearity was examined using correlations between continuous variables which were graded as negligible (0.0-0.3), low (0.3-0.5), moderate (0.5-0.7), high (0.7-0.9) and very high (0.9-1.00) (Mukaka, 2012). Variables which were correlated ($p > 0.50$) were removed from further analysis to prevent over-fitting of the model (Courville & Thompson, 2001) unstable estimates and inaccurate variances (Shen & Gao, 2008). Thus, variables which were moderately, highly and very highly correlated were removed. No new variables were added between Phase 1 and Phase 2 as Phase 2 was designed to assess the reliability and predictive validity of the tool developed in Phase 1. Additionally, no variables were omitted in Phase 2 as participants were recruited into Phase 2 immediately following Phase 1, before the analysis of the follow-up data.

5.4 Phase 2

The predictive validity of the tool was examined in this phase of the study.

5.4.1 Phase 2 participants

Identical inclusion and exclusion criteria were used as in Phase 1 (please refer to section 5.3.2).

5.4.2 Phase 2 recruitment process

The recruitment process was identical to that used in Phase 1 (please refer to section 5.3.3). Briefly, participants in this phase of the study had been identified as potentially eligible by ACC and the study had been introduced to potential participants by ACC. Recruitment, checking of eligibility and consenting was the responsibility of the researcher.

5.4.3 Phase 2 data collection

Phase 2 commenced at the conclusion of data collection in Phase 1 as no new variables would be added between Phase 1 and Phase 2. Participants were followed up with phone calls/email/letters in an identical manner to Phase 1 (please refer to section 5.3.4).

5.4.4 Phase 2 sample size

Increased power in a prospective cohort study results in a decreased chance of a Type II error, i.e. a decreased risk of finding no effect of the risk factors on recurrent shoulder instability (Akobeng, 2016). Therefore, using estimates based upon Robinson et al. (2006), who reported mean recurrence following a FTASD to be 37.6% (95% CI (31.4,43.7)), with a sample size of 131, and alpha at 0.05, the study was powered above 99% to observe a recurrence rate of 50% for ages 15-20 and 21-25 and 25% for age groups 26-30, 31-35 and 36-40 years respectively. As discussed in section 5.3.6., a 50% non-response rate was anticipated as the cohort was young, ethnically diverse and potentially mobile. Based upon loss to follow-up rates of 15% in Phase 1 of the study (which had already been completed), the sample size for Phase 2 was calculated based on a loss to follow-up of 15%. A total of 97 participants were therefore required for Phase 2 (Table 5.5).

Because separate populations are required to establish the validity of the tool, Phase 1 data and Phase 2 data were not pooled. Thus, the temporal validity of the tool could be examined (Altman & Royston, 2000).

Table 5.5 Sample size calculations for Phase II with age stratification based upon the data of Robinson et al. (2006)

Ages (years)	Recurrence rate (95% CI)±	N	Assumed recurrence rate	Sample size	Assuming a non-response rate of 15%¥
15-20	52.0 (41.5-62.5)	92	50%	21	25
21-25	40.8 (29.6-52.1)	79	50%	20	23
26-30	15.9 (5.1-26.7)	47	25%	16	9
31-35	21.2 (7.3-35.3)	34	25%	9	10
36-40	unknown	-	25%	9	10
TOTAL				75	97

N = number of participants. Power = 80%, alpha = 0.05, sides = 2

± Observed recurrence rate from the Robinson et al. (2006) study

¥ Adding 50% more to the sample size± to account for non-response rates

5.4.5 Phase 2 data analysis

Phase 2 examined the predictive validity and reliability of the tool developed in Phase 1. Data were gathered until there were sufficient participants in each category. The ability of the tool to discriminate between those who did not have any further episodes of instability and those who did have recurrent shoulder instability (i.e. predictive validity) was evaluated using receiver-operator characteristic (ROC) curve analysis. Estimates of sensitivity, specificity, and positive and negative predictive values with 95% confidence intervals were calculated for each potential decision threshold of the scoring system (Kumar & Indrayan, 2011; Riffenburgh, 2012). The cut-off point for the tool was chosen as the point of the ROC curve with the best sensitivity and specificity (i.e. the point in the upper most left corner of the ROC curve) (Kumar & Indrayan, 2011).

5.5 Ethics

Ethical approval for Phase 1 and 2 was sought from both the Auckland University of Technology Ethics Committee (AUTEC) and the ACC Research Ethics Committee. Approval from AUTEC was achieved on 12 May 2015 (Appendix L) and from ACC on 11 May 2015 (Appendix M). Subsequent amendments were also sought from AUTEC (Appendix N), as the frequency of data recruitment initially changed from monthly recruitment, which ACC had initially agreed, to quarterly.

5.5.1 Ethical and cultural issues

While this research did not specifically target Māori and Pacific participants, research within a New Zealand population involves both Māori and Pacific people (Hudson, Milne, Reynolds, & Russell, 2014). Additionally, shoulder dislocations in contact sports such as rugby league may have potentially increased the involvement of Māori and Pacific people as rugby and rugby league have been shown to have high percentages of involvement from these ethnicities (New Zealand Government, 2017). Therefore, the four requirements of working in line with the Te Ara Tika document from the Health Research Council of New Zealand were considered (Hudson et al. (2014). With respect to the first principle of Tika (Research Design), this project was considered mainstream since it did not specifically target a particular cultural, ethnic or community group. Other principles include Manaakitanga (Cultural and Social Responsibility), Whakapapa (Relationships), and Mana (Justice and Equity) and these principles were incorporated into the study design as described below.

The three principles of the Treaty of Waitangi (partnership, participation and protection) were observed in the following ways. The principle of partnership requires consultation and action in honesty and good faith (Hudson et al., 2014). Consultation with health providers working in Māori, Pacific and Asian communities was undertaken to ensure that all communication and gathering of data was culturally appropriate. An effort was made to learn the correct pronunciation of Māori, Pasifika and Asian names. Consultation was also undertaken with the Mātaurangi Māori Committee (an Auckland University of Technology research committee) and with Māori, Pacific and Asian people following a FTASD. The appropriateness of text messaging people following a FTASD was discussed as was the timing of phone calls. Phone calls were not made on a Sunday morning when potential participants may have been attending religious ceremonies.

The principle of participation was addressed by including all those who were eligible and consenting irrespective of ethnicity. All potential participants received information about the study and had the opportunity to ask the lead researcher any questions during the initial telephone conversation and to decide if they wished to take part. Collecting data via telephone interview or online questionnaires would also have enhanced participation. The language of the information sheet and all communications was clear and simple so that everyone, irrespective of reading ability would be able to comprehend the instructions and easily understand the content. The principle of protection was addressed by the provision of confidentiality of the participant information. The medical records accessed by the researcher were kept on a secure password protected spreadsheet and any hard copies of the medical notes were shredded.

Participants entered the study after they had been invited by ACC via a letter and once they had provided informed consent to the researcher. Consent from the participant was gained only after they had been informed of the study by the researcher and had the opportunity to ask any questions. Privacy of the participant was assured as only the researcher and research assistants were aware of the participant's name and contact details. Additionally, each participant was allocated a unique identification number. Any information which may have identified participants was not shown to any other person, and this information will be destroyed 10 years after the data being collected, in keeping with the New Zealand Health Information Privacy Code (1994) (New Zealand Privacy Commisioner, 1994).

The letter from ACC to the participant may have been perceived by the person that ACC has a financial interest in their outcome. Therefore, the information letter, and the researchers clearly stated they were from Auckland University of Technology; every effort was made to reassure the participant that the researchers were independent from ACC and that involvement in the research would not affect their medical care. Additionally, it was explained to the participant that the telephone conversations were confidential between the researcher and the participant and that no data would be shared with ACC.

Chapter 6 The development of a tool to predict recurrent shoulder instability in first-time traumatic anterior shoulder instability

6.1 Preface

This chapter relates to Aim 2 of the thesis: to develop a predictive tool which can differentiate between people at increased risk of having a recurrent shoulder instability and people who will not develop recurrent shoulder instability in a population of people with FTASD who are managed conservatively.

Although many prospective cohort studies have been undertaken to predict recurrent shoulder instability after a FTASD, only one (Murray et al., 2013) has developed an algorithm for clinicians. This algorithm was primarily based upon the work of Robinson et al. (2006) and predominantly uses age and sex to decide a clinical pathway. Furthermore, the outcome of recurrent shoulder instability and a decision to undergo surgical stabilisation are interpreted as synonymous in this algorithm, when it is known that up to 1/3 of people following a FTASD will become stable over time (Hovelius et al., 2008). This study aimed to include all known risk factors into a tool that can be used by clinicians to inform people with a FTASD regarding the likelihood for recurrent shoulder instability.

As previously discussed, children represent a unique group within the population of people with a FTASD. Ethical considerations such as assent and parental consent were difficult to navigate over the telephone. Despite high rates of recurrent shoulder instability in children, we were unable to gain ethical consent to include children in the larger prospective study. This study therefore only pertains to the prediction of recurrent shoulder instability after a FTASD in adults over the age of 16 years.

In relation to this aim, a prospective cohort study in adults was undertaken, which examined the ability of risk factors gathered at baseline to predict recurrent shoulder instability 12 months following injury. Variables were examined and those with significant associations from univariate analyses ($p \leq 0.10$) were collated into a multi variate predictive tool.

The contents of this chapter have been accepted by the *British Medical Journal Open Sports and Exercise Medicine* (Olds, Ellis, Parmar and Kersten, 2019). Therefore, the presentation of this chapter is in line with the criteria stipulated by this journal with some editorial changes in accordance with presenting this formal thesis. http://dx.doi.org/10.1136/bmjsem-2018-000447

6.2 Predicting recurrent shoulder instability following a first-time traumatic anterior shoulder dislocation: A multivariate model

6.2.1 Abstract

Objective: The ability to predict recurrent shoulder instability following a FTASD enables clinicians to discuss with patients appropriate and relevant management for their injury. We aimed to develop a multivariate tool that would predict recurrent shoulder instability after a FTASD.

Methods: Participants aged 16 to 40 years, were recruited across New Zealand into a prospective cohort study. Baseline data were collected during a telephone interview and through examination of radiology records. Variables associated with recurrent shoulder instability were selected for the multivariate logistic regression model using backwards selection (p<0.10). Coefficients for those variables retained in the model were used to develop the predictive tool.

Results: One hundred and twenty-eight participants were recruited. Overall rate of recurrent shoulder instability at 12 month follow-up was 35.9%. Univariate analysis showed an increased likelihood of recurrent dislocation with the presence of an associated bony Bankart lesion (OR=3.65, 95% CI (1.05 - 12.70), p=0.04), those not immobilised in a sling (OR=0.38, 95% CI (0.15 - 0.98), p=0.05), higher levels of shoulder activity (OR=1.13, 95% CI (1.01 - 1.27), p=0.03), higher levels of pain and disability (OR=1.03, 95% CI (1.01 - 1.06), p=0.02), higher levels of kinesiophobia (OR=1.12, 95% CI (1.01 - 1.26), p=0.04) and decreased quality of life (OR=1.01, 95% CI (1.00-1.02), p=0.05). There was a trend towards decreased risk of recurrent shoulder instability in those with non-dominant shoulder dislocations (p=0.10) and increased risk of recurrent shoulder instability in those aged 16-25 years (p=0.07).

Conclusion: Physical and psychosocial factors can be used to predict recurrent shoulder instability following a FTASD. These factors can be used to develop a tool which may predict recurrent shoulder instability after a FTASD. Further validation of this tool is required in a separate population of people following a FTASD.

Keywords: Shoulder instability, recurrent instability, dislocation

6.2.2 Introduction

The incidence of FTASD has been reported as 23.1 per 100,000 person-years (Leroux et al., 2014) with increased dislocation rates in contact athletes (Owens, Agel, et al., 2009). Recurrent instability following a FTASD ranges from 26% (te Slaa et al., 2004) to 92% (Postacchini et al., 2000). This wide variation may be explained by the heterogeneous populations in these studies with regards to study location, different health-care systems and age of participants (Murray et al., 2013).

Risk factors for recurrent shoulder instability following a FTASD have been described in recent systematic reviews and meta-analyses (Olds et al., 2016, 2015; Wasserstein et al., 2016). These risk factors may be categorised as either modifiable or non-modifiable. Modifiable risk factors include manual occupations (Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993), occupations where the upper limb is used above shoulder height (Sachs et al., 2007), immobilisation following the dislocation (Hoelen et al., 1990), involvement in collision sport (Robinson et al., 2006) and time to return to sport (Robinson et al., 2006). Psychosocial factors such as higher levels of pain (Parr et al., 2014) and kinesiophobia (Bot et al., 2005; Lentz et al., 2009) may also be modifiable risk factors. Non-modifiable risk factors include greater tuberosity fractures (Hoelen et al., 1990; Kralinger et al., 2002; Robinson et al., 2006; te Slaa et al., 2004; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993), Hill Sachs lesions (Hoelen et al., 1990; Kralinger et al., 2002; Salomonsson et al., 2010), bony Bankart lesions (Hoelen et al., 1990; Pevny et al., 1998;

Salomonsson et al., 2010; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993), axillary nerve palsy (Pevny et al., 1998; Robinson et al., 2006), age (Hoelen et al., 1990; Kralinger et al., 2002; Pevny et al., 1998; Salomonsson et al., 2010; te Slaa et al., 2004; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993), sex (Hoelen et al., 1990; Robinson et al., 2006; te Slaa et al., 2004; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993), and hypermobility (Robinson et al., 2006; Salomonsson et al., 2010).

While knowledge of individual risk factors is important in clinical practice, prognostic models use multiple predictive factors to calculate risk of recurrent shoulder instability in individual patients (Steyerberg et al., 2013). Current clinical practice is transitioning towards the personalisation and customisation of care based upon evolving evidence (Federer et al., 2013). Customisation of health care has associated increased costs of additional communication, cognition, coordination and capability (Benning et al., 2012; Federer et al., 2013). However, these costs can be minimised by using decision-making aids which enable patients and clinicians to make informed choices regarding their healthcare.

Decision-making tools and algorithms have been developed to assist clinicians and to enable patients with shoulder instability to make informed choices about their healthcare (Ahmed et al., 2012; Balg & Boileau, 2007; Bishop et al., 2011; Calvo et al., 2005; Crall et al., 2012; Emond et al., 2004; Mather et al., 2011; Piasecki et al., 2009; van Kampen et al., 2013). Of these, two tools have been developed to predict outcomes or management for people with a FTASD (Mather et al., 2011; Murray et al., 2013). These tools primarily use age and sex to predict recurrent shoulder instability (Mather et al., 2011; Murray et al., 2013). Incorporation of other known significant risk factors into a prognostic model would improve the accuracy of identifying those more likely to have recurrent instability and enhance clinical decision-making for people following a FTASD.

Currently, there is a lack of high quality prospective studies examining risk factors for recurrent shoulder instability following a FTASD (Olds et al., 2016, 2015). This study aimed to develop a multivariate predictive tool, which can be used to predict recurrent shoulder instability, based upon known risk factors. It was hypothesised that key variables, in addition to the established variables of age and sex (Robinson et al., 2006), would predict recurrent shoulder instability following a FTASD.

6.2.3 Methods

6.2.3.1 Design and Setting

This prospective cohort study was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cohort studies (see Appendix O). The study was approved by the Auckland University of Technology (approval number 14/256) and ACC (approval number 272) ethics committees (see Appendix L and M respectively). Consultation with two orthopaedic surgeons, two sports physicians and two physiotherapists, who had a special interest in shoulder pathology, was undertaken to examine previously reported risk factors (Olds et al., 2015) and determine whether additional variables of perceived clinical importance could be identified. Following this consultation, the variables identified from the meta-analysis (Olds et al., 2015) and the clinical team were combined to form the beta-version of the clinical prediction tool (see 5.3.1).

6.2.3.2 Participants

A prospective study was undertaken with people who had suffered a FTASD to examine the risk factors which predisposed them to recurrent shoulder instability or protected them from further instability. The inclusion and exclusion criteria have been described in section 5.3.2.

Participants were excluded if they had undergone surgical intervention for their current shoulder injury within 12 weeks of the injury as they were no longer able to demonstrate the natural history of a FTASD (n=3). Participants were also excluded if they reported a previous shoulder instability episode or other shoulder pathology such as impingement/acromio-clavicular joint (ACJ) disruption at the initial interview (n=43) or showed radiological evidence of a previous shoulder instability episode in a subsequent radiological report (n=15). Radiological evidence also excluded those who demonstrated pathology other than an anterior dislocation (n=18). People who did not speak conversational English (n=2) were excluded (as they would be unable to participate in the telephone interview).

6.2.3.3 Recruitment procedure

Please refer to 5.3.3 for the recruitment procedure along with reference to Figure 6.1.

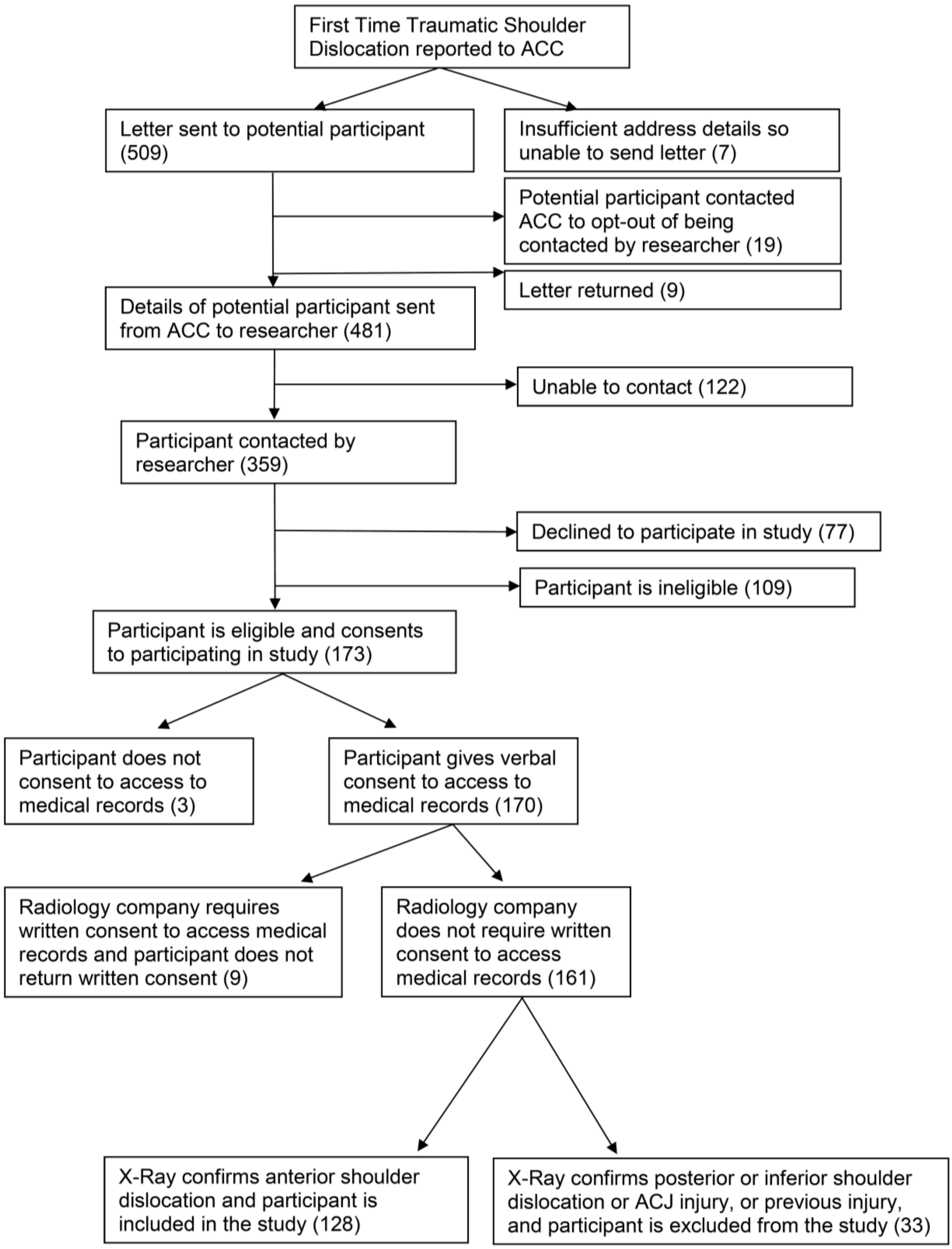

Figure 6.1 Flow of people through the study

6.2.3.4 Participant involvement

People with a FTASD were not involved in setting the research question or study design. They were included in the development of the tool to be tested as research participants. Dissemination to participants took the form of an email summarising the main results.

6.2.3.5 Data Collection

6.2.3.5.1 Baseline Data

Following consent and inclusion in the study, participants completed the beta-version of the tool either verbally over the phone, online via an internet hosted version (URL link provided by email) or using a paper version that was posted. The beta-version of the tool recorded participants' primary predictive variables including age, sex, height, weight, ethnicity, hand dominance, side of dislocation, occupation, family history of instability, self-reported hypermobility, period of immobilisation and number of physiotherapy sessions attended after their injury (Table 6.1). Operational definitions of these variables are provided in Table 6.3. Ethnicity was categorised as per New Zealand statistics (Ministry of Health, 2004) with up to six ethnic categories recorded and the minority ethnicity coded if the alternate was NZ European. Mechanism of injury was categorised as sports injuries, motor vehicle accidents (MVA), assault, fall, or other (Robinson et al., 2006). Falls that occurred during sporting activities were classified as sports injuries.

Table 6.1 Variables obtained from initial contact with participants

Demographic	**Clinical**	**Sport**	**Secondary Variables**
Age	X-Ray	Level of sport	Quality of life (WOSI)
Sex	Bony Bankart	Position played sport	Pain and function (SPADI)
Patient estimated height	Greater tuberosity fracture	Hours per week	Kinesiophobia (TSK-11)
Patient estimated weight	Hill Sachs	Time to return to sport	Shoulder Activity Scale (SAS)
Hand dominance	Ultrasound– Rotator cuff tear	Type of sport (collision vs. overhead)	
Side affected	Ultrasound - Bursitis		
Occupation	Ultrasound– Haemarthrosis		
Ethnicity			
Family history			
Hypermobility			
Period of immobilisation			
Physiotherapy sessions			

Secondary variables such as quality of life, level of shoulder activity, shoulder function, and kinesiophobia were measured with the WOSI (Kirkley et al., 1998), SAS (Brophy et al., 2005), SPADI (Roach et al., 1991) and TSK-11 (Woby et al., 2005) respectively (Table 6.2). Radiology records were reviewed to confirm an anteriorly directed shoulder dislocation and to confirm the presence of associated bony pathology. Radiology records that confirmed a dislocation in a direction that was not anterior or confirmed ACJ disruption or clavicle fracture, resulted in participant exclusion. Those participants whose shoulder was reduced prior to X-Ray and showed no evidence of another shoulder pathology or posterior/inferior dislocation were included in the study.

Table 6.2 Descriptive data of continuous variables

	N	Minimum	Maximum	Mean	s.d.
Age (years)	128	16	40	24.63	7.10
Height (cm)	127*	154	198	179.00	8.71
Weight (kg)	128	50	128	82.95	16.31
Body Mass Index	127	18	41	25.72	4.41
SPADI – Total	128	0	89	18.41	17.30
SPADI-Pain	128	0	76	15.77	15.38
SPADI-Function	128	0	93	15.33	17.68
TSK-11	128	16	37	26.74	3.88
WOSI-Total	128	0	166	78.16	46.31
WOSI-Physical	128	0	80	33.44	20.84
WOSI-Life	128	0	39	16.46	10.73
WOSI-Recreation	128	0	35	13.27	10.46
WOSI-Emotion	128	0	30	14.95	8.28

*One participant was unable to recall his exact height, SPADI = Shoulder Pain and Disability Index, TSK-11 = Tampa Scale of Kinesiophobia 11, WOSI = Western Ontario Shoulder Instability Index

6.2.3.5.2 Follow-up data

Follow-up phone calls were made regularly at 3, 6, 9 and 12 months following the date of injury, by research assistants blinded to baseline variables to limit recall and experimenter bias. When the participants preferred to be contacted by email, they were emailed with a link to the online version of the tool. Participants who reported recurrent shoulder instability at the time of the phone call were not contacted further and recorded as having recurrent shoulder instability at all future time points through to 12 months follow-up.

The primary outcome was recurrent instability of the previously dislocated shoulder within 12 months of the FTASD. For the definition of 'recurrent instability' used in this study please refer to 5.3.4.3. Research assistants with a health background were trained to identify recurrent instability events (Table 6.3), and discussions of individual cases were undertaken at regular meetings to reach a consensus when there was uncertainty regarding the instability event.

Some studies (Marshall et al., 2017; Polyzois, Dattani, Gupta, Levy, & Ali Narvani, 2016) have advocated primary surgical intervention in this population of people following a FTASD, which would occur within the 12 month timeframe. One year follow-up was used to study the shorter term impact of a FTASD as approximately 70% of all dislocations that occur take place within 12 months (Robinson et al., 2006). Additionally, this study was designed to elucidate variables, which can be used to predict recurrent shoulder instability for the development of a multivariate prediction tool. It was not envisaged that these variables would alter beyond the first year of follow-up. For these reasons follow-up was limited to one year following a FTASD.

6.2.3.6 Sample Size

For a detailed description of the sample size calculation, please refer to 5.3.5. In summary, the study was powered at 90% with a sample size of 84 participants and alpha at 0.05 to observe a recurrence rate as found by Robinson et al. (2006) of 50% for those aged 15-20 and 21-25; and a 25% recurrence rate for those in age groups 26-30, 31-35, and 36-40 years (Table 6.3). It was anticipated that 50% of patients would drop-out of the study as the population was young and mobile. Therefore, a minimum of 127 participants were required for recruitment.

Table 6.3 Sample size calculation based upon Robinson et al. (2006)

Robinson et al. (2006)			**Assumptions to power this study at 90%**		
Age (years)	**Recurrence rate (95% CI)** ±	**N**	**Recurrence rate**	**Sample size**	**Assuming a non-response rate of 50%¥**
16-20	52.0 (41.5-62.5)	92	50	26	39
21-25	40.8 (29.6-52.1)	79	50	26	39
26-30	15.9 (5.1-26.7)	47	25	10	15
31-35	21.2 (7.3-35.3)	34	25	11	17
36-40	Unknown	-	25	11	17
TOTAL				84	127

Power = 90%, alpha=0.05, sides =2, ± Observed recurrence rate from Robinson et al. (2006)

¥ Adding 50% more the sample size to account for the non-response rates

6.2.3.7 Data and Statistical Analysis

For a detailed description of the statistical analyses used in Phase 1, please refer to 5.3.6. In summary, univariate logistic regression models were used to identify significant risk factors predictive of recurrent shoulder instability ($p \leq 0.10$) for inclusion in the development of the multivariate tool. Traditional levels of significance (such as $p \leq 0.05$) can exclude variables known to be important (Bendel & Afifi, 1977; Bursac, Gauss, Williams, & Hosmer, 2008), hence $p \leq 0.10$ was used. Multivariate logistic regression models were used to identify the combined effect of variables for recurrent shoulder instability. Beginning with a model containing all statistically significant variables from the univariate analyses, and any additional variables deemed clinically relevant, the final model was produced after applying backwards selection process until all remaining variables were significant to $p \leq 0.10$. This lower cut-off was the statistical threshold used to identify when variables should be retained in a multivariate model (when other variables were being adjusted for) (Bursac et al., 2008). Coefficients for those variables retained in the multivariate model were used to develop the predictive tool (Courville & Thompson, 2001; Kraha et al., 2012).

6.2.4 Results

6.2.4.1 Recruitment and participant demographics

One hundred and twenty-eight participants (110 males) were recruited from 441 people who had a FTASD from May 2015 to February 2016 (Figure 6.1). Forty-nine (38.3%) participants were aged between 16-20 years, 30 (23.4%) between 21-25 years, 18 (14.1%) between 26-30 years, 17 (13.3%) between 31-35 years, and 14 (10.9%) between 36-40 years. Baseline outcomes for demographic variables and secondary outcome measures are displayed in Table 6.2.

There were 110 (85.9%) right hand dominant participants, and the right shoulder was affected in 72 (56.3%) participants. The dominant limb was affected in 63 (49.2%) participants. The ethnicity of participants was similar to the distribution of ethnicity in New Zealand (Table 6.4) (Statistics New Zealand, 2015).

Table 6.4 Ethnicity of participants

Ethnicity	N	Mean age	Overall Rate of Recurrent instability	Recurrent Instability	No recurrent Instability	Loss to follow-up
Asian	7	25.7	42.7%	3	4	0
European Other	14	32.9	15.4%	2	12	0
NZ European	71	24.7	45.9%	28	33	10
NZ Māori	19	27.1	57.1%	8	6	5
Other	2	22.5	50.0%	1	1	0
Pasifika	15	22.5	33.3%	4	8	3

NZ = New Zealand

There were 51 (39.8%) manual workers and 77 (60.2%) sedentary workers. There were 35 (27.3%) participants who participated in occupations above shoulder height, while 93 (72.7%) participants were involved in occupations at shoulder height or below. Twenty-two (17.2%) participants had a family history of shoulder dislocation and 105 (82.2%) participants did not have a family history of shoulder dislocation (1 dataset missing). Thirty-one (24.2%) participants self-reported generalised hypermobility. The majority of participants (103; 80.5%) were immobilised following the dislocation, 24 (18.8%) were not immobilised, and one participant did not recall their immobilisation status. Most participants (92; 71.9%) had received physiotherapy treatment while 35 (27.3%) had not, and one did not recall.

The most common mechanism of injury was a sports injury (95; 74.2%), followed by a fall (13; 10.1%), other mechanism (12; 9.3%), MVA (4; 3.1%), and assault (4; 3.1%). Because of the small number of MVAs and large variance, they were grouped with “other” for univariate analysis. There were 33 (25.8%) participants whose injury was not sport related. Of the 95 (74.2%) participants whose injury was sports related, 87 (91.6%) were recreational athletes and 8 (8.4%) were semi-professional or professional. Of the 95 participants who identified a sports injury, 52 (54.7%) were involved in contact sport, 25 (26.3%) were involved in limited contact sports, and 18 (18.9%) were involved in non-contact sports, using the classification by Rice (2008). At the time of injury, 38 of the 52 (73.1%) participants reporting contact injury were involved in collision sports. Rugby union, football, towed water-sports (e.g. water-skiing) and skateboarding all had a rate of recurrent instability of 50% or above. With regards to pathological injuries, there were 2 (1.6%) greater tuberosity fractures, 13 (10.2%) bony Bankart lesions, and 36 (28.1%) Hill Sachs lesions.

6.2.4.2 Recurrent Instability

At 12 months following their injury, 46 (35.9%) participants had an episode of recurrent shoulder instability, 64 (50.0%) participants had no episode of instability, and 18 (14.1%) participants were lost to follow-up. The greatest recurrence occurred in those aged 16 to 25 (Figure 6.2).

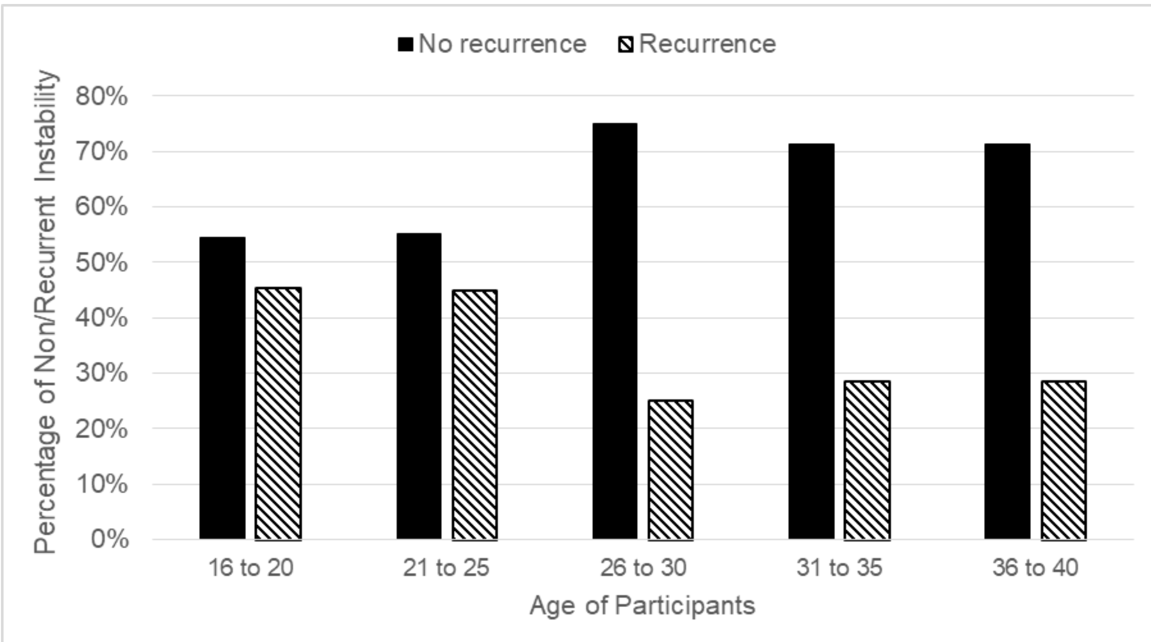

Figure 6.2 Rate of recurrent shoulder instability at 12 months after a FTASD stratified by age

6.2.4.3 Univariate analysis

The relationship between the baseline variables included in the beta-version of the model and recurrent shoulder instability is displayed in Table 6.6. Statistically significant univariate baseline predictors ($p \leq 0.05$) of recurrence at 12 months were: bony Bankart lesion ($\beta=1.29$, $p=0.04$); not being immobilised ($\beta=0.97$, $p=0.05$); ethnicity that was not European Other ($\beta=1.63$, $p=0.04$) (where European Other refers to people who are of European descent but not born in New Zealand), SAS (shoulder activity level) ($\beta=0.13$, $p=0.03$), TSK–11 (kinesiophobia) ($\beta=0.12$, $p=0.04$), and WOSI (quality of life) total score ($\beta=0.01$, $p=0.05$); two subsections of the WOSI (Physical ($\beta=0.02$, $p=0.03$), and Emotion ($\beta=0.07$, $p=0.01$)), total scores for SPADI (shoulder pain and disability) ($\beta=0.03$, $p=0.02$) and the SPADI Function score ($\beta=0.04$, $p=0.01$).

Identifying with an ethnicity of ‘European Other’ was associated with decreased risk ($p=0.04$) of recurrent shoulder instability. Examples of ‘European Other’ included Australian, South African, English and German people. The people in this ethnic group tended to be older (mean = 31 years, s.d. (6.4)), and had migrated to New Zealand from other countries. People identifying with European Other were significantly older than for New Zealand European and Pasifika groups ($p<0.05$). Shoulder activity level was similar across ethnicities ($p>0.05$).

When groups of ethnicities were investigated, there was a trend towards increased recurrent shoulder instability in people who belonged to the combined group of ethnicities of New Zealand European, New Zealand Māori, or Pasifika ($p=0.09$). This combined group was significantly younger in age when compared with others (mean = 23.78 (6.79) compared with 28.52 (7.32); $F=8.94$, $p=0.003$). Again, there was no difference in shoulder activity level between these ethnic groups.

People immobilised for 25 days or more were more likely to have recurrent shoulder instability when compared to those immobilised for less than 25 days. There was no statistically significant difference in initial pain scores, pain at the time of data collection, SPADI pain scores, kinesiophobia scores, nor frequency of bony Bankart lesions, Hill Sachs lesions or greater tuberosity fracture between people immobilised for 25 days or more and others.

Sex was not a statistically significant risk factor for recurrent shoulder instability (β=0.16, p=0.79). Women who had a FTASD had significantly increased levels of shoulder activity (SAS) when compared with men (F=20.964, p<0.01, t=-1.782). There was no statistically significant difference between sexes with regards to manual or sedentary occupations; kinesiophobia (TSK-11); SPADI Total, Pain or Function sub-scores; or WOSI Total or sub-scores.

Those aged between 16 and 25 years showed a trend towards increased rates of recurrent shoulder instability over the 12 months when compared with people aged 26-40 years (β=0.74, p=0.07). People who were aged 16-25 years were more likely to be in a sedentary occupation, and more likely to be involved in contact sport (Chi square = 13.64, p<0.001). Additionally, our study showed a weak correlation between increasing age and increasing levels of shoulder activity (r=0.402, p<0.001).

Associations between patient reported outcomes were explored and categorised (Mukaka, 2012). There was a statistically significant high correlation between the SPADI and WOSI scores (r=0.72, p<0.001), a statistically significant moderate correlation between TSK-11 and WOSI (r=0.53, p<0.01) and a statistically significant weak correlation between SPADI and TSK-11 scores (r=0.39, p<0.01). There was no correlation between baseline levels of shoulder activity (SAS) and levels of quality of life (WOSI), shoulder pain and disability (SPADI) or kinesiophobia (TSK-11). Furthermore, shoulder activity did not vary between manual/sedentary occupations (F=0.430, p=0.51, t=-1.102). However, our study showed a weak correlation between increasing age and increasing levels of shoulder activity (r=0.402, p<0.001). With regards to kinesiophobia (TSK-11), there was no association with the presence of a bony Bankart lesion, age or pain at the time of injury. There were weak statistically significant correlations between TSK-11 and pain at the time of data collection (r=0.21, P=0.02).

Table 6.5 Univariate analysis of baseline variables which predict recurrent shoulder instability

	Regression Coefficient	Standard Error	p value	Odds ratio	95% confidence interval
Bony Bankart**	1.29	0.64	0.04	3.65	1.05 - 12.70
Hill Sachs Lesion	0.37	0.43	0.38	1.45	0.63 - 3.35
Age	-0.05	0.03	1.07	0.96	0.90 - 1.10
16-20 vs other	-0.54	0.40	0.17	0.58	0.27 - 1.27
21-26 vs other	-0.23	0.45	0.61	0.79	0.33 - 1.92
26-30 vs other	0.78	0.62	0.21	2.18	0.65 - 7.34
31-35 vs other	0.42	0.59	0.48	1.52	0.48 - 4.79
36-40 vs other	0.41	0.65	0.53	1.50	0.42 - 5.32
16-25 vs other*	0.74	0.41	0.07	2.10	0.94 - 4.72
Sex	-0.16	0.61	0.79	0.85	0.36 - 3.84
Height	-0.00	0.02	0.87	1.00	0.95 - 1.04
Weight	0.01	0.01	0.40	1.01	0.99 - 1.04
BMI	0.04	0.05	0.36	1.04	0.95 - 1.14
Ethnicity					
Asian	-0.05	0.79	0.95	0.96	0.20 - 4.50
European Other**	-1.63	0.79	0.04	5.08	1.08 - 23.92
NZ European	-0.38	0.39	0.33	0.68	0.32 - 1.48
NZ Māori	0.71	0.58	0.22	2.04	0.65 - 6.33
Other	0.34	1.43	0.81	1.40	0.09 - 22.98
Pasifika	0.41	0.65	0.53	1.50	0.42 - 5.32
Ethnic Group: Other vs. NZEuro/NZ Māori /Pasifika*	-0.88	0.52	0.09	0.415	0.15 - 1.15
Limb Side					
Dominance	-0.98	0.69	0.16	0.38	0.10 - 1.46
Side Affected	-0.47	0.40	0.23	0.62	0.29 - 1.35
Dominant Affected*	0.63	0.39	0.10	1.877	0.87 - 4.06
Occupation					
Manual Sedentary	0.30	0.40	0.46	1.34	0.62 - 2.94
Overhead Below Shoulder	0.55	0.44	0.21	0.58	0.25 - 1.36
Family History	0.07	0.51	0.90	1.07	0.40 - 2.87
Hypermobile	0.49	0.45	0.27	0.61	0.25 - 1.47

	Regression Coefficient	Standard Error	p value	Odds ratio	95% confidence interval
Mechanism					
Sports	0.06	0.44	0.90	1.06	0.45 - 2.52
Assault	-0.34	1.02	0.74	0.71	0.10 - 5.23
Other/MVA	0.67	0.63	0.29	0.54	0.15 - 1.76
Falls	-0.81	0.68	0.23	0.44	0.12 - 1.68
Immobilised**	-0.97	0.48	0.05	0.38	0.15 - 0.98
Physio	0.25	0.43	0.56	0.78	0.33 - 1.81
Sport					
Contact vs other	-0.74	0.47	0.11	0.48	0.19 - 1.19
Collision vs other	-0.69	0.46	0.13	0.50	0.20 - 1.23
Limited Contact vs other*	-0.97	0.58	0.09	0.38	0.12 - 1.17
Non-contact vs other	0.07	0.58	0.90	1.08	0.34 - 3.37
Sports Prof / Recreation	-0.40	1.03	0.70	0.67	0.09 - 5.04
SAS Contact Y/N*	0.72	0.40	0.07	2.05	0.94 - 4.46
OH vs Non-OH	-0.33	0.50	0.51	0.72	0.27 - 1.90
Global Rate of Change	-0.02	0.01	0.18	0.98	0.96 - 1.01
SAS**	0.13	0.06	0.03	1.13	1.01 - 1.27
Pain - Initial	0.03	0.07	0.71	1.03	0.90 - 1.17
Pain - Now	0.15	0.11	0.15	1.16	0.95 - 1.43
SPADI - Total**	0.03	0.01	0.02	1.03	1.01 - 1.06
SPADI - Pain*	0.03	0.01	0.06	1.03	1.01 - 1.06
SPADI - Function**	0.04	0.02	0.01	1.04	1.01 - 1.07
TSK - 11**	0.12	0.06	0.04	1.12	1.01 - 1.26
WOSI - Total**	0.01	0.01	0.05	1.01	1.00 - 1.02
WOSI - Physical**	0.02	0.01	0.03	1.02	1.00 - 1.04
WOSI - Life*	0.03	0.02	0.10	1.03	0.99 - 1.08
WOSI - Recreation	0.01	0.02	0.69	1.01	0.97 - 1.05
WOSI - Emotion**	0.07	0.03	0.01	1.07	1.02 - 1.13

*= significant at $p \leq 0.10$ and taken forward to multivariate tool, ** statistically significant at $p \leq 0.05$,

BMI = Body Mass Index, NZ = New Zealand, MVA = Motor Vehicle Accident, Prof = professional, SAS = Shoulder Activity Scale, SPADI = Shoulder Pain and Disability Index, TSK-11 = Tampa Scale of Kinesiophobia 11, WOSI = Western Ontario Shoulder Instability Index

6.2.4.4 Multivariate analysis.

Results of the multivariate analysis using backwards stepwise regression are shown in Table 6.6. Variables were retained in the model if p<0.10, after adjusting for other significant risk factors of recurrent shoulder instability. Risk of recurrent shoulder instability at 12 months was predicted using both demographic, physical and psychosocial factors.

Based on the multiple regression equation:

$$Y = a + b_i X_i$$

Where;

Y = the outcome being predicted (e.g. recurrent instability)

a = the intercept value ("Constant" as listed in Table 6.6)

b = the partial slope of the linear relationship between independent variable X and the outcome Y (the regression coefficients as listed in Table 6.6)

X = the independent variable (risk factor)

The following risk of recurrent shoulder instability at 12 months post-injury was formulated:

$$Risk\ of\ recurrence = -4.73 + 1.06\ (Age\ 16 - 25\ years) +$$

$$1.80\ (bony\ Bankart\ Lesions) + 0.80\ (Dominant\ side\ affected)$$

$$-1.27\ (Immobilised) + 0.03\ (SPADI\ TOTAL) + 0.13\ (TSK - 11\ TOTAL)$$

Table 6.6 Multivariate analysis of variables which predict recurrent shoulder instability

	Regression Coefficient	**Standard Error**	**p value**	**Odds ratio**	**95% confidence interval**
Bony Bankart*	1.798	0.746	0.016	6.040	1.40-26.062
Age16-25 vs other*	1.062	0.482	0.028	2.892	1.124-7.439
Dominant Affected**	0.801	0.454	0.077	2.227	0.916-5.418
Immobilised*	-1.270	0.571	0.026	0.281	0.092-0.859
SPADI - Total*	0.033	0.015	0.031	1.034	1.003-1.066
TSK - 11**	0.133	0.071	0.061	1.142	0.994-1.313
Constant	0.061	1.142	0.016	0.009	

* = significance at p≤0.05, ** = significance at p≤0.10

SPADI = Shoulder Pain and Disability Index, TSK-11 = Tampa Scale of Kinesiophobia 11

The equation above can be used to calculate a continuous score based on these variables. It shows that those with a bony Bankart lesions were at higher risk of having recurrent shoulder instability within 12 months of a FTASD (OR=-6.04, p=0.02). Those who were aged between 16 and 25 years were also at increased risk of recurrent shoulder instability (OR=2.89, p=0.03). With regards to modifiable risk factors, people who had a shoulder dislocation on their affected side (OR=2.23, p=0.07), high levels of shoulder pain and dysfunction (OR=1.03, p=0.03) and high levels of kinesiophobia (OR=1.12, p=0.06) were at increased risk of recurrent shoulder instability. People who were immobilised following their FTASD were less likely to experience recurrent shoulder instability (OR=0.28, p=0.03). In summary, non-modifiable factors (including bony Bankart lesions and age) and modifiable factors (including hand dominance, being immobilised after a shoulder dislocation, kinesiophobia and shoulder pain and disability) can be used to predict recurrent shoulder instability.

6.2.5 Discussion

This prospective cohort study was undertaken to develop a multivariate tool which can predict shoulder instability following a FTASD. The findings from this study concluded a positive relationship between psychosocial factors and self-reported pain and function near the time of injury, with recurrent shoulder instability following a FTASD. Psychosocial variables are common sequelae of a FTASD (Dickens et al., 2014). However, in this population kinesiophobia, self-reported pain and disability also identified those who were most at risk of further instability events at 12 month follow-up.

6.2.5.1 Variables associated with recurrent shoulder instability

Similar to other studies (Hovelius et al., 1996; Robinson et al., 2006) our findings show that being aged between 16 and 25 years was associated with increased rates of recurrent shoulder instability following a FTASD. While not statistically significant as a standalone variable following univariate analysis (p=0.07), age did reach statistical significance after adjustment through multivariate analysis (p=0.03).

While other authors (Robinson et al., 2006) have found sex to be a statistically significant risk factor related to recurrent instability following a FTASD, the current study was in line with findings from Sachs et al. (2007) and te Slaa et al. (2003) in that sex was not predictive of recurrent shoulder instability. Despite some evidence that sex is a clinically important predictor, sex was not included in the model as the decisions were made based on the data at hand. Additionally, the New Zealand population may be different from international studies with regards to factors such as levels of activity. For example, involvement in contact sport and the age of the participant may confound the influence of sex in that young males are more involved in contact sport in New Zealand than young females (Sport New Zealand, 2015).

Following the univariate analysis, participants who injured their dominant shoulder were more likely to have recurrent instability (p=0.10). Likewise, following the multivariate analysis, in the presence of other variables, dislocation to the dominant limb trended towards significance (p=0.08). This may be related to the amount of use of the affected limb. However, this study was not sufficiently powered to examine whether the level of shoulder activity affected the relationship between limb dominance and recurrent shoulder instability.

This study found that the presence of a bony Bankart lesion was associated with recurrent shoulder instability. In contrast, Salomonsson et al. (2010) found bony Bankart lesions were a prognostic indicator for shoulder stability. Salomonsson et al. (2010) excluded participants with large bony Bankart lesions, thus biasing their sample. Our study showed that people with any sized bony Bankart lesion were more likely to have recurrent shoulder instability. The large variance within our study (95% CI (1.05 - 12.70)) could result from dichotomising the size of bony Bankart lesions to present or absent.

The presence of a Hill Sachs lesion was not a statistically significant predictive variable for recurrent shoulder instability, in line with other authors findings (Hoelen et al., 1990; Salomonsson et al., 2010). This is in contrast to the findings of a previous study (Kralinger et al., 2002) and may be due to the heterogeneity of pathological Hill Sachs lesions. In our study, radiological examination was undertaken by a number of practicing radiologists who were not trained for the purpose of the research study, and these records were collected retrospectively. They may not have been consistent in the way they reported the size, shape, location or interaction of bony lesions. Further analysis of Hill Sachs and bony Bankart lesions was not possible because of variations in the way these lesions were reported. While our study was not sufficiently powered to examine the relationship between greater tuberosity fractures and recurrent shoulder instability, others have reported that these decrease the risk of recurrent instability (Hoelen et al., 1990; Kralinger et al., 2002; Robinson et al., 2006; te Slaa et al., 2003; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993).

Immobilisation of the limb following a shoulder dislocation was found to decrease the risk of recurrent instability at 1 year follow-up when dichotomised to immobilised or not immobilised. The specific number of days patients were immobilised ranged from one to 70 days and was not associated with recurrent shoulder instability. Itoi and colleagues (Itoi et al., 2007b; Itoi, Sashi, Minagawa, et al., 2001) reported decreased recurrence when the shoulder was immobilised in external rotation. However, more recent systematic reviews (An Liu, Xue, Chen, Bi, & Yan, 2014; Paterson, Throckmorton, Koester, Azar, & Kuhn, 2010) have failed to support the finding of Itoi and colleagues (Itoi et al., 2007a; Itoi, Sashi, Minagawa, et al., 2001). This may be due to differences in adherence to medical advice as well as other regional differences in culture or differences in healthcare costs or access. All participants in the current study who were immobilised, reported they wore their arm in a sling across the body (internal rotation).

The current study is one of the first to examine the ability of patient reported shoulder outcome measures to predict recurrent shoulder instability. Following the univariate analysis, all the questionnaires used (SAS, SPADI, TSK-11 and WOSI) were predictive of recurrent shoulder instability. However, following multivariate analysis, in the present of other variables, only the SPADI and the TSK-11 were predictive of recurrent shoulder instability. This finding illustrates the multi-factorial nature of recurrent shoulder instability and the influence of patient beliefs, level of activity, kinesiophobia and self-reported pain and function as predictors of recurrent instability. Shoulder pain along with decreased function and quality of life are common sequelae of a FTASD. This study found that these variables were not only consequences of a FTASD, but also predicted future recurrent shoulder instability events.

Current non-surgical management appeared to be effective for over 60% of those who reported with a FTASD and were retained in the study at 12 month follow-up. Addressing factors such as patient education, psychosocial factors such as kinesiophobia, and developing criteria for return to sport/work after a dislocation could further improve non-surgical management.

6.2.5.2 Limitations

This was the first prospective cohort study of people following a FTASD in New Zealand, however, there were some limitations. The outcome of recurrent shoulder instability was self-reported and was not validated with a follow-up X-Ray. The requirement for X-Ray to confirm a dislocation would have excluded subluxation events from the outcome of recurrent instability. However, categorising recurrent shoulder instability based on participants self-report may have influenced the results, particularly in the context of the ability of self-reported questionnaires to predict self-reported instability.

6.2.6 Conclusions

This prospective cohort study reports the rate of recurrent shoulder instability in New Zealand within one year of a FTASD, and an association between kinesiophobia and self-reported pain and function with recurrent shoulder instability. The findings from this study showed that a bony Bankart lesion, age between 16 and 25 years, dislocation of the dominant shoulder, not being immobilised, and higher SPADI and TSK-11 scores can be used to develop a tool which may predict recurrent shoulder instability. Validation of this predictive tool based on these findings is required in a separate population. Further analysis of the tool is also required before use in clinical practice.

Chapter 7 A prospective study to evaluate the validity of a tool in predicting recurrent instability in adults with first-time traumatic anterior shoulder instability

7.1 Preface

This chapter relates to Specific Aim 3 of the thesis: to establish the predictive validity of the tool by undertaking a prospective cohort study examining recurrent shoulder instability following a FTASD in people who are managed conservatively.

Predictive validation of the tool is necessary to establish generalisability to a different population. For example, it is possible the predictive tool may have over-fitted and contain unnecessary variables. Types of validity include internal validation, external validation and temporal validation. This study demonstrates temporal validity as it differs from the original population in the time period that the data were collected (Altman et al., 2009). Temporal validation can be considered external in time and is therefore an intermediate step between internal and external validity (Altman et al., 2009). The population examined in this study was similar in all other accounts, i.e. people with a FTASD that occurred in New Zealand in people between the ages of 16 and 40, through similar seasons and sporting exposures.

To be considered clinically useful, a tool should have clinical credibility, be accurate and valid (for example, with an area under the ROC curve to be above 0.7 (Mandrekar, 2010)), have generalisability, be valid in a separate population, and ideally be clinically effective (Altman et al., 2009). Prognostic models which are not externally validated, have limited use in clinical practice because clinicians may under or overestimate the conclusions of the model, and the findings from the model may not be generalisable to other populations (Altman et al., 2009; McIntosh, Steenstra, Hogg-Johnson, Carter, & Hall, 2018). This validation study positions this predictive tool to impact clinical practice in New Zealand by enabling clinicians to work collaboratively with people who have had a FTASD to decide their best management.

In relation to this aim, a prospective cohort study was undertaken in the same manner as described in Chapter 5. Results from this prospective cohort study were examined to assess the predictive validity and reliability of the tool presented in Chapter 8. This paper has been drafted for submission to the journal *Shoulder and Elbow*. Therefore, the presentation of this chapter is in line with the criteria stipulated by this journal with some editorial changes in accordance with presenting this formal thesis.

7.2 Can we predict recurrent shoulder dislocation? Validation of a predictive tool

7.2.1 Abstract

7.2.1.1 Background

While previous predictive algorithms report increased recurrent shoulder instability for males under the age of 25 years, many have not undergone a full validation process. In a previous study we developed a tool to predict recurrent shoulder instability following a FTASD. Validation of this tool was required before it can be used in clinical practice. The purpose of this study was to evaluate the sensitivity, specificity and validity of the predictive tool.

7.2.1.2 Methods

Predictive risk factors in a cohort of people with a FTASD were recorded within 12 weeks of their shoulder dislocation. The cohort was followed prospectively for one year post-injury. The predictive tool was used to predict recurrent shoulder instability. The sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV) and validity of the tool were examined.

7.2.1.3 Results

The sensitivity and specificity of the tool were 38.9% and 94.7% respectively. The area under the curve (AUC) was 0.69 (95% CI (0.55, 0.84), p=0.01). NPV and PPV were 83.4% and 70.0% respectively.

7.2.1.4 Conclusions

The predictive tool can be useful to rule out those people who will not have a further instability event and has acceptable validity. It is not able to accurately predict those who will have further instability events.

7.2.1.5 Level of Evidence

Example: Level II, Prospective validation study.

7.2.2 Introduction

7.2.2.1 Background

Predicting the clinical pathway following a FTASD is a difficult task, with many authors citing age and sex as the most likely predictors (Hoelen et al., 1990; Robinson et al., 2006; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993). Other risk factors for recurrent instability, such as bony Bankart lesions (Hoelen et al., 1990; Vermeiren, Handelbery, Casteleyn, Opdecam, et al., 1993), duration or position of immobilisation (Simonet & Cofield, 1984), and hypermobility (Robinson et al., 2006; Salomonsson et al., 2010) have been reported in the literature. A tool which encompasses multiple risk factors may provide increased accuracy in the prediction of recurrent shoulder instability.

The benefits of establishing a tool which could reliably predict recurrent shoulder instability are clear. It would allow more efficient streamlining of healthcare services, and faster, more appropriate care for people with a FTASD. This would result in decreased treatment delay, as well as decreased loss of work/study and unnecessary uncertainty.

7.2.2.2 Rationale

In 2016-2017, a prospective cohort study was undertaken in people following a FTASD, confirmed by radiological examination (see Chapter 6). This cohort was followed for one year post-injury to establish the rates of recurrent shoulder instability. A predictive tool was established based on a set of variables retained in a multivariate regression model (which reached significance at $p \leq 0.10$). This tool expanded the risk factors from the well-known variable of age to also include bony Bankart lesions, immobilisation after dislocations, dislocation of the dominant side shoulder, kinesiophobia and perceived pain and disability.

Previous tools which have been used in people with shoulder instability include those which predict the type of surgical intervention which will result in post-surgical recurrent shoulder instability (Balg & Boileau, 2007), predict fracture/dislocations with a dislocation (Emond et al., 2004), analyse cost effectiveness of surgical or non-surgical management (Bishop et al., 2011; Crall et al., 2012) and predict recurrent shoulder instability after a FTASD (Mather et al., 2011).

The model by Mather et al. (2011) was externally validated against two previous cohorts of people with a FTASD (Bottoni et al., 2002; Hovelius et al., 1996). Validation of tools is required before they can be used in clinical practice to ensure generalisability to different populations, across different time periods and age groups (Moons, Kengne, Grobbee, et al., 2012). The model produced by Mather et al. (2011) was adjusted for sex when compared with the results of Hovelius et al. (1996) and adjusted with a relative risk of 1.2 when compared with the results of Bottoni et al. (2002). One of the limitations of the model from Mather et al. (2011) was the reliance on published data and the inability to incorporate the different impact of surgery or conservative management on loss of function and decreased quality of life (Mather et al., 2011). Further limitations included omission of other relevant variables (such as collision sport or bony Bankart lesions) or intermediate health states (such as transitioning from recurrent shoulder instability to becoming stable over time) (Mather et al., 2011). While the use of Monte-Carlo Markov modelling to predict health states may be useful, limitations from computer modelling simplifies what occurs in real-life scenarios. Additionally, other risk factors are known to affect recurrent shoulder instability, and these have not been included in the Mather et al. (2011) model.

The predictive tool developed in a New Zealand population incorporated other relevant variables including the presence of a bony Bankart lesion, immobilisation status, kinesiophobia, dislocation of the dominant side shoulder, and shoulder pain and disability. Therefore, the aim of this study was to validate the predictive tool developed within this thesis. It was hypothesised that this tool will have high levels of specificity, sensitivity and validity in this population.

7.2.3 Methods

7.2.3.1 Study Design and Setting

This prospective cohort study was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cohort studies. Predictive validity was examined in a cohort of people living in New Zealand who had a FTASD between February 2016 and May 2017. Participants were followed prospectively for 12 months following their FTASD.

7.2.3.2 Participants / Study Subjects

The inclusion and exclusion criteria for participants (refer to 5.3.2) along with the recruitment procedures (refer to 5.3.3) were identical to that used in Phase 1 (as presented in Chapter 6).

For Phase 2, a total of 77 people were excluded from the study. People were excluded if they reported a previous shoulder instability episode or other shoulder pathology such as impingement/ACJ disruption at initial interview (n=57) or showed radiological evidence of a previous shoulder instability episode in subsequent radiological review (n=10). Radiological evidence also excluded those who demonstrated pathology other than an anterior dislocation (n=10). People would have been excluded if they did not speak conversational English or had undergone surgical intervention for their current shoulder injury within 12 weeks. These people would have been unable to participate in the telephone interview and no longer able to demonstrate the natural history of a FTASD. Neither events occurred in this study.

7.2.3.3 Accounting for All Patients / Study Subjects

For a detailed description of the sample size calculation, refer to 5.4.4. In summary, participants were recruited for each age group (5 yearly intervals) from 16 years to 40 years as in similar studies (Robinson et al., 2006). Sample size estimates were based upon rates of recurrent shoulder instability found in Phase One (refer to 6.2.4), powered at 0.8 with alpha set at 0.05, with loss to follow-up predicted at 15%.

Eighty-five participants were recruited from 337 people who had a FTASD from February 2016 through to May 2017 (Figure 7.1). Data collection ceased for each age group, once sufficient participants were recruited to reach power as calculated in Table 7.1. Data collection continued until the target for each age group was reached, except for age groups 31-35 and 36-40 which were one and two participants short of target respectively. The decision to stop recruitment was made because of time and funding restrictions.

Table 7.1 Sample size calculation based on power=0.80, alpha at 0.05.

Age Group	**Phase Two required Sample size (power= 80%, anticipated LTF*=15%)**	**Total participants recruited**
15-20	25	26
21-25	23	31
26-30	9	12
31-35	10	9
36-40	10	8
Total	77	85

*LTF = Loss to follow-up

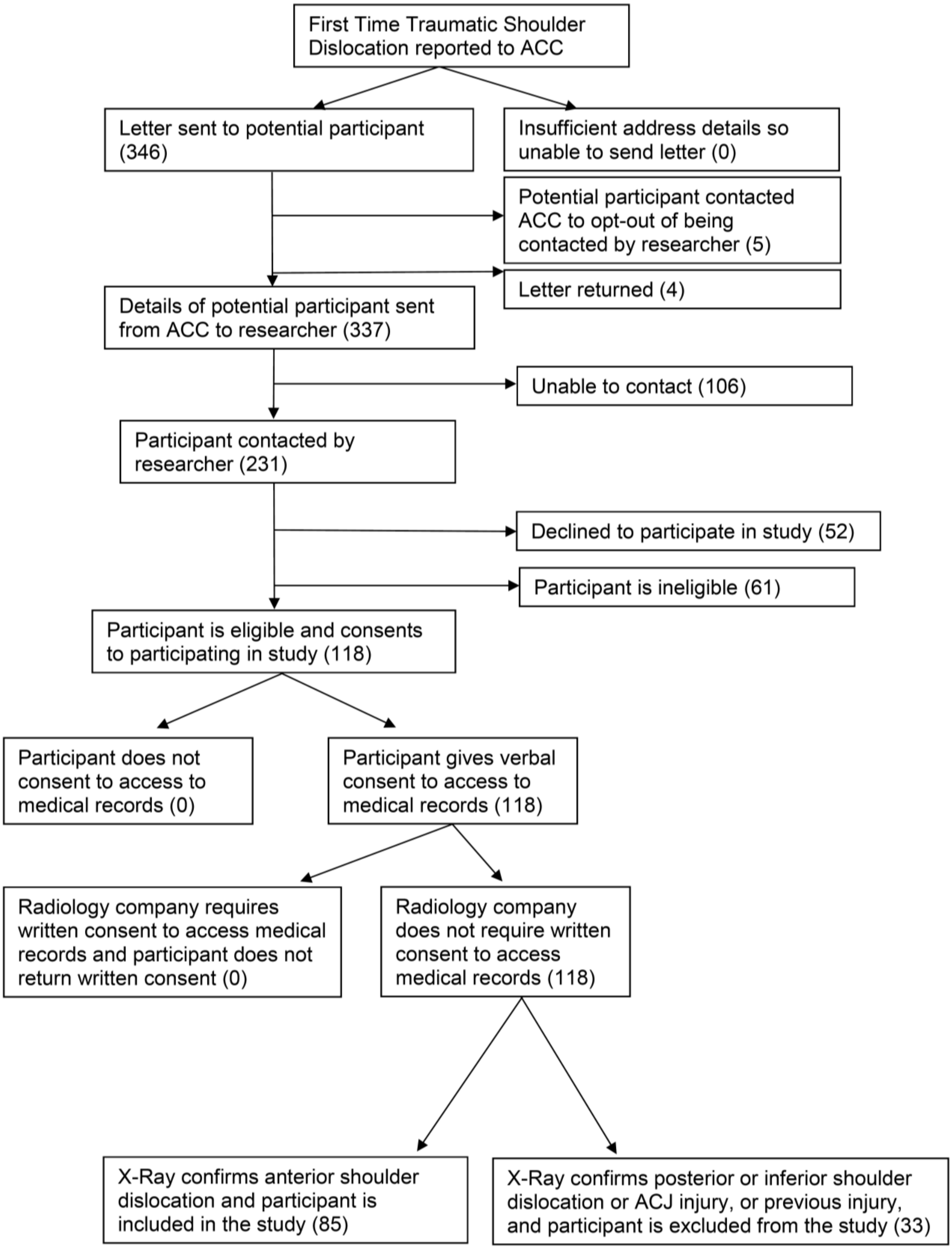

Figure 7.1 Flow chart of people through the study

7.2.3.4 Description of the study

Baseline data collection for Phase 2 was exactly the same as for Phase 1. Refer to 5.4.3 for details regarding baseline data collection.

7.2.3.5 Variables, Outcome Measures, Data Sources and Bias

Research assistants, all health professionals, were trained to identify recurrent shoulder instability events, and discussions of individual cases were undertaken at regular meetings to reach a consensus when there was uncertainty regarding the instability event. The research assistants were blinded to baseline data and were unaware which of the baseline data were shown to be statistically significant predictors of recurrent shoulder instability in Phase 1. Follow-up phone calls were made regularly at 3, 6, 9 and 12 months following the date of injury, by the research assistants. They were blind to the baseline data collection, to limit recall and experimenter bias. When the participants preferred to be contacted by email, they were emailed with a link to the online version of the tool.

The primary outcome was recurrent instability of the previously dislocated shoulder. For the definition for ‘recurrent instability’ used in this study refer to 5.3.4.3.

Some studies have advocated primary surgical intervention in this population of people following a FTASD, which would occur within the 12 month timeframe (Marshall et al., 2017; Polyzois et al., 2016). Additionally, approximately 70% of people who will have recurrent instability, will do so within 12 months following their initial injury (Robinson et al., 2006). This study was designed to elucidate variables which can be used to predict recurrent instability for the development of a multivariate prediction tool. It was not envisaged that these variables would alter beyond the first year of follow-up. Therefore, one year follow-up was used to study the shorter term impact of recurrent shoulder instability after a FTASD.

7.2.3.6 Statistical Analysis

For a detailed description of the statistical analyses used for Phase 2, refer to 5.4.5. In summary, the ability of the tool to discriminate between those who did not have any further episodes of instability and those who did have recurrent shoulder instability (i.e. predictive validity) was evaluated using receiver-operator characteristic (ROC) curve analysis. Receiver-operator characteristic curves plot continuous data to include a comprehensive review of all possible cut-points to establish a threshold with maximal sensitivity and specificity along the curve (Mandrekar, 2010). The AUC is a measure of the accuracy and validity of the predictive tool, with a larger area under the ROC curve indicating increased accuracy and validity (Mandrekar, 2010). Values of the AUC of 0.5 and below represent no discriminative validity from the tool, values between 0.5 and 0.7 limited validity, between 0.7 and 0.8 acceptable validity, between 0.8 to 0.9 excellent validity, and above 0.9 outstanding validity (Mandrekar, 2010). Calibration of the tool was assessed using the Hosmer-Lemeshow test to establish goodness-of-fit between the observed and predicted data. Estimates of sensitivity, specificity, and positive and negative predictive values with 95% confidence intervals were calculated for each potential decision threshold of the scoring system (Kumar & Indrayan, 2011; Riffenburgh, 2012). There is no apparent consensus as to what level of sensitivity or specificity is clinically acceptable, partly because these levels change depending upon the severity of consequences of the decision-making (Griner, Mayewski, Mushlin, & Greenland, 1981; Haneline, 2007; Sackett, 1992). The cut-off point for the tool was chosen as the point of the ROC curve with the cumulative highest sensitivity and specificity (known as Youden's index) (Perkins & Schisterman, 2005). Comparisons were made between the development and validation population to ensure the demographic make-up of the respective populations were similar. Statistical analysis was undertaken with Statistical Package for the Social Sciences software (SPSS 24.0, IBM Corp., Armonk, NY, USA).

7.2.4 Results

7.2.4.1 Demographics and Description of Study Population

There were a total of 75 participants followed for one year (12% loss to follow-up n=10), 64 (85%) of whom were male. Other demographic data can be seen in Table 7.2. Sixty-six (88%) participants were right hand dominant, 44 (59%) participants dislocated their right shoulder and 42 (56%) participants dislocated their dominant shoulder. Forty-five (60%) participants had manual occupations while the remaining had sedentary occupations. Thirty-one (41%) participants had an occupation where they were required to work with their arm above their shoulder. Fifteen (20%) participants had a family history of shoulder instability and 16 (21%) participants self-reported hypermobility. Sixty-one (81%) participants were immobilised after their shoulder dislocation. Six (8%) participants had a bony Bankart lesion, two (2%) had a great tuberosity fracture, 18 (24%) had Hill Sachs lesions.

Table 7.2 Demographic data of participants

	Mean	s.d.	Min	Max
Age (yrs)	24.24	6.63	16	40
Height (cm)	177.21	8.94	152	198
Weight (kg)	83.99	17.46	52	125
BMI	26.66	4.87	18.94	42.24
SPADI	24.45	21.78	0	92.31
TSK	24.68	4.80	10	26
SAS	12.68	4.14	4	19
WOSI	938.60	470.20	0	1820

BMI = Body Mass Index, SPADI = Shoulder Pain and Disability Index (range 0-100, higher scores denote worse pain and function), TSK-11 = Tampa Scale of Kinesiophobia 11 (range 11-44, higher scores denote worse kinesiophobia), SAS = Shoulder Activity Scale (range 0-20, higher scores denote increased activity level), WOSI = Western Ontario Shoulder Instability Index (range 0-2100, higher scores denote worse quality of life)

Of the 75 participants who were followed for one year, 18 (24%) had recurrent instability. Across the 12 months, the majority of recurrent instability episodes occurred at the 12 month time point (7 episodes (58%)), with 3 episodes at 9 months (15%), 6 at 6 months (33%), 1 at 3 months (5%) and 1 at baseline (5%). The optimal cut-point was calculated using Youden's index (Perkins & Schisterman, 2005). Using this equation, the value of the cut point of 0.895 was used. With the cut-point at 0.895, the predictive tool had 38.9% sensitivity and 94.7% specificity. These values can be seen in Figure 7.2.

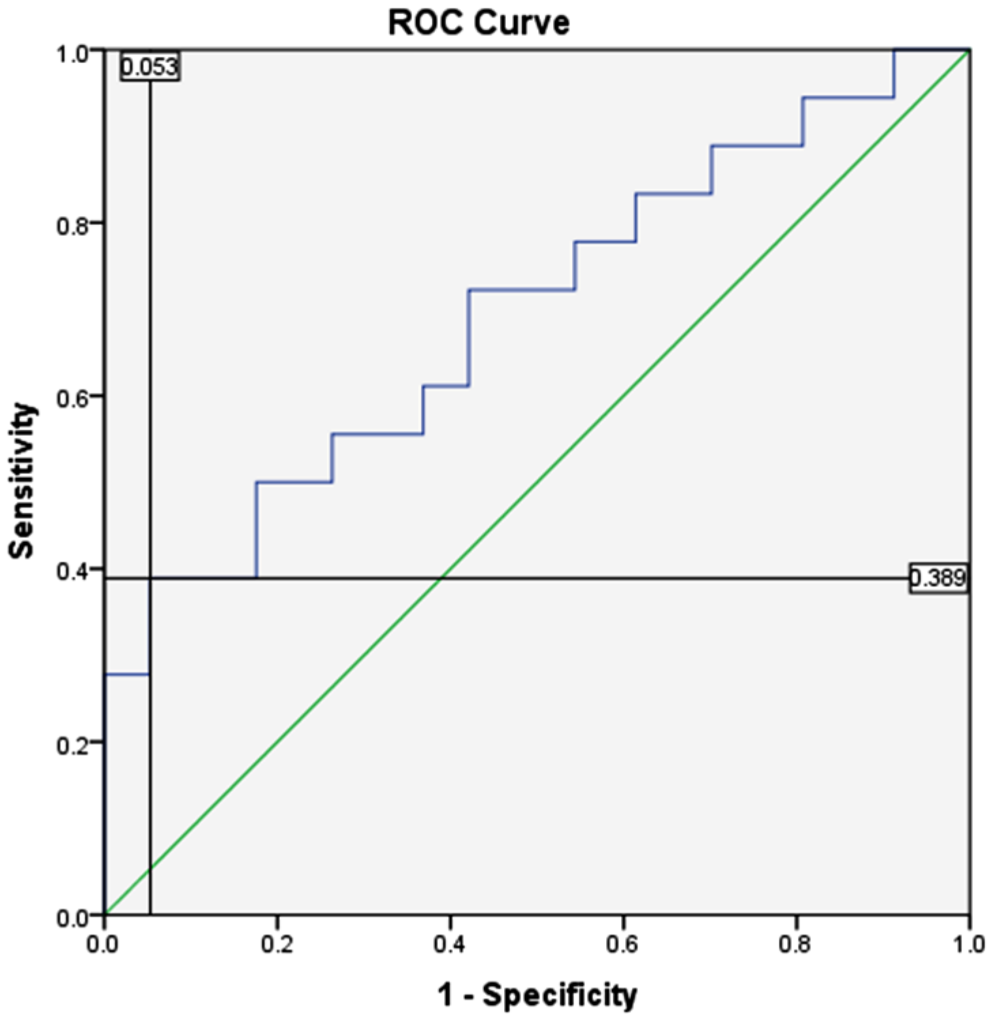

Figure 7.2 Receiver Operator Characteristic Curve for the predictive tool

The predictive validity of the tool was represented by the AUC which was 0.694 (95% CI (0.545, 0.843), p=0.014). The tool has limited predictive value, given the 95% CI includes the values of 0.5 and 0.7 (Mandrekar, 2010). Positive predictive values (PPV) (70%) and negative predictive values (NPV) (83.1%) can be seen in Table 7.3. The Hosmer-Lemeshow test was 13.39 (p<0.001) which indicated that the model was not well calibrated and there was poor goodness of fit of the model.

Table 7.3 Diagnostic values of the predictive tool in predicting recurrent shoulder instability

Diagnostic Value	Cut-point = 0.895	95% CI
Prevalence (%)	24.00%	14.89% - 35.25%
Sensitivity (%)	38.89%	17.30% - 64.25%
Specificity (%)	94.74%	85.38% - 98.90%
AUC	0.69	54.50% - 84.30%
PPV (%)	70.00%	40.20% - 89.01%
NPV (%)	83.08%	77.16% – 87.70%
+LR	7.39	2.13 – 25.65
-LR	0.65	0.44 – 0.94
Accuracy	81.34	70.67% – 89.40%

AUC = Area Under the Curve, PPV = Positive Predictive Value, NPV = Negative Predictive Value, +LR = positive likelihood ratio, -LR = negative likelihood ratio

With the cut-point set at 0.895, the negative likelihood ratio (-LR) was 0.65 and the positive likelihood ratio (+LR) was 7.33. Comparisons between the development and the validation population can be seen in Table 7.4. Participants in the development and validation population were similar with regards to age, height and weight. There were 128 participants in the development population and 75 participants in the validation population. The study was not powered to detect statistically significant differences between the groups. Other variables were similar with the exception of a higher percentage of overhead and manual workers in the validation population, compared to the development group.

Table 7.4 Comparison of demographic data between formation and validation population

Variable	**Formation Population Mean (s.d.)**	**Validation Population Mean (s.d.)**
Age	24.6 (7.1)	24.2 (6.6)
Height	180.2 (8.5)	177.2 (8.9)
Weight	82.0 (15.8)	84.0 (17.5)
BMI	25.5 (4.3)	26.7 (4.9)
SPADI	17.02 (15.1)	24.5 (21.8)
TSK	36 (3.6)	24.7 (4.8)
SAS	11.6 (3.5)	12.7 (4.1)
WOSI	758.8 (441.9)	939.0 (470.0)
	Percentage	**Percentage**
Male	97 of 110 (88%)	64 of 75 (85%)
Dominant shoulder	57 of 110 (52%)	42 of 75 (56%)
Manual occupation	41 of 110 (37%)	45 of 75 (60%)
Overhead occupation	29 of 110 (26%)	31 of 75 (41%)
Family history of recurrent shoulder instability	20 of 110 (18%)	15 of 75 (20%)
Hypermobility	30 of 110 (27%)	16 of 75 (21%)
Immobilised	86 of 109 (78%)	61 of 75 (81%)
Bony Bankart lesion	13 of 18 (12%)	6 of 75 (8%)
Greater Tuberosity fracture	4 of 110 (4%)	2 of 75 (3%)
Hill Sachs Lesion	31 of 110 (28%)	18 of 75 (24%)
Recurrent Instability	46 of 110 (42%)	18 of 75 (24%)

BMI = Body Mass Index, SPADI = Shoulder Pain and Disability Index (range 0-100, higher scores denote worse pain and function), TSK-11 = Tampa Scale of Kinesiophobia 11 (range 11-44, higher scores denote worse kinesiophobia), SAS = Shoulder Activity Scale (range 0-20, higher scores denote increased activity level), WOSI = Western Ontario Shoulder Instability Index (range 0-2100, higher scores denote worse quality of life)

7.2.4.2 Post-hoc power calculation

For 57 (76%) people without recurrent instability and 18 (24%) people with recurrent shoulder instability, this study was powered at 72.5% (two-sided alpha=0.05) to observe an AUC of 0.694. Given the ratio of people without recurrent shoulder instability to people with recurrent shoulder instability was 3.2 and the AUC 0.694, we would have required 69 people without recurrent shoulder instability and 22 people with recurrent shoulder instability to be powered at 80%. This power analysis indicates that 11 more people without recurrent shoulder instability were required and 4 more people with recurrent shoulder instability to be powered to 80%.

7.2.5 Discussion

7.2.5.1 Background and Rationale

Validation of a clinical tool is imperative before its use in clinical practice to ensure that the tool is generalisable to the wider population (Moons, Kengne, Grobbee, et al., 2012). Many tools have been published describing risk factors for recurrent shoulder instability. However, only the model from Mather et al. (2011) has undergone validation procedures. The predictive tool of recurrent shoulder instability following a FTASD developed in the current study, showed high specificity (96.4%). Thus, out of all participants who did not go on to develop a recurrent instability (n=57) the tool accurately predicted 55 people (96.4%) who indeed would not experience a further episode of recurrent shoulder instability.

The PPV estimate for recurrence was 0.70. Therefore, out of all those people identified as having recurrent shoulder instability, 70% were correctly identified within 12 months. Further, the NPV estimate for recurrence was 83.08%. In other words, out of all those people identified as not having recurrent shoulder instability, 83% were correctly identified.

However, despite replication of a prospective cohort study in a similar population, across similar seasons and sporting exposures, the predictive tool showed limited accuracy (AUC=0.694) and limited sensitivity (38.89%). In other words, out of all 18 participants who did go on to develop a recurrent instability, 38.89% (n=7) were correctly identified by the tool. This translates to 61.1% of people (n=11) who did develop further recurrence within the 12 month follow-up were incorrectly predicted not to have further recurrence (false negatives) if the tool was applied. Additionally, the Hosmer-Lemeshow test indicated the model was not well calibrated with the observed data (Parmar et al., 2015). Thus, there are significant differences between the observed and expected data. Low levels of sensitivity may be because the cohort that was used to validate the tool had lower prevalence rates for recurrent shoulder instability (24%) compared to the initial cohort that was used to develop the tool (36%) (Table 7.4).

The rate of recurrent shoulder instability following a FTASD in New Zealand, appears to be lower than in other countries, despite the increased rates of participation in contact and collision sports. Rates of recurrent instability have been shown to be 57% in Sweden (Hovelius et al., 2008), 33% in the USA (Simonet & Cofield, 1984) and 67% in Scotland (Robinson et al., 2006). Participation in sports appears to vary widely between these countries with 71% of New Zealanders involved in sport (Statistics New Zealand, 2018), compared with 31% of those in the USA (Woods, 2017) and 51% percent of those in Scotland (Scottish Government, 2016). The result of life-long involvement in sport has not been compared globally, but could result in increased coordination, levels of cardiovascular fitness and muscular endurance in those countries with higher levels of sports participation (O’Donovan et al., 2010). Thus, rather than increased risk of recurrent shoulder instability in a population more engaged in sport, this could lead to a reduced risk of recurrent shoulder instability for a fitter, stronger recreational athlete.

Additionally, the healthcare system in New Zealand is heavily subsidised for those people that have traumatic injuries (Gianotti & Hume, 2007). This enables all New Zealanders equitable access to emergency medicine and heavily discounted rates for rehabilitation following traumatic injuries, however mild. Both the high level of sports participation and equitable access to healthcare may be responsible for the lower rate of recurrent instability when compared with rates of recurrent shoulder instability seen globally.

The cohort used for the validation study was also different to that used for the tool formation study (Chapter 6) in that there were a greater percentage of manual labourers and overhead workers in the validation population (Table 7.4). Although the level of shoulder activity (as measured via the SAS) was not different in these populations, it may be that people who are involved in manual labour have greater strength than those who are not and may have influenced the rate of recurrent shoulder instability. Increased muscle strength results from total time the muscle is under tension (Burd et al., 2012), and it may be that measuring the frequency of activity across a week, does not accurately measure the total load on the muscle. The SAS does not examine endurance capacity of muscle, but gives an overall indication of how often a person reports partaking in a particular type of activity. Furthermore, while Brophy et al. (2016) have shown type of employment to be associated with different levels of shoulder activity, this may not be the case in New Zealand occupations. Therefore, it may be that differences in occupation type between the development and validation populations, affected the decreased rate of recurrent shoulder instability seen in the validation population.

The findings of high specificity in a tool that utilises patient reported outcome measures support their use in clinical practice (Fritz & Wainner, 2001; Lalkhen & McCluskey, 2008). Baseline measures of kinesiophobia (TSK-11) and shoulder pain and disability (SPADI) provide valuable information for clinicians working with people following a FTASD. The use of these tools in clinical practice, in combination with other variables, allows clinicians to predict the outcome of a FTASD. For example, people with low levels of kinesiophobia (TSK-11) and shoulder pain and disability (SPADI) appear less likely to go on to have recurrent shoulder instability. Clinicians could therefore enhance their clinical practice by using the TSK-11 and SPADI in patients following a FTASD and use the results to collaborate with patients to decide their optimal management. This study showed limited predictive ability of a VAS pain score and this was not included in the predictive tool. Therefore, whilst this may be a useful measure to examine pain, it is not helpful in informing whether someone will have a further recurrence or not.

While sensitivity and specificity are useful metrics of a clinical test, clinicians want to know the chances of their patient having a positive or negative result (i.e. the positive or negative predictive value) of the test. Increased positive and decreased negative predictive values of a clinical test are seen when there is a low prevalence rate (Fritz & Wainner, 2001). The low prevalence rate in this validation population resulted in lower PPVs and higher NPVs in the study, which may influence the accurate identification of people who were going to have recurrent shoulder instability. The use of likelihood ratios overcomes the limitation of sensitivity, specificity, PPVs and NPVs by combining sensitivity and specificity. The positive likelihood ratio of 7.39 indicates that when the test is positive (i.e. cut point of 0.895 and above), the likelihood that a person will actually have recurrent instability, will increase by 30-45%. The -LR of 0.65 indicates that it is unlikely (0-15%) to decrease the post-test probability of detecting recurrent shoulder instability. Thus a negative result (less than 0.895) indicates that it is unlikely that a person will actually have a recurrent shoulder instability event (Fritz & Wainner, 2001).

High levels of specificity in this tool are useful for identifying those people who are not likely to have recurrent shoulder instability. This information can be used to identify those people who are not likely to have recurrent shoulder instability, with the current level of intervention, and accordingly do not require a different treatment pathway. The utilisation of this tool in clinical practice has benefits not only for the medical community in improving decision-making, but also for stakeholders where it may result in more efficient use of the healthcare dollar, and people who will have increased certainty about the expected outcome from their FTASD. In conjunction with shared decision-making, predictive tools enable clinicians to be free of clinical bias, which may result inadvertently from their role or position in the healthcare system (Borkhoff, Hawker, & Wright, 2011). This tool allows clinicians to provide objective data for people in New Zealand following a FTASD. However, limited accuracy and low rates of sensitivity make it difficult to accurately identify those people will go on to have recurrent shoulder instability following a FTASD.

7.2.5.2 Limitations

This study had a number of limitations, which may have resulted in the low rates of sensitivity of the tool. Firstly, participants were followed for one year only. Although previous research has shown that around 70% of people who were going to have another shoulder dislocation would have done so within 12 months (Robinson et al., 2006), there may be some who sustained a recurrence beyond 12 months and were therefore not captured in this study.

Fewer people in the study had a recurrent shoulder instability than anticipated following the systematic review. Post-hoc analysis of the power calculation showed that this study was powered at 72.5% with 18 people who reported recurrent shoulder instability. Consequently, this study was under-powered and had an increased chance of reporting no difference when a true difference exists (false negative finding (Type II error)) (Biau, Kernéis, & Porcher, 2008). Our recurrence rates can be used to inform sample size calculations for future studies.

There may have been some bias in the recruitment of participants in both Phase 1 (Chapter 6) and Phase 2, particularly in those who declined to take part in the study, or who were lost to follow-up. Unfortunately, it was not possible to ascertain the reasons for non-participation, but it is possible that those with poorer outcomes following their FTASD were less likely to agree to take part or remain the study.

Other limitations included an inability to carry out clinical assessment of risk factors. Milgrom et al. (2014) reported that a clinical apprehension test was predictive of recurrent shoulder instability in a cohort of Israeli soldiers. While the use of a clinical apprehension test may have increased sensitivity of this tool, this was not practicable in a nationwide study as none of the participants attended in person for the study. While this enabled access to a wide range of participants across the country, different socioeconomic, ethnic and environmental areas, the utilisation of some clinical assessment measures may have strengthened the accuracy of the tool.

Salomonsson et al. (2010) investigated the role of labral tears as a predictive variable for recurrent shoulder instability after a FTASD and found no relationship between the presence of a labral tear and recurrent shoulder instability. No other cohort studies have been undertaken to examine the role of the glenoid labrum as a risk factor for recurrent shoulder instability. Despite this finding, many decisions to surgically intervene in a person following a FTASD are often based on the presence of a labral tear (Murray et al., 2013). This study was not able to identify labral injuries as a result of the initial dislocation. Not all subjects underwent MRI (used to identify labral tears) as this study was designed to replicate usual practice in primary level care. Further information regarding the type or extent of labral damage may provide more insight into recurrence. Furthermore, shoulder instability is a complex and multi-factorial entity. Other yet to be determined risk factors such as psychosocial factors (e.g. resilience (Tokish et al., 2017)) may provide more information regarding the rate of recurrent shoulder instability and could be incorporated in future tools.

7.2.6 Conclusions

The predictive tool can be used to identify people who are not going to have further episodes of recurrent shoulder instability following a FTASD, but has limited validity and accuracy. Follow-up beyond 12 months and examination of other risk factors including physical assessment tests need to be included in future studies in order to assess if this will improve the validity of the tool.

Chapter 8 The impact of a FTASD on quality of life, kinesiophobia, shoulder pain and disability and shoulder activity and the association between recurrent instability and these outcomes.

8.1 Preface

This chapter relates to Aim 4 of the thesis: to assess the impact of a FTASD on patient perceived pain, function, kinesiophobia and quality of life and examine the association between these psychosocial variables and recurrent shoulder instability.

While it is useful for people with a FTASD to have knowledge regarding the likelihood of recurrent shoulder instability, it would also be useful to have some knowledge regarding the length of time to expect shoulder pain, and the extent to which their shoulder function and quality of life may be affected. Additionally, information regarding kinesiophobia may open dialogue regarding the psychosocial impact of a FTASD.

Previous authors have examined the immediate and two year impact of a shoulder dislocation on quality of life (Dickens et al., 2014; Gerometta et al., 2018). However, there is no information specific to people who have had a FTASD. Additionally, neither the variance across time, nor the time taken to recover from a FTASD have been previously examined.

Kinesiophobia is another psychosocial factor that has been reported in people with knee injuries (Ardern et al., 2012), chronic lumbar spine pain (Vlaeyen et al., 1995), and non-specific shoulder pain (Mintken et al., 2010), but has not previously been explored in people following a FTASD. Increased cortical activity in the emotion and fear centres of the brain has been shown in people with anterior shoulder instability (Cunningham et al., 2015; Shitara et al., 2015) (see 4.2). Additionally, fear is the main emotion that is associated with return to sport following a shoulder dislocation (Gerometta et al., 2018). However, there has been little examination of kinesiophobia following a FTASD or how fear changes across time following the injury.

Further examination of kinesiophobia, and other psychosocial factors such as quality of life and perceived shoulder pain and disability is warranted to improve clinical practice. In relation to this aim, secondary outcomes of kinesiophobia, shoulder pain and disability, quality of life and shoulder activity level were recorded at baseline and then three monthly until recurrent shoulder instability occurred or until 12 months following the FTASD. This paper has been prepared for submission to *Clinical Orthopaedics and Related Research*. Therefore, the presentation of this chapter is in line with the criteria stipulated by this journal with some editorial changes in accordance with presenting this formal thesis.

8.2 What is the immediate and subsequent impact of a first-time traumatic anterior shoulder dislocation on pain, disability, kinesiophobia and quality of life, and is there an association with recurrent shoulder instability?

8.2.1 Abstract:

8.2.1.1 Background

Limited evidence exists detailing the changes in quality of life, shoulder activity level, kinesiophobia, and shoulder pain and disability following a FTASD. Provision of these variables one year after a FTASD may improve patient expectations, treatment delivery and quality of care.

8.2.1.2 Objectives

This study had three objectives; 1) to examine the level of quality of life, pain and disability, shoulder activity, and kinesiophobia after a FTASD within 12 weeks, 2) to examine whether these variables were different in people with and without recurrent shoulder instability over the following year and 3) to assess how these outcome variables changed over the following 12 months for the entire cohort who had a FTASD.

8.2.1.3 Methods

A prospective cohort study was undertaken in a population of people with a FTASD. Measures of quality of life, kinesiophobia, shoulder activity, and shoulder pain and disability were recorded within 12 weeks of a FTASD and also at 3, 6, 9 and 12 months following injury via a telephone-based questionnaire.

8.2.1.4 Results

People had statistically significant decreases in quality of life, shoulder pain and function within 12 weeks of a FTASD and these variables improved over time. People with recurrent shoulder instability had more shoulder pain and kinesiophobia and poorer quality of life 12 months after a FTASD compared with people who did not have recurrent shoulder instability. Across the entire cohort, shoulder function was improved from baseline measures at 9 months after a FTASD, but kinesiophobia did not significantly change across time in people following a FTASD. Unfortunately, there was insufficient data to reach an appropriate level of statistical power to draw meaningful conclusions regarding Objectives 2 and 3 (see page 14).

8.2.1.5 Conclusion

Quality of life, kinesiophobia and shoulder pain were significantly affected by a FTASD. Adequately powered cohort studies in young active populations are required to investigate differences in psychosocial variables over time following a FTASD between people with and without recurrent shoulder instability. Across the entire cohort of people with a FTASD, whilst shoulder function and pain improved after 9 months, kinesiophobia did not change over time and remained elevated in people following a FTASD.

8.2.2 Introduction

Anecdotally, patients who have a FTASD are interested in how long their shoulder will be painful for, and how it will affect their level of function and quality of life. While recurrent shoulder instability is a much-studied topic (Robinson et al., 2002;

Wasserstein et al., 2016), there is limited literature available regarding the impact of recurrent shoulder instability on quality of life, shoulder pain and disability, shoulder activity levels, and kinesiophobia.

Patient's subjective assessment of shoulder function was examined in a large prospective study in Sweden, and found to be similar in people with recurrent shoulder instability who did not seek surgical intervention and became 'stable over time' when compared to those with a single dislocation and those that were treated surgically (Hovelius et al., 2008). Shoulder pain following a FTASD was examined in a prospective cohort study and pain greater than 8/10 on the numeric pain rating scale (NPRS), was a statistically significant multivariate predictor for subsequent recurrent shoulder instability (Sachs et al., 2007).

Quality of life has recently been examined in 62 rugby players in Italy who had suffered a shoulder instability event (dislocation or subluxation) while playing rugby. The findings indicated that quality of life (measured with the WOSI) was negatively affected by the FTASD at two years after their injury (Gerometta et al., 2018). The more immediate impact of a shoulder instability event (dislocation or subluxation) on quality of life (also measured with the WOSI) was examined by Dickens et al. (2014) in 45 collegiate athletes. Decreased quality of life was related to increased time away from sport, and the WOSI score accounted for 16% of the variance in return to play. Total WOSI scores and the values of the four domains which make up the WOSI were not published in this study (Dickens et al., 2014). Thus, while there is already literature available which reports quality of life following a shoulder instability event, there is no information available specific to people who have had a FTASD.

There is a plethora of research that has examined the effects of recurrent shoulder instability following shoulder dislocation, but little of this research has examined patient reported factors, such as how long their shoulder will be painful for, how long their function will be affected and what the impact will be on their quality of life. While this PhD study was not powered to find a difference between people with and without recurrent shoulder instability with respect to the patient reported outcome measures, data were collected as part of the two studies (Chapters 6 and 7) that examined predictors of recurrent shoulder instability.

There were three main objectives of this study:

1. Examine the levels of quality of life, shoulder pain and disability, kinesiophobia, and shoulder activity in the entire cohort of people with a FTASD within 12 weeks of their injury.
2. Examine if these variables differed between people who developed recurrent shoulder instability following a FTASD, over the subsequent 12 months, compared with people who did not develop recurrent shoulder instability.
3. Assess how these outcome variables changed over the following one year for the entire cohort of people who have had a FTASD:
    a. Assess the change in shoulder activity from pre-injury (reported retrospectively) to 12 months post-injury.
    b. Assess the change in quality of life, pain and disability, and kinesiophobia from baseline measure (first measurement point within 12 weeks post-injury) to 12 months post-injury.

8.2.3 Methods

8.2.3.1 Study Design

Secondary outcome data from two prospective cohort studies (Chapters 6 and 7) were combined since they utilised the same methods. These studies were reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cohort studies (Appendix O). Ethical approval was obtained from the ethics committees of the Auckland University of Technology (approval number 14/256) (Appendix L) and the Accident Compensation Corporation (ACC) (approval number 272) (Appendix M).

8.2.3.2 Participants

The inclusion and exclusion criteria for participants (refer to 5.3.2) along with the recruitment procedures (refer to 5.3.3) were identical to that used in Phase 1

(Chapter 6) and Phase 2 (Chapter 7). Participants were excluded if they had a previous shoulder instability episode (n=105) and if they did not speak conversational English (n=2) (as they would be unable to participate in the telephone interview). Participants were also excluded if radiological records showed injury other than an anterior dislocation or previous instability event (n=65). Participants would have been excluded if they had undergone surgical intervention for their current shoulder injury within 12 weeks of the injury, but no participants presented in this category. The flow of participants can be seen in Figure 8.1.

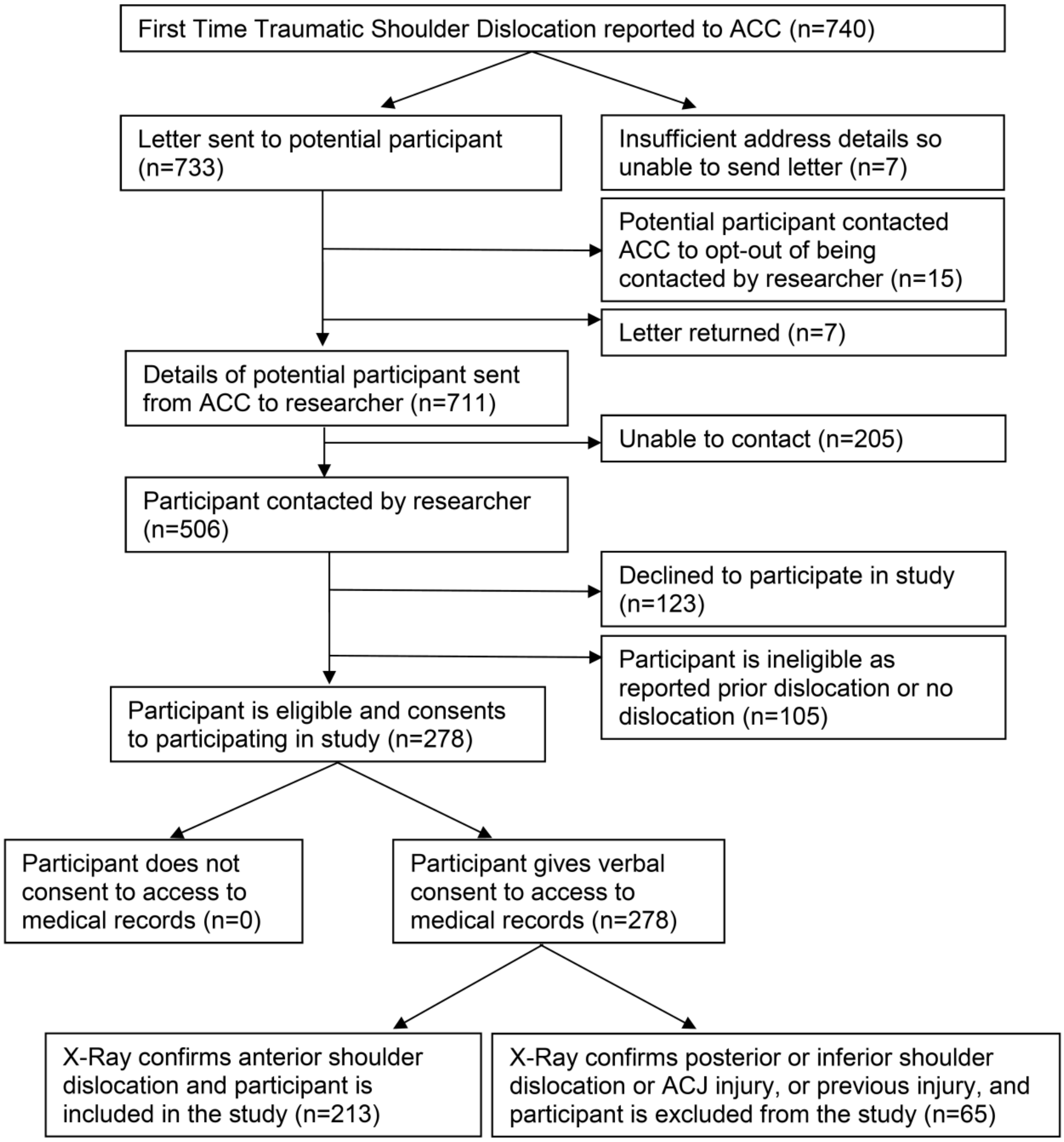

Figure 8.1 Flow of people through the study

8.2.3.3 Data Collection

Data collection has been previously described (refer to Chapter 5.3.4). At the recruitment interview, the lead researcher administered the questionnaire based outcome measures. Some people were still immobilised in a sling at the time of the initial interview, while others had minimal levels of activity. Additionally, the level of shoulder activity prior to the FTASD may have been a risk factor for recurrent shoulder instability. Therefore, the baseline level of shoulder activity level (as assessed with the SAS) was recorded as the level of activity the participant was engaged in prior to the FTASD. The SAS was reported retrospectively at the time of the initial interview. Quality of life, kinesiophobia, and shoulder pain and disability were recorded using the WOSI, TSK-11 and SPADI respectively at the time of the initial interview. These latter measures reflected people's experiences post-injury.

Some studies have advocated primary surgical intervention in this population of people following a FTASD, which would occur within the 12 month timeframe (Marshall et al., 2017; Polyzois et al., 2016). Therefore, participants were followed up for one year after their FTASD, or until the time they sustained a recurrent shoulder instability if this was prior to the 12 month follow-up. Thus, people were only interviewed and reported their shoulder activity level, level of kinesiophobia, shoulder pain and disability, and quality of life if an episode of recurrent shoulder instability had not previously occurred. People who had an episode of shoulder instability were not followed past the time point of this recurrence and they were not represented in the subsequent analyses. Therefore, the sample size numbers vary at each time point reported in the analysis.

8.2.3.4 Data and Statistical Analysis

Data were analysed using Statistical Package for the Social Sciences software (SPSS 24.0, IBM Corp., Armonk, NY, USA) and R 3.0.2 (R Core Team, Vienna, Austria). For objective (1) descriptive statistics were used to describe quality of life, kinesiophobia, shoulder activity level and shoulder pain, and disability within 12 weeks of a FTASD. To examine objective (2), Mann-Whitney U-tests assessed the difference in mean outcome measure scores at each time point (0, 3, 6, 9 and 12 months) between those with and without recurrent shoulder instability. A Bonferroni-corrected p-value of 0.001 adjusting for multiple-testing (alpha=0.05/ (10 outcomes x 5 time-points)) was used to indicate statistical significance and was used for objective (2). For objective (3) linear mixed model analyses were undertaken to assess the difference between these secondary measures at the relevant follow-up time points, compared to a) the pre-injury activity levels measured with the SAS and b) the levels of quality of life, kinesiophobia and shoulder pain, and dysfunction measured with the WOSI, TSK-11 and SPADI respectively at the time of the initial interview. A p-value ≤ 0.05 indicated statistical significance. Participants who sustained an episode of recurrent shoulder instability prior to the final data collection point were no longer followed.

8.2.4 Results

Baseline data were collected from 213 people. 12 month follow-up data were available for 86 people, though not all completed every measure. Descriptive statistics for quality of life, shoulder activity, kinesiophobia, and shoulder pain and dysfunction are shown in Table 8.1.

8.2.4.1 Objective 1: Examine the levels of quality of life, pain and disability, kinesiophobia, and shoulder activity in the entire cohort of people within 12 weeks following a FTASD.

A wide range of scores were seen for all variables at baseline. Within 12 weeks of a FTASD, people had decreased quality of life, indicated by a mean WOSI score of 844.2 of a possible 2100 (Table 8.1). A WOSI score of 0 indicates no decrease in quality of life, whereas a score of 2100 indicates an extreme decrease in quality of life (Kirkley et al., 1998). Within 12 weeks of a FTASD, people had some pain and disability with a mean SPADI score of 20.82, where a score of 0 indicates no pain or disability and 100 represents the maximum level of impairment (Table 8.1) (Roach et al., 1991). Likewise, people experienced some kinesiophobia with mean TSK-11 values of 25.92 within 12 weeks of a FTASD, where 11 represents the minimum level of kinesiophobia and 44 the maximum level. People were asked in their initial interview (which occurred within 12 weeks of the FTASD) to recall the amount of pain they experienced at the time of dislocation. They recalled that the pain experienced at the time of the FTASD was an average numeric pain rating score (NPRS) of 7.99 (s.d. 2.17) out of 10. At the time of the initial interview, this had decreased to an average NPRS of 1.68 (s.d. 2.14).

8.2.4.2 Objective 2: Examine the levels of quality of life, pain and disability, kinesiophobia, and shoulder activity between people who developed recurrent shoulder instability following a FTASD, over the subsequent 12 months, compared with people who did not develop recurrent shoulder instability.

The rate of reported recurrent shoulder instability can be seen in Figure 8.2. Of the 213 people with a FTASD in the study, 12 (5.6%) reported recurrent instability at the time of initial interview, 22 (10.3%) at 3 months, 41 (19.3%) at 6 months, 47 (22.1%) at 9 months and 26 (30.5%) at 12 months.

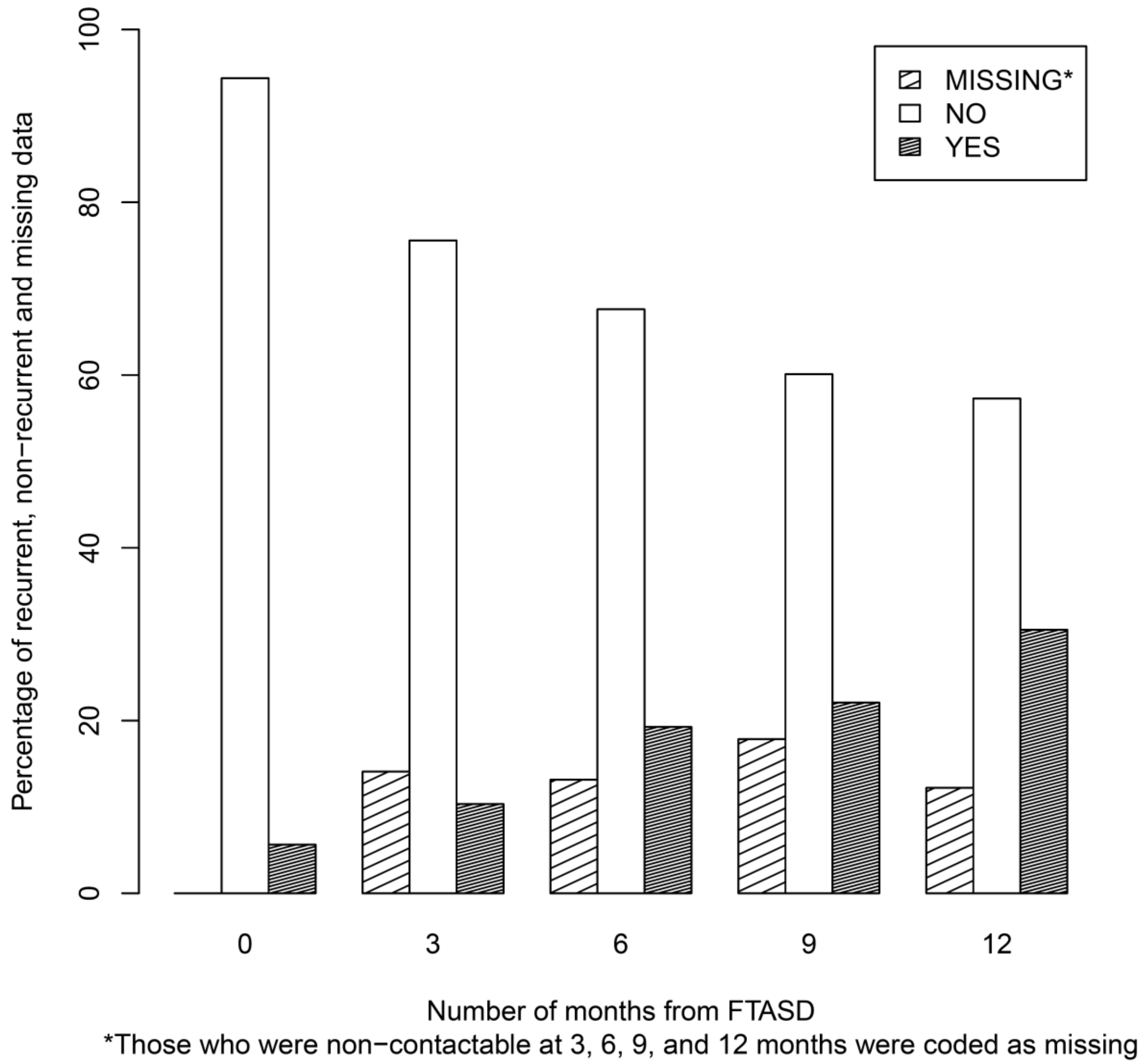

Figure 8.2 Percentage of recurrent and non-recurrent shoulder instability over 12 months after a FTASD

The difference in outcome scores of quality of life, shoulder pain and disability, kinesiophobia and shoulder activity, between people with and without recurrent shoulder instability, are shown in Table 8.1. Except for SPADI Total scores (p=0.04), no statistically significant difference between these two group was evident at baseline. Across all time points, shoulder activity levels (SAS) did not differ between people with and without recurrent shoulder instability (Table 8.1, Figure 8.2).

People who had recurrent shoulder instability had more shoulder pain (SPADI Pain) compared to people without recurrent shoulder instability. People with recurrent shoulder instability had more shoulder dysfunction (SPADI Function) (Figure 8.4) at 0, 3 and 6 months. People with recurrent shoulder instability had higher total SPADI scores compared to those without recurrent shoulder instability (Table 8.1, Figure 8.5).

Kinesiophobia was higher in people with recurrent shoulder instability at 6, 9 and 12 months compared to those who did not suffer recurrence.

WOSI Total and sub-scores of recreation and emotion were higher in people with recurrent shoulder instability when compared to those without recurrent shoulder instability (Table 8.1, Figure 8.7). WOSI Life sub-scores were higher at 6 months in people with recurrent shoulder instability compared to those without recurrent shoulder instability (Table 8.1).

Variable name	Time point	N	Overall mean (s.d.)	Range	Recurrent Mean (s.d.)	Non-Recurrent Mean (s.d.)
SAS		211	12.23 (3.89)	3-20	11.83 (4.51)	12.25 (3.86)
SPADI PAIN		213	25.17 (20.91)	0-96	31.33 (22.65)	24.81 (20.80)
SPADI FUNCTION		213	18.80 (19.6)	0-93	29.66 (25.75)	18.15 (19.06)
SPADI TOTAL		213	20.82 (19.39)	0-92	34.29 (26.20)	20.02 (18.69)
TSK-11 TOTAL	0	213	25.92 (4.38)	10-37	26.67 (5.35)	25.88 (4.33)
WOSI (physical)		213	362.30 (215.30)	0-880	426.70 (168.20)	358.50 (217.50)
WOSI (recreation)		213	182.40 (110.20)	0-400	215.80 (96.00)	180.40 (112.80)
WOSI (life)		213	144.80 (104.60)	0-380	165.80 (119.90)	143.50 (103.80)
WOSI (emotion)		213	154.60 (83.60)	0-300	172.50 (77.60)	153.60 (84.00)
WOSI TOTAL		213	844.20 (471.2)	0-1820	980.80 (434.90)	836.10 (473.00)
SAS		77	10.39 (5.01)	0-19	10.44 (4.72)	10.58 (4.89)
SPADI PAIN	3	76	20.95 (22.23)	0-100	28.50 (21.61)	18.47 (21.06)
SPADI FUNCTION		76	20.41 (30.00)	0-100	30.16 (33.42)	18.65 (29.95)
SPADI TOTAL		76	22.24 (23.58)	0-100	29.52 (20.84)	20.50 (23.64)
TSK-11 TOTAL		77	25.40 (6.37)	11-40	23.11 (7.72)	25.62 (6.25)
WOSI (physical)		75	294.50 (223.10)	0-880	322.50 (253.60)	283.90 (221.30)
WOSI (recreation)		75	139.90 (112.00)	0-400	151.20 (127.40)	133.10 (106.80)
WOSI (life)		75	107.30 (86.40)	0-350	85.00 (88.20)	108.10 (85.60)
WOSI (emotion)		75	125.90 (82.40)	0-300	120.00 (89.00)	125.50 (81.80)
WOSI TOTAL		75	657.10 (471.20)	0-1850	678.80 (538.50)	638.40 (460.90)
SAS		80	11.14 (5.25)	0-20	9.61 (5.57)	11.34 (4.96)
SPADI PAIN		77	14.83 (16.10)	0-100	21.29 (15.1)	13.43 (16.32)
SPADI FUNCTION		76	13.26 (23.98)	0-100	28.12 (34.41)	8.28 (15.62)
SPADI TOTAL		76	13.94 (18.16)	0-100	26.01 (24.03)	10.26 (13.31)
TSK-11 TOTAL	6	76	25.12 (4.910)	11-40	27.35 (6.17)	24.36 (4.31)
WOSI (physical)		77	262.70 (209.80)	0-830	354.70 (239.90)	247.0 (197.00)
WOSI (recreation)		77	113.40 (106.20)	0-380	183.50 (124.20)	93.90 (90.80)
WOSI (life)		77	95.70 (89.90)	0-380	140.60 (110.90)	82.50 (79.40)
WOSI (emotion)		77	115.20 (82.30)	0-300	174.10 (79.60)	98.60 (74.40)
WOSI TOTAL		77	588.30 (455.50)	0-588	852.90 (522.40)	523.80 (412.90)
SAS		67	11.25 (4.26)	0-20	12.00 (2.74)	11.52 (3.99)
SPADI PAIN		66	13.36 (14.76)	0-80	22.80 (17.12)	10.25 (10.25)
SPADI FUNCTION	9	65	8.95 (20.05)	0-100	6.00 (7.04)	6.04 (15.25)
SPADI TOTAL		65	10.73 (15.43)	0-75	12.46 (9.21)	7.74 (11.41)
TSK-11 TOTAL		64	25.39 (5.63)	7-40	27.40 (3.29)	25.25 (5.51)
WOSI (physical)		63	210.20 (166.10)	0-800	266.0 (131.50)	188.70 (146.30)
WOSI (recreation)		63	87.90 (96.10)	0-380	86.00 (82.60)	81.30 (88.70)
WOSI (life)		63	73.70 (78.00)	0-320	86.00 (47.70)	65.70 (69.80)
WOSI (emotion)		63	92.50 (82.60)	0-300	102.00 (78.50)	85.70 (76.30)
WOSI TOTAL		63	464.30 (388.70)	0-1760	540 (287.10)	421.30 (345.10)
SAS		87	11.45 (4.42)	0-20	11.68 (5.23)	11.38 (4.21)
SPADI PAIN		87	10.55 (12.96)	0-72	18.67 (19.96)	8.43 (9.52)
SPADI FUNCTION		76	7.29 (17.46)	0-100	6.90 (10.42)	7.39 (18.96)
SPADI TOTAL		86	8.52 (13.10)	0-67	11.28 (13.24)	7.79 (13.06)
TSK-11 TOTAL	12	87	24.84 (5.42)	8-40	27.05 (5.54)	24.22 (5.27)
WOSI (physical)		82	208.50 (163.60)	0-730	284.40 (198.60)	187.70 (147.70)
WOSI (recreation)		82	93.70 (89.40)	0-330	145.60 (99.20)	79.50 (81.80)
WOSI (life)		82	68.70 (78.70)	0-350	98.30 (94.60)	60.60 (72.50)
WOSI (emotion)		82	92.40 (77.70)	0-290	152.20 (88.70)	76.10 (66.20)
WOSI TOTAL		82	484.50 (368.0)	0-1540	726.10 (419.60)	416.60 (324.50)

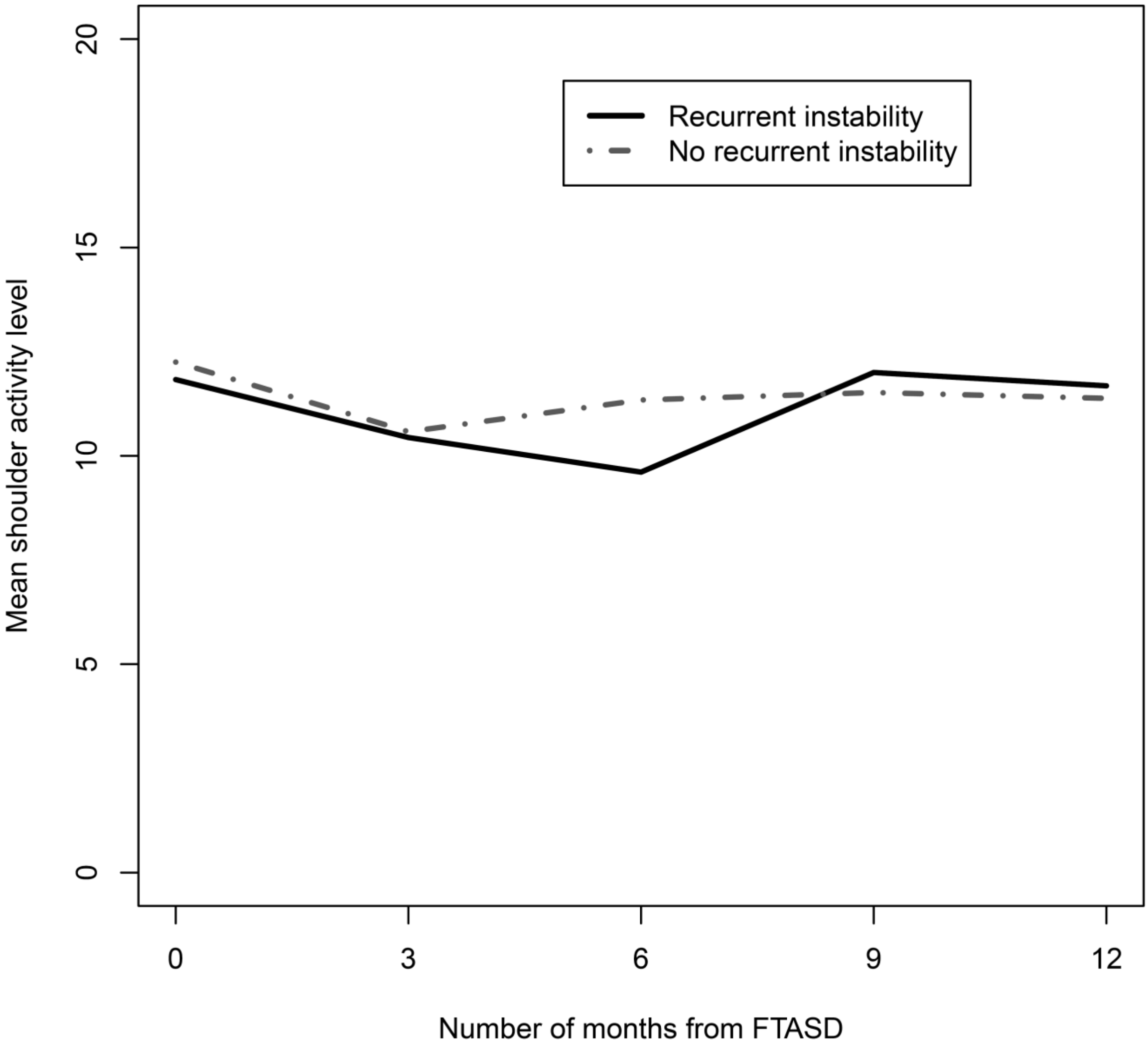

Figure 8.3 Mean shoulder activity values (SAS) in people with and without recurrent shoulder instability from baseline to final follow-up after a FTASD

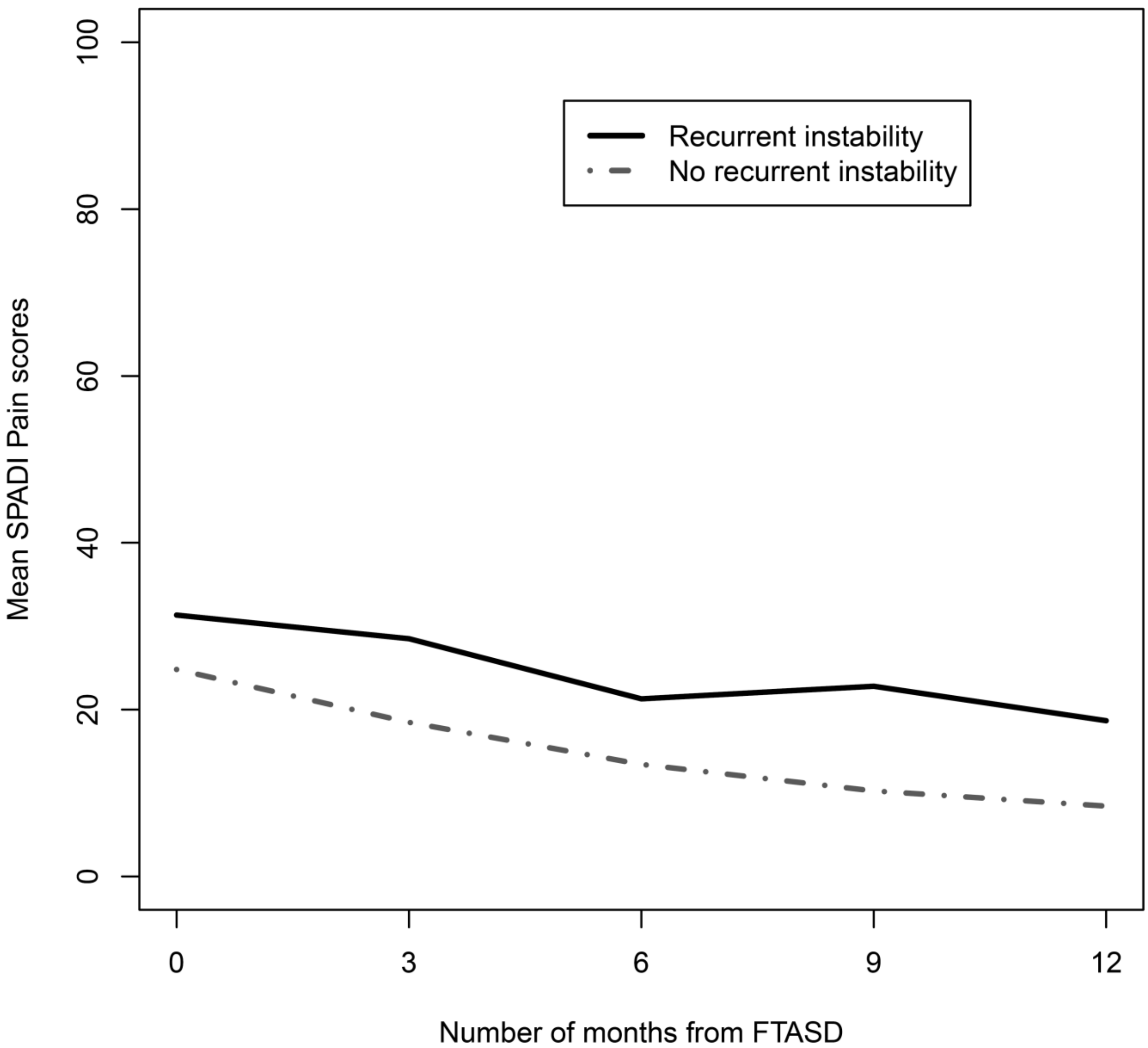

Figure 8.4 Mean SPADI Pain scores in people with and without recurrent shoulder instability from baseline to final follow-up after a FTASD

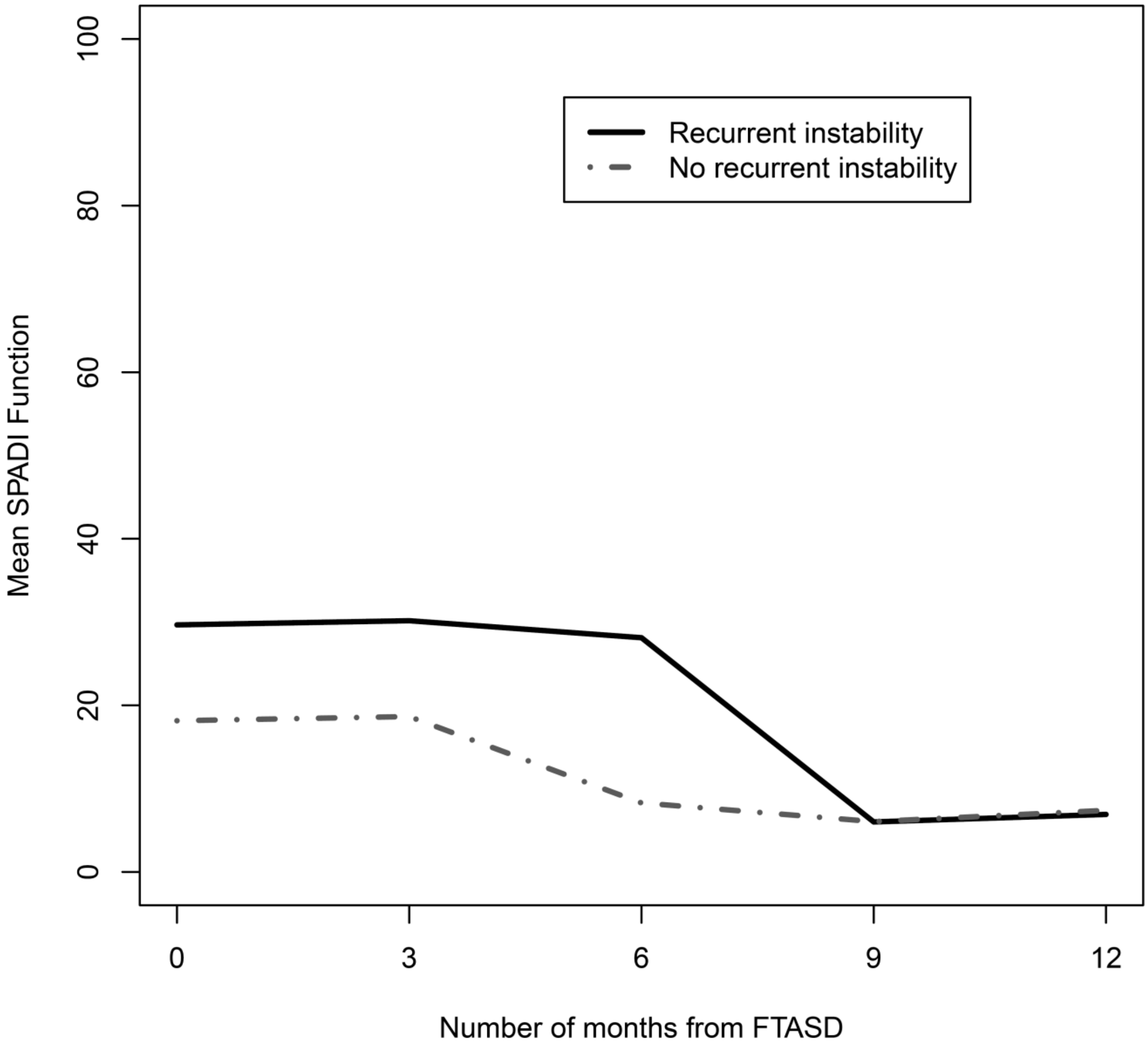

Figure 8.5 Mean SPADI Function scores in people with and without recurrent shoulder instability from baseline to final follow-up after a FTASD

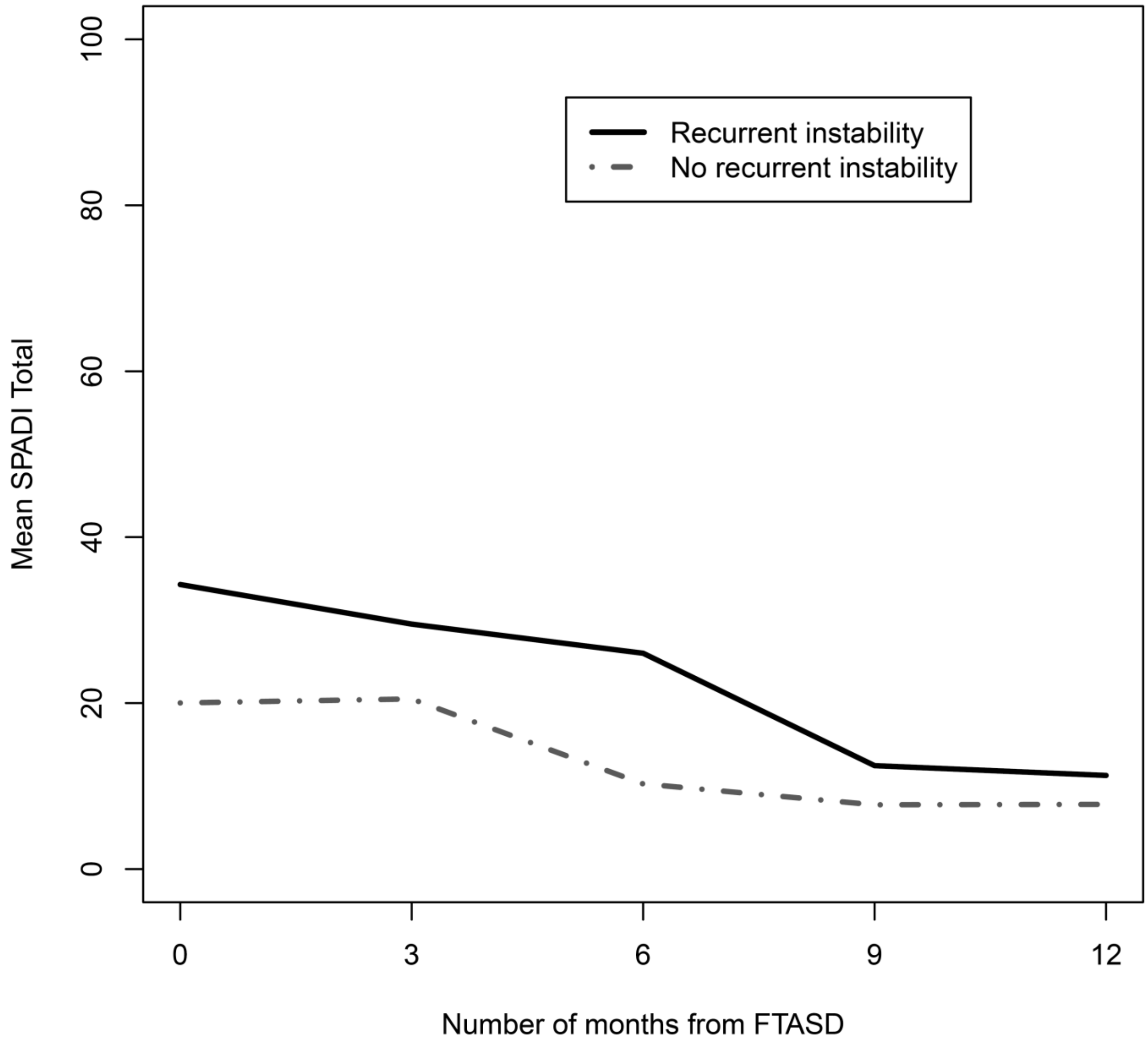

Figure 8.6 Mean SPADI Total scores in people with and without recurrent shoulder instability from baseline to final follow-up after a FTASD

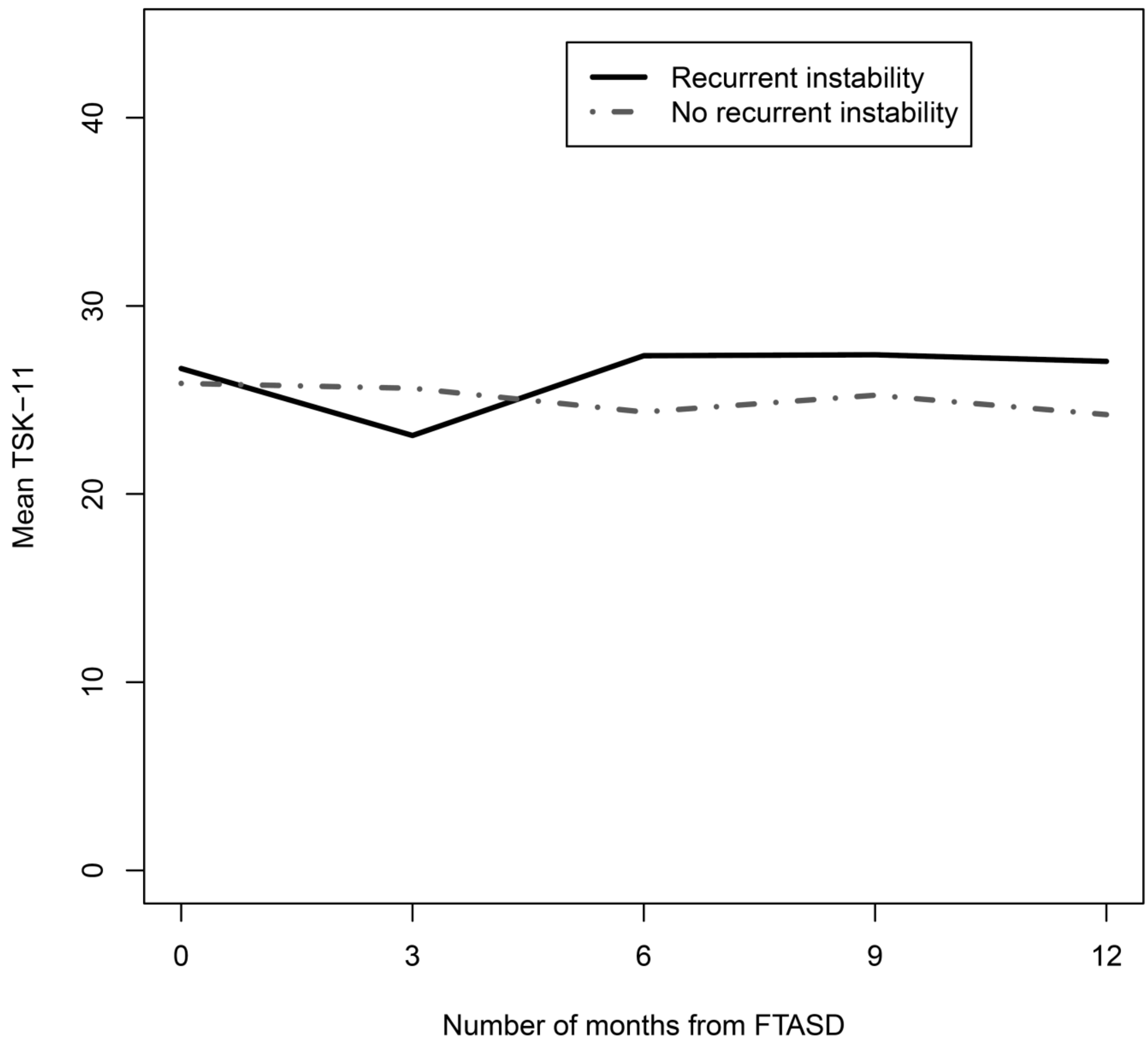

Figure 8.7 Mean kinesiophobia (TSK-11) scores in people with and without recurrent shoulder instability from baseline to final follow-up after a FTASD

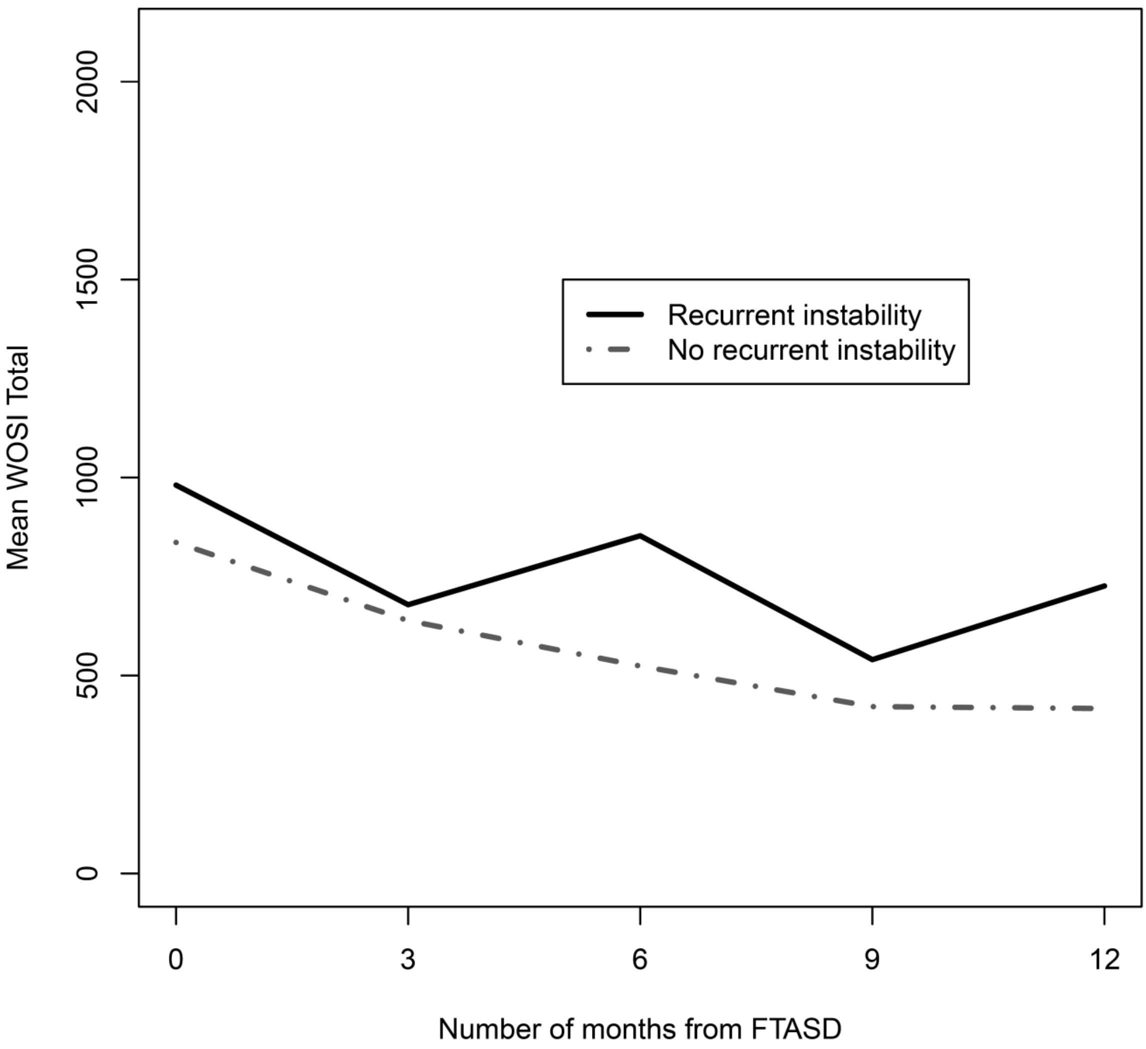

Figure 8.8 Mean quality of life (WOSI-Total) scores in people with and without recurrent shoulder instability from baseline to final follow-up after a FTASD

8.2.4.1 Objective 3: Assess the change in patient reported outcome measures in the entire cohort to 12 months post-injury

This objective was set to examine changes for the patient reported outcome measures for the entire cohort of people following a FTASD, regardless of whether or not they went on to develop recurrent instability. This information may be useful to provide expectations for people who have just had a FTASD regarding timeframes for resolution or pain, dysfunction and quality of life. Unfortunately, due to response rate, only 30% of people were followed over the one year after a FTASD, preventing any meaningful results. Therefore, descriptive analyses have been presented but have not been supported by means comparisons. Further studies are required to assess the change in patient reported outcome measures after a FTASD.

8.2.4.1.1 Objective 3a: Assess the change in shoulder activity in the entire cohort of people with a FTASD from pre-injury (reported retrospectively) to 12 months post-injury.

Across the entire cohort of people who had a FTASD, shoulder activity (SAS scores) was decreased at all times points compared with pre-injury levels. (Table 8.1).

8.2.4.1.2 Objective 3b: Assess the change in quality of life, pain and disability, and kinesiophobia in the entire cohort of people with a FTASD from baseline measure (first measurement point post-injury) to 12 months post-injury.

Shoulder pain (SPADI Pain scores) was improved across all time points when compared with baseline values in the entire cohort of people with a FTASD (Table 8.1). Shoulder function (SPADI Function scores) improved over time in the entire cohort of people with a FTASD (Table 8.1).

There was no change in kinesiophobia (TSK-11) across all time points compared with baseline in the entire cohort of people with a FTASD (Table 8.1). Quality of life (WOSI scores) was improved across all time points when compared to baseline values in the entire cohort of people with a FTASD (Table 8.1).

8.2.4.2 Post-hoc power analysis

This study recruited 213 participants. Not all participants were retained in the study and of those who were followed not all made themselves available for all the questionnaires. Between 81 and 86 participants were available to complete the questionnaires at 12 months following their FTASD. Post-hoc power analysis (with alpha set at 0.05 (two-sided), power=80% to see a difference between people with recurrent instability compared to those without recurrent shoulder instability within 12 months follow-up) revealed the study was powered at 91% for quality of life (WOSI total), and powered >85% for the physical and emotional WOSI sub-domains. Based on the levels of recruitment, differences between people with recurrent and non-recurrent shoulder instability for kinesiophobia (TSK-11) were powered at 66%, shoulder pain and disability (SPADI Total) powered at 23% and shoulder activity (SAS) was powered at 5%.

8.2.5 Discussion

This study sought to examine patient reported outcome measures for people following a FTASD and to see whether these variables changed over time. For the entire cohort (irrespective of whether they went on to develop recurrent shoulder instability), the immediate (within 12 weeks) influence of a FTASD was significant. Quality of life, fear of reinjury (kinesiophobia), shoulder activity, and shoulder pain and function were all negatively influenced. This finding speaks to objective one of this study, where the descriptive analysis of these patient reported variables indicated the detrimental impact of a FTASD.

The lack of sufficient follow-up data over the 12 months following a FTASD precluded the presentation of any meaningful data through the form of means comparisons and analyses across time. Further studies are required to examine how patient reported factors change over time after a FTASD.

The next objective of this study was to take the analysis further and ascertain whether there were any differences in these patient reported variables, over the 12 months following a FTASD, between those people that developed recurrent shoulder instability compared to those that did not. Those people who went on to have recurrent shoulder instability had greater levels of shoulder pain and dysfunction at 6 months compared to the group without recurrence. However, in spite of the group with recurrence having greater shoulder pain at 12 months, their levels of shoulder function had returned to similar levels as the group without recurrence, at the same 12 month time point. Thus, while pain levels are elevated in people with recurrent shoulder instability, they are still able to perform functional tasks with the same capacity as people without recurrent shoulder instability. T

The final objective of the study was to examine the change in shoulder activity, pain and dysfunction, quality of life and kinesiophobia over time compared to the baseline measures. As stated previously, all variables were reported at the time of the initial interview, with the exception of shoulder activity, which was reported retrospectively as the level of shoulder activity prior to the injury. When looking across the entire cohort of people who had suffered a FTASD, shoulder function was improved at 9 months after a FTASD when compared with initial injury levels. Shoulder pain steadily improved from baseline and was improved at all time points from the initial injury. There was a improvement in quality of life from baseline at all time points over the entire 12 months. There was a decrease in shoulder activity levels from pre-injury levels at all times points, although a smaller difference at 9 and 12 months post-injury, which may indicate a return to similar pre-injury activity levels. Overall, kinesiophobia did not greatly change across the entire 12 months, but there were indications of a decrease in kinesiophobia over the 12 months following a FTASD.

While quality of life, pain, function and shoulder activity in the total cohort improved across time, kinesiophobia in the total cohort showed no decrease across the 12 months following a FTASD. This is in contrast to Johnston and Carrol (1998) who reported a ‘U’ effect where kinesiophobia was affected initially after an injury, improved over time with treatment, and then worsened again as people planned to returned to sport (Johnston & Carroll, 1998). However, Johnston and Carrol (1998) specifically studied athletes who were returning to sport, while the population in our study was a general population that included both sporting and non-sporting people.

The mean TSK-11 score at baseline in our study in people with a FTASD (25.92) was higher when compared with people without a FTASD reported in a different study (mean (s.d.) males 18:00 (4.98), females=17.99 (3.96)) (Parr et al., 2012) and indicated increased levels of kinesiophobia in people with a FTASD. A possible explanation for the elevated TSK-11 levels at baseline and across time is that kinesiophobia may represent a personality trait that is inherent to those who suffered a FTASD and was already elevated prior to the FTASD. Alternatively, the TSK-11 score may not be a responsive measure of change in kinesiophobia over time in a population of people with an acute FTASD. For example, the TSK-11 has had limited use in an acute population, and some of the questions are not specific to the immediate time point but ask for participants beliefs about situations (e.g. “pain always means I have injured my body”). Beliefs like this may not change over time. Woby et al. (2005) have reported responsiveness of the TSK-11 to be a score of 3.4 (95% CI (1.5-5.4)) in a population of people with chronic back pain, but this may not hold true in a population of people with acute shoulder pain. Furthermore, Hapidou et al. (2012) reported that the minimal detectable change (MDC) score of the TSK-11 is 5.6 points which indicates that the difference detected in our study (2.83 points at 12 months) between people with and without recurrent shoulder instability may not be clinically meaningful. Despite this, the findings of Chapter 7, which indicated that kinesiophobia at baseline was predictive of recurrent shoulder instability at 12 months, indicate that this is an area worthy of further research. Further investigation into the effects of a FTASD on psychosocial variables such as kinesiophobia is warranted.

When compared to other people with anterior shoulder instability, the quality of life scores in this study (65.7% +/-22.4%) were higher than other studies which have examined quality of life in people with anterior shoulder instability (50.8% +/- 21.5% (Cunningham et al., 2015)) and those about to undergo shoulder stabilisation surgery (43.3% +/- 19.9% (Kraeutler, McCarty, et al., 2018)). Both these studies reported quality of life in people who were presenting for further medical intervention, while our study measured quality of life in all people who had had a FTASD. People who present for medical intervention a FTASD may have poorer quality of life and be different from the total population of people who have suffered a FTASD. The minimal clinically important difference (MCID) for the WOSI has been reported as 220 (10.4%) (Kirkley, Griffin, & Dainty, 2003) which indicates that difference in the quality of life reported in our study and the populations of both Cunnigham et al. (2015) and Kraeutler et al. (2018) was clinically meaningful. Mean overall scores of shoulder activity level for the total cohort, as measured with the SAS, decreased compared with pre-injury levels to 10.39 at 3 and 11.14 at 6 months. However, they had increased to 11.25 at 9 months and 11.45 at 12 months following a FTASD (with a score of 12 before the injury indicating that participants' levels of shoulder activity had returned to near their pre-injury state by 9 months).

People in this study had lower levels of shoulder activity than people in the USA with shoulder instability who were about to undergo shoulder stabilisation, as measured with the SAS (mean (s.d.) 13.2 (4.5)) (Kraeutler, McCarty, et al., 2018). Again, people who present for further medical intervention are only a subset of the entire cohort of people who have had a FTASD. Their higher levels of shoulder activity may result in more perceived limitation in total function. Neither MDC or MCID have been reported for the SAS (Ruzbarsky, Marom, & Marx, 2018).

The SPADI has not been widely used in people with shoulder instability (Buteau et al., 2007) and the significance of our findings supports further use of this measure in a population of people with shoulder instability. The SPADI Total scores in our population with a FTASD were 20.82 shortly after their FTASD. and decreased to 8.37 at 12 months following their injury, indicating decreased levels of shoulder pain and dysfunction over this time period. Asymptomatic people have reported a SPADI score of 3.3 if they had no history of shoulder pathology (McLean et al., 2018). Roy et al. (2009) have reported that the MDC for the SPADI is 18 points and the MCID is between 8 to 13 points. Therefore, the findings from our study indicated a clinical improvement in pain and dysfunction from the time of initial injury (a change of 12.45 points). Furthermore, the difference between the SPADI Total scores recorded in our population at 9 and 12 months and the healthy cohort of McLean et al. (2018) was not greater than the minimal clinical difference for the SPADI Total score (7.43 and 5.07 points respectively). This indicates that at 9 and 12 months after a FTASD, people who have had a FTASD do not have a clinically meaningful different level of shoulder pain and function compared with healthy people. Additionally, the SPADI has been shown to be associated with psychosocial distress (Menendez, Baker, & Oladeji, 2015). Multivariate analysis of people with shoulder pain who reported to a shoulder clinic in Alabama (USA) demonstrated an association between SPADI scores and greater catastrophic thinking, lower self-efficacy, higher body mass index and disability (Menendez et al., 2015). Therefore, further analysis of the association between SPADI and other psychosocial variables such as kinesiophobia is warranted.

8.2.5.1 Limitations

Considerable effort was made to establish contact with all participants at each follow-up point. However, as with many prospective studies, continual contact with a relatively young mobile population across the 12 month follow-up period was difficult. New Zealanders have high migration rates (Statistics New Zealand, 2016) and this may have contributed to these challenges. While we were able to contact 186 of the original 213 participants to establish the presence of recurrent shoulder instability, only 86 were willing to answer questionnaires to record the patient reported outcomes. It is not possible to establish whether the people who did not want to answer the questionnaires were different from those who did. The final numbers of 86 participants, from the original 213 participants, represents approximately one third of the original population and may not accurately represent the quality of life, shoulder pain and disability, level of activity, and kinesiophobia for the entire cohort. Post-hoc analysis for 12 month follow-up data demonstrated that with 86 participants we were sufficiently powered for quality of life analysis only. This study was not adequately powered for analyses of shoulder activity level or kinesiophobia, and had limited power for shoulder pain and function (8.2.4.1).

There may be some systemic measurement error as the questionnaires may not have accurately measured these psychosocial variables. Self-reported questionnaires are proxy measures of an individual's actual state as these measures, by their very nature, are unobservable and must be inferred (Atkinson & Lennox, 2006; Nunnally & Bernstein, 1994). Additionally, limitations in the capture of intended constructs may have arisen. For example, as the SAS measures only the frequency of activity, people who were engaged for intense efforts of activity on a weekly basis would score lower in activity level than a person who engaged in moderate levels of activity on a daily basis.

8.2.6 Conclusion

Quality of life, kinesiophobia and shoulder pain were significantly affected by a FTASD. Adequately powered cohort studies in young active populations are required to investigate change in psychosocial variables over time following a FTASD. Kinesiophobia do not greatly change across the 12 months following a FTASD and may be either an inherent predisposition, in a constant elevated state following a FTASD, or require longer follow-up.

Chapter 9 **Summary, Discussion & Conclusion**

9.1 Preface

This final chapter of the thesis begins with a summary of the main findings, contextualised with the relevant thesis aims, from the systematic reviews, analyses of univariate and multivariate predictors of recurrent shoulder instability following a FTASD, and validation of the predictive tool, and analysis of the impact of a FTASD upon patient reported outcome measures. This is followed by a discussion of the development and validation of the tool and the patient reported outcome measures. Limitations of the research are then discussed, as are the clinical implications of this work. Finally, the conclusions of this thesis are presented.

9.2 Summary of the main findings

<u>Aim 1: to identify risk factors which predispose those with a FTASD to further episodes of shoulder instability.</u>

Two systematic reviews and meta-analyses were undertaken to examine the key risk factors for recurrent shoulder instability following a FTASD in adults and children. The statistically significant findings were that people between the ages of 15 and 40 years were 13 times more likely to experience recurrent shoulder instability after a FTASD, than people over the age of 40 years. Children aged 14 to 18 years were 24 times more likely to experience recurrent shoulder instability following a FTASD, compared with those aged 13 years and under. Children with a closed physis were 14 times more likely to experience recurrent shoulder instability compared to those with an open physis. Males (adults and children) were 3 times more likely to experience recurrent shoulder instability following a FTASD than females, although this did not reach statistical significance in the children. Adults with a greater tuberosity fracture were 7 times less likely to experience recurrent shoulder instability. Adults with hyperlaxity were 3 times more likely to experience recurrent instability when compared to those without hyperlaxity. Other common risk factors identified in adults and children, which did not reach significance, included mechanism of injury; the presence of a bony Bankart lesion, labral Bankart and/or

Hill Sachs lesion; nerve palsy; occupation; hyperlaxity; participating in physiotherapy treatment; limb dominance and side of dislocation.

Aim 2: to develop and pilot a predictive tool which can differentiate between people who will have recurrent shoulder instability and people who will not develop recurrent shoulder instability, in a population of people with FTASD who are managed conservatively.

Risk factors for the development of recurrent shoulder instability were examined in a one-year prospective cohort study of New Zealanders, aged 16 to 40 years, following a FTASD. Key findings were that a bony Bankart lesion, aged between 16 and 25 years, dislocation of the dominant shoulder, not being immobilised, and higher shoulder pain and dysfunction (SPADI) and kinesiophobia (TSK-11) were key predictors of recurrent shoulder instability following a FTASD and could be used to formulate a clinical tool.

Aim 3: to examine the predictive validity of a predictive tool in differentiating between people who will have recurrent shoulder instability and people who will not develop recurrent shoulder instability, in a population of people with FTASD who are managed conservatively.

The predictive tool established in Chapter 6 was validated in a separate population to establish external validity. The predictive tool had excellent specificity, which indicated that clinicians could use the tool to correctly predict which people were not going to have recurrent shoulder instability following a FTASD, out of those who indeed did not have a recurrence. However, the tool had limited accuracy and limited sensitivity, indicating that it was not able to discern people who were going to have recurrent shoulder instability following a FTASD, of those who did go on to have a recurrence.

Aim 4: to evaluate the impact of a FTASD on patient perceived pain, function, kinesiophobia and quality of life and examine the association between these psychosocial variables and recurrent shoulder instability.

The immediate impact of a FTASD (within 12 weeks from the time of injury) was significant, which was evident in negatively influenced levels of quality of life, shoulder pain and dysfunction, kinesiophobia and shoulder activity in all people following a FTASD. Further analysis of the data was not possible due to low levels of engagement by the participants in completing the questionnaires which examined quality of life, kinesiophobia and shoulder pain and dysfunction. The large amount of incomplete or missing data meant that the study was underpowered to report differences in shoulder pain and dysfunction in people with and without recurrent shoulder instability.

People who had recurrent shoulder instability had, on average, more pain and decreased quality of life when compared to those people without recurrent shoulder instability, following a FTASD. Kinesiophobia was more severe in people with recurrent shoulder instability at 6 and 12 months after a FTASD when compared to people without recurrent shoulder instability. Shoulder function was on average not different in people with or without recurrent shoulder instability. People who had recurrent shoulder instability, did not on average, have different levels of shoulder activity compared with people without recurrent shoulder instability, following a FTASD.

When looking at the entire cohort, irrespective of whether people had recurrent shoulder instability or not, over the 12 month period people initially had decreased quality of life and function, and increased pain, following a FTASD, which improved over the 12 months post-injury. Kinesiophobia did not alter over the 12 months for the total cohort of people following a FTASD. There was a decrease in shoulder activity for the total cohort from pre-injury levels at 3 and 6 months but a smaller differences from pre-injury levels at 9 and 12 months.

9.3 Key risk factors for recurrent shoulder instability after a FTASD

Review of the literature was undertaken with two systematic reviews and meta-analyses, one in adults and one in children, in order to highlight the key risk factors associated with recurrent shoulder instability following a FTASD. In the adult population, key variables which predicted recurrent shoulder instability included: sex, age less than 40 years, involvement in contact or collision sports, greater tuberosity fracture, nerve palsy and bony Bankart lesion. In the population of children, the key risk factors were age younger than 14 years, sex and the presence of an open physis. Following the two reviews, the difference in risk factors between adults and children for the development of recurrent shoulder instability following FTASD were emphasised. Clearly these are two different groups of people and, as such, require different methods of analysis to understand the relevance of these risk factors. A decision was therefore made, for the remainder of this doctoral work, to concentrate on the adult population.

The key variables identified from both the systematic review in adults and children, along with others that were included following suggestions sought from an expert panel, were recorded in the prospective cohort study as participants entered the study. These variables were examined to see if there was an association with recurrent shoulder instability at 3, 6, 9 and 12 months post-injury.

The first prospective cohort study found that statistically significant univariate predictors of recurrent shoulder instability following a FTASD were: bony Bankart lesion; not being immobilised; total scores for SPADI, SAS, TSK–11, and WOSI; two subsections of the WOSI (Physical, and Emotion); SPADI Function score; and ethnicity that was not ‘European Other’ (where ‘European Other’ referred to people who were of European descent but not born in New Zealand). Variables that had a p-value of 0.10 and less were also entered into the model. These variables included: age 16 and 25 years; ethnic group of New Zealand European, New Zealand Māori and Pasifika; dominant side dislocated; limited contact sports versus other categories of sport; and involvement in contact sport. A backwards selection process identified the multivariate predictors of recurrent shoulder instability ($p \leq 0.10$) which included: bony Bankart lesion, aged between 16 and 25 years, dislocation to the dominant shoulder, lack of immobilisation following the FTASD, high levels of shoulder pain and disability and kinesiophobia.

Each of the key risk factors, as identified by the adult systematic review, have been grouped below as demographic, physical and patient reported outcome variables and will now be discussed.

9.3.1 Demographic risk factors for recurrent shoulder instability after a FTASD

9.3.1.1 The role of sex as a risk factor for recurrent shoulder instability after a FTASD.

Our systematic review in both adults and children found an increased risk of recurrent shoulder instability in males compared with females. There may be an interaction between sex and other risk factors such as neuromuscular factors (e.g. coordination) or mechanism of injury (Owens, Agel, et al., 2009). For example, increased involvement in contact sports for men may result in an increased likelihood of sustaining an instability event (Owens, Agel, et al., 2009). Additionally, there may be a sex bias in collision sports, with a modified set of rules for women across many sports which may limit or reduce contact (Keeler, 2007). However, this is not the case for collision sports in New Zealand (such as rugby union and rugby league) with the same rules for men and women's rugby (Rugby League International Federation, 2013; World Rugby, 2016).

The lack of a statistically significant finding in the role of sex as a statistically significant variable to predict recurrent instability following a FTASD, in our study was unexpected, given that several other studies have found that males are more likely to suffer recurrent shoulder instability (Robinson et al., 2006; te Slaa et al., 2004) and the findings of our systematic reviews and meta-analyses indicated a similar conclusion. As is the case with several studies, in our prospective cohort study, there was a low ratio of female:male (18 females:110 males) with FTASD. Similar to the findings from our study, Sachs et al. (2007) had a ratio of 29 females:102 males and showed no difference in rates of recurrent shoulder instability between sexes. However, Robinson et al. (2006) also had low ratio of females to males (27 females:225 males) and reported increased rates of recurrent shoulder instability in males ($p<0.01$). The study of te Slaa et al. (2004) had a ratio of 38 women:69 males, and showed a trend towards increased rates of recurrent shoulder instability in males ($p=0.08$), and no interaction effect between age and sex. Conversely, Hoelen et al. (1990) showed higher incidence rates for a FTASD in younger men and older women and higher recurrence rates for males (40%) compared with females (8%). Additionally, male athletes have been shown to return to pre-operative levels of sporting activity faster than females which may predispose them to increased rates of recurrent shoulder instability (Gerometta, Rosso, Klouche, & Hardy, 2016). The lack of a statistically significant finding in our study may have been because it was not powered sufficiently to find a difference between sexes.

In a study of shoulder activity levels in a population in the USA, males were shown to have higher levels of shoulder activity than females (Hepper et al., 2013). In contrast, our study showed that while females were less likely to participate in contact sport (4 of 18 females (22%) compared with 51 of 110 males (46%)), females had significantly increased levels of self-reported shoulder activity compared to males ($F=20.964$, $p<0.01$, $t=-1.782$). Additionally, in our study there was no statistical difference between sexes in occupation (sedentary vs. manual).

9.3.1.2 The role of age as a risk factor for recurrent shoulder instability after a FTASD.

Both the adults' and children's systematic reviews and meta-analyses found age to be a statistically significant risk factor in predicting recurrent shoulder instability after a FTASD. In the adults' study, there was overwhelming evidence that people under the age of 40 were more likely to have recurrent shoulder instability after a FTASD than people over the age of 40. This is consistent with a more recent systematic review (Wasserstein et al., 2016). There is further evidence that people aged between 15-25 years have increased risk of recurrent shoulder instability compared with those older than 25 years (Robinson et al., 2006). This may be due to several factors including increased exposure to activities which cause instability events or biomechanical factors related to tensile strength of shoulder ligaments, capsule and labral tissue (Lee et al., 1999). These biomechanical factors may result in increased frequency of capsulo-labral pathology in those aged 15-25 years as people in this age group are more likely to sustain capsule-labral pathology than ligamentous or tendon pathology (Brophy, Hettrich, et al., 2016; Lee et al., 1999). Conversely, those aged over the age of 25 years are more likely to present with ligamentous or tendon pathology (Brophy, Hettrich, et al., 2016; Lee et al., 1999). These biomechanical factors may contribute in part to the increased rates of recurrent shoulder instability in those aged 15-25 years and decreased rates of recurrent instability in those aged over 25 years.

From the review conducted in children, those younger than 14 years were less likely to have recurrent shoulder instability than those aged 14-18 years. This is consistent with the findings of a more recent systematic review (Leroux et al., 2015). The protective factors may be confounded by exposure to sporting environments as rules for contact or collision sports are modified for younger competitors (Gastin, Allan, Bellesini, & Spittle, 2017). Skeletal differences, such as an open humeral physis, may be a protective factor against recurrent shoulder instability. It is possible that when there is an open physis, the physis is more likely to dislodge during a shoulder dislocation and this does not have the same implications for recurrent shoulder instability as it does not affect articular surfaces of the glenoid or humeral head (Choi, Potter, & Scher, 2005). Alternatively, the open physis may be associated with the tensile load of the capsule-ligamentous structures, as the physis remains open during periods of skeletal growth (Lin et al., 2018). During periods of growth it is logical to assume that capsule-ligamentous tissue may also be undergoing periods of growth and have increased elasticity (Wolf, Cameron, Clifton, & Owens, 2013). The increased elasticity of the capsule and ligaments may result in less labral or bony pathological damage to the shoulder as the capsular tissue would stretch under load. This may result in decreased risk of recurrent shoulder instability.

Many authors have reported that being of a younger age is a predictive variable for recurrent shoulder instability after a FTASD (Hoelen et al., 1990; Kralinger et al., 2002; Robinson et al., 2006). It was unexpected that being aged 16-25 years was not statistically significant as a predictor of recurrent shoulder instability following FTASD following the univariate analysis, but trended towards significance in this current study ($p=0.07$). This may have been because of the relatively narrow age band for study inclusion (i.e. less than 40 years), compared with other studies which included participants up to 100 years (Hoelen et al., 1990; Kralinger et al., 2002). Robinson et al. (2006) reported an increased risk of recurrent shoulder instability following FTASD in people 15-25 compared with people aged 26 to 35 years. The current study used this finding from Robinson et al. (2006) for the sample size calculation and was therefore powered to find a difference in the various age groups that were examined (see Table 7.1). Despite being powered to detect an effect, our study did not identify a statistically significant result for the 16-25 years of age group following the univariate analysis (however did provide strong indicatory trends (p=0.07) akin to Robinson et al. (2006)). The differences may be due to regional differences between Scotland (the location of Robinson et al. (2006)) and New Zealand (such as activity level or ethnicity) which may explain why our study only trended towards a statistically significant finding. Similar to the findings of Robinson et al. (2006), our study also found that age 16-25 was a significant predictor (p=0.03) for recurrent shoulder instability in the presence of other variables (i.e. multivariate analysis). Findings that are not significant with univariate analysis, but become significant with multivariate analysis may occur due to the following reasons; an unbalanced sample size, the effect of missing data, large variation within the group compared to between group variation, and the presence of an interaction between variables (Lo, Li, Tsou, & See, 1995)

Some authors have proposed that rates of recurrent shoulder instability may decrease as people age because of decreased activity levels (Hepper et al., 2013; Rowe, 1956). However, our study showed a moderately weak correlation between increasing age and increasing levels of shoulder activity (r=0.402, p<0.001). Hepper et al. (2013) reported decreased levels of shoulder activity with increased age. These authors reported shoulder activity in 2403 participants with an age range of 18 to over 70 years who completed an internet survey administered by a marketing research firm. In contrast, our population was aged between 16 and 40 years, and this narrow age band may explain the lack of association in this finding. We also found that people who were in the younger age group (16-25 years), were more likely to be involved in a sedentary occupation (Chi square=4.138, p=0.04) (possibly indicating their involvement at school or university).

Another confounding factor may have been the involvement in contact sport as significantly more younger people (16-25 years) in our study were involved in contact sport when compared to people aged between 26 and 40 years (Chi square=13.64, p<0.001). Robinson et al. (2006) have shown increased risk of recurrent shoulder instability in people who participate in contact or collision sports, and thus this may explain our trend towards increased risk of recurrent shoulder instability in people aged 16-25 years.

9.3.1.3 Ethnicity as a predictive variable for recurrent shoulder instability after a FTASD

Some authors have proposed a genetic predisposition to shoulder dislocation that may be related to the specific genetic biomarkers such as collagen type, or glenoid orientation within that ethnic group (Churchill, Brems, & Kotschi, 2001; Khoschnau et al., 2008; Nixon & Young, 1956). However, ethnicity is not dichotomous and people in New Zealand can define their ethnicity as belonging to up to 6 different groups (Statistics New Zealand, 2015). Many people in New Zealand identify with mixed and sometimes multiple ethnic groups. Furthermore, conventional classification in New Zealand dictates that if a person identifies with more than one ethnicity, the minority ethnicity will be the one that is retained in the classification (Statistics New Zealand, 2015). Therefore, somebody may be categorised as New Zealand Māori even if they are also New Zealand European. Thus, findings related to ethnicity can be unrepresentative, and differences in ethnic groups should therefore be interpreted with caution.

As a univariate predictor, a reduced risk of recurrent shoulder instability was associated with an ethnicity of ‘European Other’ (which indicated a person of European descent, who was not born in New Zealand). Examples of ‘European Other’ included Australian, South African, English and German people. The people in this ethnic group had migrated to New Zealand from other countries. People identifying with ‘European Other’ were significantly older than those from New Zealand European and Pasifika groups ($p<0.05$), indicating an interaction between age and ethnicity. Shoulder activity level was similar across ethnicities ($p>0.05$).

When groups of ethnicities were investigated, there was a trend towards increased recurrent shoulder instability in people who belonged to the combined group of ethnicities of New Zealand European, New Zealand Māori, or Pasifika ($p=0.09$). This combined ethnic group was more likely to have been born in New Zealand and not emigrated from another country. This combined ethnic group was significantly younger in age compared when compared with people who did not identify as New Zealand European, New Zealand Māori or Pasifika ((mean = 23.78 (6.79) compared with 28.52 (7.32), $F=8.94$, $p=0.003$). Again, there was no difference in shoulder activity level between these ethnic groups.

In summary, predicting recurrent shoulder instability following a FTASD based on ethnicity is difficult and may be unrepresentative of particular ethnic groups due to the current methods of classification. Further investigations into specific genetic biomarkers may be more useful in predicting recurrent shoulder instability than categorisations of ethnicity. Additionally, the age of participants in this study may have confounded results as people classified as 'European Other' were statistically significantly older than the remaining cohort, and people classified in the group of NZ European, NZ Māori and Pasifika were statistically significantly younger than the remaining cohort.

9.3.1.4 Dominant side affected as a predictive variable for recurrent shoulder instability after a FTASD

The systematic review in adults did not find shoulder dominance to be a statistically significant predictor of recurrent shoulder instability following a FTASD. Several studies in our systematic review showed that neither arm dominance (Hoelen et al., 1990; Sachs et al., 2007; Salomonsson et al., 2010; Vermeiren, Handelbery, Casteleyn, & Opdecam, 1993) or affected/injured side (Simonet & Cofield, 1984) was associated with recurrent shoulder instability after FTASD.

Similar to the findings of many authors (Hoelen et al., 1990; Sachs et al., 2007; Salomonsson et al., 2010; Vermeiren, Handelbery, Casteleyn, & Opdecam, 1993), this prospective cohort study found that limb dominance (independent of the side that was dislocated) was not a statistically significant predictor of recurrent shoulder instability following a FTASD in univariate analysis. However, once we had accounted for the side of the dislocation and the relationship with dominance, our study showed that people with a shoulder dislocation to the non-dominant side, did trend towards being less likely to have recurrent shoulder instability ($p=0.10$) in univariate analysis. Our first prospective study had 110 of 128 (86%) people who were right handed, 72 of 128 (56%) who dislocated their right side and 63 of 128 (49.2%) who dislocated their dominant side. Hoelen et al. (1990) showed that people dislocated their dominant and non-dominant sides similarly (53% dominant side dislocations compared to 46% non-dominant side dislocations). Likewise, Sachs et al. (2007) showed similar injuries to the dominant arm (40%) as the non-dominant (60%) and no association between arm dominance and people who underwent surgical stabilisation surgery. While previous studies have had similar proportions of dominant and non-dominant sides affected, our study had a much larger percentage of people who dislocated their dominant limb. This may have affected our findings with regards to dominance because the proportion of people who dislocated their non-dominant limb were under-represented in the sample. Under-representation of the sample results in decreased power, which can result in an increased risk of Type II error (a false negative i.e. not finding a difference when a difference truly exists). A greater percentage of people who had a FTASD on their non-dominant side may have increased the significance of both the univariate and multivariate results.

9.3.2 Physical risk factors for recurrent shoulder instability after a FTASD

9.3.2.1 Bony Bankart lesions as a predictive variable for recurrent shoulder instability after a FTASD

An interesting finding from the adults' systematic review was the presence of a bony Bankart lesion decreased the risk for recurrent shoulder instability after a FTASD. Large bony Bankart lesions are more likely to be immediately surgically stabilised (Robinson et al., 2006; Salomonsson et al., 2010) and these people are then often excluded from prospective cohort studies. In their prospective cohort study in Sweden, Salomonsson et al. (2010) excluded people with large bony Bankart lesions which occurred following a FTASD as these people immediately underwent surgical stabilisation. Similarly, the 10 people with a large bony Bankart lesion in the prospective cohort study by Robinson et al. (2006) underwent surgical stabilisation within 2 years and were excluded from further analysis. People with smaller bony Bankart lesions were included in the studies conducted by Salomonsson et al.(2010) and Robinson et al. (2006).

In our study, people with large bony Bankart lesions were not excluded. We found that the presence of a bony Bankart (of any size) lesion was predictive of recurrent shoulder instability after a FTASD (OR=3.65, p=0.04). This finding was in agreement with the findings of Robinson et al. (2006) but in contrast to the findings by Salomonsson et al. (2010), although those studies did not include people with large lesions as described above. One of the strengths of the current study was that people with a bony Bankart lesion of any size remained in the study (if they had not been operated on, which accounted for the exclusion of one participant). Thus, it was possible to illustrate the increased likelihood of recurrent shoulder instability in the presence of a bony Bankart lesion. Other authors have proposed that the presence of a bony Bankart lesion results in decreased stability of the glenohumeral joint because of decreased bony congruity and reduced glenoid contact surface (Burkhart & De Beer, 2000). The decreased joint stability results in increased recurrent shoulder instability. Further investigation into the size, location and interaction of bony Bankart lesions with other pathological lesions (such as Hill Sachs lesions) is required to establish a precise indication of recurrent shoulder instability.

9.3.2.2 Hill Sachs lesions as a predictive variable for recurrent shoulder instability after a FTASD

In our meta-analysis which investigated risk factors for recurrent shoulder instability in adults, we showed that people who have had a Hill Sachs lesions were 1.55 times more likely to have recurrent instability. However, this finding was not significant ($p=0.72$) and had a large degree of variability between studies ($I^2=61.51$). Similarly, the current prospective cohort study showed a trend towards increased risk of recurrent instability in people with a Hill Sachs, that was not statistically significant ($OR=1.45$, $p=0.38$). The lack of a statistically significant finding with regards to the presence or absence of a Hill Sachs lesion is in agreement with other studies (Hoelen et al., 1990; Salomonsson et al., 2010). Other authors have proposed that the combination of Hill Sachs and bony Bankart lesions (glenoid track) may be more relevant to recurrent shoulder instability because of the interaction on the bony contact areas in these lesions which result in decreased stability of the joint (Di Giacomo et al., 2014). Further prospective investigation is required to investigate whether the size of a Hill Sachs lesion (Kralinger et al., 2002), or the interaction with bony Bankart lesions (Di Giacomo et al., 2014) has an impact on recurrent instability. In summary, our study, like many others, found no statistically significant association between Hill Sachs lesions and recurrent shoulder instability for people following a FTASD.

9.3.2.3 Greater tuberosity fractures as a predictive variable for recurrent shoulder instability after a FTASD

A finding from the systematic review in the adult population, was that the presence of a greater tuberosity fracture decreased the rate of recurrent shoulder instability by over seven times (OR=0.135, p=0.00). It has been postulated that this may be due to the loss of shoulder external rotation ROM associated with this injury, as those with a loss of external rotation with the elbow by the side had decreased risk of recurrence (Kralinger et al., 2002). Furthermore, greater tuberosity fractures result in decreased movement of the limb for a significant period of time (Kralinger et al., 2002). This may increase the strength of the anatomical repair and limit exposure to high risk dislocation positions such as abduction/external rotation (Kralinger et al., 2002).

In Phase 1 of our study, there was one greater tuberosity fracture (1%). The lack of a statistically significant finding in our study was therefore likely due to the low numbers of greater tuberosity fractures in our cohort. The study of Robinson et al. (2006) had 10 greater tuberosity fractures from a total population of 252 people with a FTASD (4%). Similarly, Hoelen et al. (1990) followed people with a FTASD and reported 3 greater tuberosity fractures in people aged 11-30 years (5%), 18 in people aged 31-60 (35%) and 9 in people aged 61-100 (15%). Greater tuberosity fractures were more common in people aged 31-60 years (Hoelen et al., 1990). The population in our study was comparatively younger than that of Hoelen et al. (1990) who included participants from 11-100 years and may explain the low prevalence of greater tuberosity fractures in our study as these injuries are more prevalent in an older population.

9.3.2.4 Nerve palsy as a predictive variable for recurrent shoulder instability after a FTASD

Findings from the systematic review in adults indicated an axillary nerve palsy does not affect the structural integrity of the joint and this lesion was found to decrease the risk of recurrent instability. As with greater tuberosity fractures, there is decreased movement following the FTASD, which may allow time for the pathology to heal, and decrease exposure to high risk situations (Kralinger et al., 2002). The clinical diagnosis of nerve palsies was not available for examination in the current study.

Further investigation of the role of nerve palsies is warranted in people with a FTASD.

9.3.2.5 Immobilisation status as a predictive variable for recurrent shoulder instability after a FTASD

The position of the joint and length of immobilisation of the shoulder following a FTASD continues to be a contentious topic in the orthopaedic literature. Our meta-analyses found that there was no statistically significant difference related to the type of immobilisation or the period of immobilisation. Our prospective cohort study showed that people who were immobilised in a sling across their body had decreased recurrent shoulder instability in both univariate (OR=0.38, p=0.05) and multivariate (OR=028, p=0.03) analysis. The length of time and position of immobilisation has been investigated at length in the literature, within several studies (Deyle & Nagel, 2007; Itoi, Sashi, & Minagawa, 2001; Liavaag et al., 2011; Maeda et al., 2002; Moxon, Walker, & Rando, 2010; Scheibel et al., 2009; Taşikoparan et al., 2010) and systematic reviews (An Liu, Xue, Chen, Bi, & Yan, 2014; Paterson et al., 2010; Whelan, Kletke, Schemitsch, & Chahal, 2016). Systematic reviews which have investigated the optimal position of immobilisation following a FTASD have reported that there is no significant difference between external or externally rotated positions (An Liu et al., 2014; Paterson et al., 2010; Whelan et al., 2016), and there is a lack of consistency between studies which report the duration of immobilisation (Deyle & Nagel, 2007).

Standard care in New Zealand is to offer a sling following a shoulder dislocation to immobilise the arm across the chest in an internally rotated position (New Zealand Guidelines Group, 2004). Immobilisation of the limb is thought to provide optimal healing of torn capsule-ligamentous structures and decrease the risk of recurrent shoulder instability (Paterson et al., 2010). None of the participants in the current study were immobilised in external rotation, a position that has been reported by Itoi and colleagues to result in decreased rates of recurrent shoulder instability (Itoi et al., 1999, 2007a). From the current study, when immobilisation was dichotomised to present or absent after a FTASD, it was found to be significantly protective against further recurrent shoulder instability (OR=0.38, p=0.05). However, when the length of time that the shoulder was immobilised was explored as a continuous variable, there was no significant finding. Of those immobilised, when the length of time of immobilisation was dichotomised to greater than 25 days, people who were immobilised for greater than 25 days were at increased risk or recurrent shoulder instability (OR=0.21, p=0.07).

In summary, our study found that being immobilised in internal rotation following a FTASD decreased the risk of recurrent shoulder instability after a FTASD. This is in contrast to findings from our systematic review which found no significant finding.

9.3.2.6 Sporting involvement as a predictive variable for recurrent shoulder instability after a FTASD

In the systematic review and meta-analysis in adults, we reported that people who were involved in collision sports trended towards a statistically significant increased risk of recurrent shoulder instability after a FTASD. Our prospective cohort study similarly found a trend towards significance in univariate analysis (p=0.09) in people who were involved in limited contact sports when compared to other types of sports as defined by Rice (2008), and when people self-reported involvement in contact sports as part of the SAS (p=0.07). Sporting involvement was retained in the model for multivariate analysis but was not found to be a statistically significant predictor of recurrent shoulder instability after FTASD in the presence of confounding variables. Similarly, Robinson et al. (2006) found that sporting involvement was a significant univariate predictor of recurrent instability (p<0.10) but was not significant in multivariate analysis. Other authors have shown that athletes are twice as likely to experience an episode of shoulder instability compared with non-athletes (Wang & Arciero, 2008). However, our study measured whether people were involved in sport prior to their injury. This baseline measure does not measure sporting involvement subsequent to a FTASD. Involvement in sport following a FTASD and the time taken to return to sport following a FTASD is worthy of further investigation.

9.3.3 Patient reported outcomes after a FTASD

Unlike variables discussed in the previous two sections (9.3.1 and 9.3.2) the following secondary outcomes were used to examine the predictive ability of these variables for predicting recurrent shoulder instability and also to examine the impact of a FTASD on these patient reported factors. These next thesis sections first summarise the predictive ability of each of the secondary outcome measures and then discusses the impact made on them following a FTASD.

9.3.3.1 Health related quality of life

9.3.3.1.1 Health related quality of life as a predictive variable for recurrent shoulder instability after a FTASD

Our systematic reviews did not find that health related quality of life had been examined as a risk factor for recurrent shoulder instability after a FTASD. However, when measured in our prospective cohort study (following univariate analysis), the Total WOSI scores, as well as the Physical and Emotion sub-scores of the WOSI, were predictive of recurrent shoulder instability after a FTASD. Investigations of correlations between variables revealed that the WOSI score was significantly correlated with the SPADI scores ($r=0.72$, $p<0.001$). Multivariate analysis of the tool with and without the SPADI or WOSI revealed that the tool had increased accuracy with the SPADI compared with the WOSI and therefore the WOSI was not included in the predictive tool.

9.3.3.1.2 The impact of a FTASD on health related quality of life

Our study found that people who have a FTASD had decreased quality of life when compared data in the literature of a healthy control group (Johannessen, Reiten, Løvaas, Maeland, & Juul-Kristensen, 2016). Additionally, quality of life showed statistically significant improvement from baseline until 12 months. However, the values at 12 months were still lower when compared to the healthy control group of Johannessen et al. (2016) which indicate that quality of life remained impaired 12 months after the FTASD. A longer term follow-up may find that quality of life continues to improve over a longer time period. Further studies are required to investigate this.

Furthermore, people who had recurrent shoulder instability had statistically significant poorer quality of life ($p=0.01$), when compared with people who did not have recurrent shoulder instability. Other authors have also shown decreased quality of life in people who have recurrent shoulder instability when compared to people who do not have recurrent shoulder instability or who have stabilisation surgery (Kirkley et al., 2005; Sachs et al., 2007). This is in contrast to Robinson et al. (2006)

who found no difference in quality of life 2 years after a FTASD, between people who underwent surgical stabilisation and those that were treated non-operatively (p=0.83).

9.3.3.2 Shoulder pain and disability

9.3.3.2.1 Shoulder pain and disability as a predictive variable for recurrent shoulder instability after a FTASD

The use of the SPADI, as an assessment of shoulder pain and function, has not previously been examined as a risk factor for recurrent shoulder instability after a FTASD and therefore was not identified in our systematic reviews. One of the papers included in the adults' systematic review found that shoulder pain but not function was predictive of recurrent shoulder instability after a FTASD (Sachs et al., 2007). In our prospective cohort, Total SPADI score, as well as Pain and Function sub-scores were predictive of recurrent shoulder instability following a FTASD. However, pain scores measured with the VAS at the time of injury and at the time of the initial phone call (up to 12 weeks post-injury) was not a statistically significant predictive variable of recurrent shoulder instability following FTASD. Levels of pain at the time of injury may be subject to recall bias that is influenced by the level of subsequent improvement from the time of injury (Rasmussen, Holtermann, & Jørgensen, 2018). Additionally, Dansie and Turk (2013) have reported that pain is not a unidimensional construct (as reported in a global VAS or NPRS) and may be more accurately reported when contextual information regarding activities that may provoke pain are provided (such as in the SPADI Pain score). The SPADI Pain score records levels of pain during 5 different activities and the overall score is averaged across the 5 activities and presented as a percentage. The SPADI Pain score may therefore provide more context for the level of pain and be a more accurate measure of current levels of pain rather than alternative measures (i.e. VAS or NPRS). The fact that shoulder pain and dysfunction (as measured with SPADI) was found to be a significant predictive risk factor for recurrent shoulder instability (following both univariate and multivariate analysis), in a cohort of people following FTASD, advocates for the use of this outcome measure more widely in this population.

9.3.3.2.2 The impact of a FTASD on shoulder pain and function

Our study found that shoulder pain decreased across all time points from the initial injury to final follow-up at 12 months. Additionally, people who had recurrent shoulder instability had significantly greater pain (p=0.02) when compared with people who did not have recurrent shoulder instability at final follow-up. This finding is in agreement with Sachs et al. (2007) who also reported increased levels of shoulder pain in people who had recurrent shoulder instability when compared with people who did not have recurrent shoulder instability.

Shoulder function improved across time when averaged across all time points and was significantly different from the measurement at the time of the initial interview at 9 and 12 months following a FTASD (p=0.01 and p=0.00 respectively). Additionally, people who had recurrent shoulder instability at 12 months had significantly decreased levels of shoulder function, compared to people who did not have recurrent shoulder instability (p<0.01). This finding is in contrast to that of Robinson et al. (2006) who reported no difference in shoulder function two years following a FTASD and may be because of the different follow-up periods.

9.3.3.3 Kinesiophobia

9.3.3.3.1 Kinesiophobia as a predictive variable for recurrent shoulder instability after a FTASD

Kinesiophobia has not previously been examined as a risk factor for recurrent shoulder instability after a FTASD and therefore was not identified in our systematic reviews. The findings from our prospective cohort study found that kinesiophobia was a statistically significant univariate predictor of recurrent shoulder instability following a FTASD (p=0.04). Following multivariate analysis, TSK-11 was retained in the model as it trended towards a statistically significant finding. This is one of the first studies to find that psychosocial variables, such as kinesiophobia, are predictive of recurrent shoulder instability. Further investigation into the relevance of other psychosocial variables, following a FTASD such as reinjury anxiety and resilience, are warranted.

9.3.3.3.2 The impact of a FTASD on kinesiophobia

While, there was insufficient data to draw any meaningful conclusions regarding the change in kinesiophobia over time in people who had a FTASD, kinesiophobia did not appear to greatly change across the subsequent 12 months. It is not known whether kinesiophobia represents a personality trait of people who sustain a FTASD, remained elevated after a FTASD due to the level of trauma that was sustained, or required longer follow-up to reach statistical significance. It may also be that the TSK-11 is not a responsive measure of kinesiophobia in a population with an acute shoulder injury, although it has been shown to be responsive in people with chronic back pain (Woby et al., 2005). Woby et al. (2005) reported that a reduction in four points of the TSK-11 in people with chronic back pain, correctly identified those people who experienced decreased kinesiophobia (Sensitivity 66%; Specificity 67%). The TSK-11 includes questions such as ‘I can’t do all the things normal people do because it’s too easy for me to get injured’ and ‘No one should have to exercise when he/she is in pain’. The beliefs that a person with an acute shoulder injury may have regarding these constructs, may not change over time without targeted intervention. Although the TSK-11 has been used previously in a population of people with acute whiplash (Buitenhuis, Jaspers, & Fidler, 2006), it has not been used in a population of people with acute shoulder pain. Furthermore, Rasch analysis has shown that people with acute neck pain may answer some of the questions in the TSK-11 differently than people who have had neck pain for longer than 6 months (Walton & Elliott, 2013). For example, question 5 of the TSK-11 (‘’my accident/injury has put my body at risk for the rest of my life“) showed greater misfit to the Rasch model in people who had a neck injury for less than 6 months than those experiencing neck symptoms for 6 months or longer. The authors concluded that question 5 may not function as intended for people who have had pain for less than 6 months. Further examination of other psychosocial measures such as anxiety, resilience, self-efficacy and hardiness and the association with kinesiophobia may provide more information regarding the overall impact of a FTASD.

9.3.3.4 Shoulder activity level

9.3.3.4.1 Shoulder activity level as a predictive variable for recurrent shoulder instability after a FTASD

One study in our adult systematic review showed a higher rate of recurrent shoulder instability after a FTASD in competitive athletes compared with non-athletes (Simonet & Cofield, 1984). However, no statistically significant finding was found across all the included studies. A previous study has reported increased levels of shoulder activity in people with shoulder instability compared with sex and age matched controls (Brophy, Hettrich, et al., 2016). Other studies have reported that shoulder activity level was not a statistically significant predictor of shoulder outcome in people following total shoulder arthroplasty and people with rotator cuff pathology (Kraeutler, Aberle, et al., 2018; Mahony et al., 2018b; Woollard et al., 2017).

Level of shoulder activity measured before a FTASD was found to be a statistically significant predictor for recurrent shoulder instability following a FTASD ($p=0.03$). However, this variable did not survive multivariate analysis, which indicated it was confounded by the presence of other variables. There was no correlation between baseline levels of shoulder activity and quality of life, shoulder pain and function, and kinesiophobia. Furthermore, shoulder activity did not vary between ethnic groups, or manual/sedentary occupations. The finding of no difference in shoulder activity between occupations is in contrast to that of Brophy et al. (2016) who reported that in the USA, shoulder activity level was associated with type of occupation.

Finally, while the SAS measures the frequency of some activities, it does not measure how long people are engaged in each activity. Muscle strength gains result from total time under tension, and it may be that doing an exercise once a week for long period of time results in more strength gains, than short periods of activity more frequently (Burd et al., 2012). This is not captured in the SAS as participants are only asked how frequently they perform an activity.

9.3.3.4.2 The impact of a FTASD on shoulder activity level

Our study showed that shoulder activity, as measured by the SAS, had returned to the pre-injury state in people who were interviewed 12 months after a FTASD. Furthermore, there was no difference in shoulder activity levels across the 12 month period between those people that had recurrent instability compared to those that did not. The participants in our prospective cohort study had higher levels of pre-injury shoulder activity (mean SAS=12) compared with a healthy control population in the USA (mean SAS=10), but less than people who underwent shoulder stabilisation surgery (mean SAS=13) (Brophy, Hettrich, et al., 2016).

9.4 Rate of recurrent shoulder instability one year after a FTASD

From the current study, the rate of recurrent shoulder instability in the development and validation cohort, across people aged between 16 and 40 years, was 38% and 24% respectively. These rates of recurrent shoulder instability after a FTASD are much lower than have been reported in the non-operative arms of RCTs. Bottoni et al. (2002) reported recurrent shoulder instability in 9 of 12 participants (75%) treated nonoperatively. Kirkley et al. (2005) similarly reported recurrent shoulder instability in 9 of 15 people (60%) who were treated non-operatively compared with 3 of 16 (19%) for people treated surgically. Both these RCTs were limited by the low numbers of participants, which may have been the result of large numbers of patients excluded due to strict inclusion criteria for the trials. Strict inclusion criteria for RCTs result in a study population that is not representative of the population of all people with a FTASD (Kersten et al., 2010).

The rates of recurrent shoulder instability found in our study (development and validation phases) are lower than other international prospective cohort studies which investigated recurrent shoulder instability after a FTASD (Robinson et al., 2006; te Slaa et al., 2003). Our development study (Chapter 6) showed rates of recurrent shoulder instability within one year of a FTASD of 49% (33/68) in people aged between 16 and 25 years and 31% (13/42) in people age 26-40 years. Similarly, Robinson et al. (2006) showed higher rates of recurrent shoulder instability in people aged 25 years and younger (44%) and lower rates when compared with those aged older than 25 years (17%). te Slaa et al. (2003), similarly reported rates of recurrent shoulder instability of 56% (9/16) people aged 18-26 years and 37.5% in people aged 27 years and over (3/8).

Both the study by Robinson et al. (2006) and te Slaa et al. (2003) were based upon presentation of the patient to the hospital, following a FTASD, and follow-up period was five years. Our study recruited participants from a general population across different hospitals and general medical practices. Our study also had a shorter follow-up period of 12 months and this may have resulted in decreased rates of recurrent shoulder instability. Robinson et al. (2006) reported that 70% of people who were going to have a shoulder dislocation over a period of 5 years, had their episode of instability within one year. A longer period of follow-up for our prospective study may have produced similar results. Further investigation over a longer follow-up period is required.

9.5 Validation of the predictive tool

Validation of the predictive tool, in a separate population following a FTASD, demonstrated high levels of specificity. Specificity of the tool was 95%. This indicates that of the people who were not going to have recurrent shoulder instability after a FTASD, the tool can accurately predict 95% of those people. Sensitivity was 39% and indicated that of all the people who were going to have recurrent shoulder instability after a FTASD, 39% were correctly identified by the predictive tool.

Sensitivity and specificity are commonly presented metrics for validity analysis of clinical tests, PPV and NPV are the most relevant to clinical practice (Lalkhen & McCluskey, 2008). Sensitivity and specificity values indicate the probability that a test result will be positive or negative when the disease is present or absent, are independent of the population in which the test was undertaken (Lalkhen & McCluskey, 2008), and remain relatively consistent across prevalence values (Fritz & Wainner, 2001). By contrast, PPV and NPV indicate how likely the person is to have or not have the disease if the test result is positive or negative respectively (Fritz & Wainner, 2001). As clinicians usually want to know whether or not the disease is present (or not present) for the person in front of them, PPV and NPV can be more clinically useful than the sensitivity and specificity of the test as they describe how likely the patient is to have the condition.

The PPV and NPV of the predictive tool were 70% and 83% respectively. This indicated that 70% of people who had recurrent shoulder instability were correctly identified by the tool, i.e. if the tool identified that a person was going to have further recurrent shoulder instability, it was correct 70% of the time. The NPV indicated that for all the negative findings of the tool, 83% were correctly identified i.e. if the tool correctly identified that a person was not going to have recurrent shoulder instability, it was correct 83% of the time. However, PPV and NPV also vary according to the prevalence of the condition of interest. The prevalence of recurrent shoulder instability in the validation population was 24%. When the prevalence of a condition is low (such as in the validation study), PPV values will be lower and NPV values will be higher (Fritz & Wainner, 2001).

Positive Likelihood Ratios (+LR) and Negative Likelihood Ratios (-LR) overcome these shortcomings by combining the values reported in sensitivity and specificity. Likelihood ratios reflect the odds of a positive test result (i.e. a score greater than 0.895) in people with recurrent shoulder instability compared to how likely it is in people without recurrent shoulder instability (Davison 2002). The value of a +LR indicates the shift in odds which favour the condition given a positive result and, therefore, the value of a large +LR indicates a test that is useful for ruling in a condition when it is positive (Fritz & Wainner, 2001). The value of a -LR indicates the shift in odds which favour the condition given a negative result, and therefore a small -LR indicates a test that is useful for ruling out a condition when negative (Fritz & Wainner, 2001). When a +LR is greater than 10 and a -LR is less than 0.1, a large and often conclusive shift in probability is represented (Fritz & Wainner, 2001). Values of between 5 to 10 for +LR and between 0.1-0.2 for -LR indicate a moderate but usually important shift in probability. Values between 0.5–1 for -LR indicate a probability of a small, and rarely important degree (Fritz & Wainner, 2001). The +LR and -LR found for the predictive tool following the validation study were 7.39 and 0.65 respectively. Likelihood ratios are used to determine the post-test probability; PPV and NPV (calculated by multiplying pre-test probability multiplied by the +LR and –LR, respectively). Therefore the +LR of 7.39 indicates that people are 30-45% likely to increase the post-test probability of having recurrent shoulder instability. Therefore, a positive finding from the tool (score of 0.895 and above) predict will increase the likelihood of actually having recurrent shoulder instability by 30-45%. The -LR indicates that it is unlikely (0-15%) to decrease the post-test probability of detecting the disease. A negative result from the tool (i.e. a score below 0.895) predicts a person will not have recurrent instability and will decrease their likelihood of having actual recurrent instability by 0-15%. Thus, if the tool predicts a non-recurrent shoulder instability event, then it is unlikely that the person will actually have a recurrent instability event occurring.

9.6 Shared decision-making

Predictive tools and predictive algorithms provide clinicians with concise evidence to facilitate shared decision-making with their patients. Use of these decision-making tools increases active participation in decision-making and facilitates people reaching a decision that is more aligned with their stated values (Stacey et al., 2014). Shared decision-making occurs when the health care professional with knowledge of evidence-based medicine works together with their patient, to arrive at the most satisfactory decision for the patient (Frosch & Kaplan, 1999; Spatz & Spertus, 2012). Essentially, it is the marrying of the expertise of the health care professional with the expertise and preferences of the patient. Shared decision-making results in increased adherence rates, and subsequent improved health outcomes (Sieber & Kaplan, 2000). The current iteration of the predictive tool developed in this study can be further developed to facilitate decision-making between clinicians and people with a FTASD. This would result in identification of people who are not going to have recurrent shoulder instability, and who therefore do not require surgical intervention, and can be managed conservatively as per current standard levels of care. Further investigations into the clinical utility of the tool are required.

9.7 Strengths and limitations of the research

This prospective cohort study is the first to document rates of recurrent shoulder instability following a FTASD in New Zealand. The methodology of reviewing the literature for risk factors, incorporating expert opinion into a baseline tool, conducting a nationwide prospective cohort study to develop a tool and then validating that tool in a separate population followed robust guidelines (Altman et al., 2009; Moons, Kengne, Woodward, et al., 2012; Royston, Moons, Altman, & Vergouwe, 2009). The prospective cohort study design and method of recruitment allowed for access to all people in New Zealand who reported their FTASD to ACC. Thus, the results are generalisable across social, economic and ethnic boundaries and reflect the rate of recurrent shoulder instability in New Zealanders between the ages of 16 and 40 years for the given years when data were collected.

However, a nationwide study also led to some limitations. Because a nationwide study required recruitment and data collection over the telephone, it was not possible to incorporate clinical tests (such as the apprehension test) which has previously been shown to be a predictor for recurrent shoulder instability (Milgrom et al., 2014; Safran et al., 2010). Another limitation of telephone interview is that accuracy is dependent upon self-report from participants. Errors that could have occurred as a result of people being referred to the study by ACC if they had a previous shoulder dislocation (one of our exclusion criteria) was avoided by interviewing them about the presence of previous dislocations. Classification of recurrent shoulder instability was based upon participant self-report and this could have resulted in erroneous estimation of the presence of recurrent shoulder instability.

Additionally, to prove that a shoulder dislocation had occurred, radiological evidence was required. This may have resulted in the exclusion of some participants who did have a shoulder dislocation but were not referred for an X-Ray by their treating clinician. Furthermore, radiological evidence of a shoulder dislocation (e.g. still dislocated on presentation to the emergency department, or the presence of Hill Sachs lesions) may represent the more severe end of the spectrum of shoulder dislocations since some may have had their dislocation reduced before arrival at the hospital (Accident Compensation Corporation, 2017a). This study required a clear clinical history of shoulder dislocation including an appropriate traumatic mechanism with the sensation that the shoulder had come out of its socket. People were included in the study if they reported a clear mechanism of dislocation, felt the shoulder come out of the socket, and the X-Ray did not show a dislocation in a posterior or inferior direction, or any ACJ trauma. Furthermore, people who presented to their primary care clinician with a shoulder dislocation may have had their condition diagnosed as a shoulder strain (ACC Read code shoulder strain S50..) and not a shoulder dislocation, and therefore were not invited into the study. Limitations such as these would be prevented if participants were not recruited nationwide and were recruited from local clinics and emergency departments. The additional benefit of local recruitment would have been the ability to train radiographers for standardised assessment of shoulder pathology, as well as the inclusion of clinical tests. However, local recruitment would limit the generalisability of the research to other populations.

Many studies have indicated that a glenohumeral labral lesion is responsible for decreased stability of the shoulder (Baker et al., 1990; Calvo et al., 2005; Kim, Yoon, & Kwon, 2010). However, in the only prospective cohort study to examine labral tears, Salomonsson et al. (2010) did not report an association between the presence of a labral tear and recurrent shoulder instability. Despite this finding, surgical intervention remains focussed on restoring labral integrity and is often a justification for surgery (Law, Yung, Ho, Jeremy, & Chan, 2008; Wellmann et al., 2011). While the addition of labral pathology as a risk factor would have added to the strength of this study, the costs associated with MRA for all people with a FTASD were prohibitive. Further investigations regarding the association between labral pathology and recurrent shoulder instability may be warranted.

The practical implications of timeframes that bind a doctoral thesis and the undertaking of a prospective cohort study with a separate validation population necessitated a follow-up period of one year. This follow-up period may not accurately represent all those participants who will go on to have further episodes of instability. Robinson et al. (2006) showed that approximately 70% of people who had recurrent shoulder instability presented within one year post-injury. If we were to extrapolate our one year findings over a 5 year period, we could then expect that the overall recurrence rate would move from 38% to 69% over a five year period. The low rates of prevalence in the validation population was surprising and in contrast to the findings of Robinson et al. (2006). Recruitment rates were slower in Phase 2 and there was a smaller percentage of people who had FTASD in the second phase. This appeared to be a result of yearly variation as there was no change in nationwide health care policy or recruitment between the two study phases.

The psychosocial variables included in this PhD were based upon best available evidence at the commencement of this PhD. In the course of this study, other literature has reported the importance of resilience, locus of control, and self-efficacy as predictors of outcome in shoulder and other joint pathology (Ardern et al., 2013; Tokish et al., 2017). The finding that kinesiophobia was a statistically significant predictor of recurrent shoulder instability provides a platform for further investigation into the role of other variables (such as resilience, locus of control and self-efficacy) to predict recurrent shoulder instability after a FTASD.

9.8 Clinical Implications

The predictive tool established and validated in this study is a step towards enabling clinicians to predict recurrent shoulder instability after a FTASD. Aided by the shared decision-making process, clinicians can use this tool to predict who is not going to have further recurrent shoulder instability. This tool should give clinicians confidence that non-surgical management for these selected patients is the appropriate course of treatment, and they do not require further radiological investigations or surgical considerations.

The tool confirms the predictive value of outcome measures in the clinical setting and should encourage clinicians to regularly record these variables in routine clinical practice. The use of the SPADI Pain sub-score provides contextual information regarding the intensity of the pain and may be a more accurate measure of pain than the VAS or NPRS, which are commonly used by clinicians. The incorporation of the TSK-11 by clinicians may encourage discussion of kinesiophobia during therapeutic consultations, which may illuminate to therapists that further education is required for them to adequately address the patient's fear of reinjury. Therapists should also use the shoulder-related quality of life index (WOSI) to measure outcomes from their treatment. The current climate in New Zealand is one where stakeholders are interested in improving overall health and wellbeing from medical treatment (Accident Compensation Corporation, 2016). Wellbeing and quality of life are the antithesis of illness, and can be used by therapists to demonstrate the value of conservative treatment in improving quality of life (Lowe, Littlewood, & McLean, 2018).

Furthermore, while therapists should strive to improve their clinical practice, the tool provides clarity of who is truly not going to have recurrent shoulder instability after a FTASD of all the people who indeed won't have recurrent shoulder instability, with current levels of care. It may be that further improvements in non-surgical care, such as increased neuromuscular training and less sessions over extended periods of time, may improve treatment outcomes.

Discussions with key stakeholders are currently underway to use the predictive tool validated in Chapter 8 in a population of New Zealanders who have a FTASD. This will be part of a pilot project to change service model delivery of healthcare to people with a FTASD. The tool will be used by staff at emergency departments to streamline services so that people who are not likely to have recurrent shoulder instability following a FTASD are identified. People who are identified as not likely to experience recurrent shoulder instability will continue to be managed as is standard practice with a referral to physiotherapy and follow-up at fracture clinic. People who are not identified by the tool as being unlikely to have recurrent shoulder instability will be reviewed by a physiotherapy specialist. A conservative treatment protocol will be designed for this group, based on the best available evidence. This would include progressive strengthening, neuromuscular control exercises and extended therapy contact over the following 12 months. Use of the tool in this manner will decrease patient uncertainty of their expected outcome. Additionally, the advanced therapy programme may improve rates of recurrent shoulder instability in the high risk group.

9.9 Future research for the predictive tool and the impact of a FTASD

Further validation of the predictive tool is required. Although previous research has shown that around 70% of people who were going to have a dislocation would have done so within 12 months (Robinson et al., 2006), a longer follow-up period in this study would have provided valuable information regarding longer term outcomes. A longer follow-up of 2 and 5 years of the current cohort of people with a FTASD may improve understanding of the longer-term implications of this predictive tool. Many other orthopaedic studies have a minimum of a 2 year follow-up in order to appreciate the longer-term implications of a condition (Castillo, MacKenzie, & Bosse, 2011). Further funding will be sought to follow up the cohort examined in this study, 5 years following their FTASD. Additional validation studies to establish generalisability to children and other international populations are also required.

Additional variables such as the size of a labral Bankart lesion detected on MRI may further enhance the tool. Other variables such as nerve palsies, collagen biomarkers, sporting involvement after a FTASD, and time taken to return to sport are also worthy of further investigation. The predictive ability of the interaction between Hill Sachs and bony Bankart lesions (glenoid track) is also required in a prospective cohort study.

Further examination is required of shoulder pain and dysfunction, kinesiophobia, quality of life and shoulder activity levels after a shoulder dislocation. The low rates of participation in this aspect of the study has precluded the drawing of any meaningful results in this area. Future studies should record these variables across time to provide further information in this area.

Future studies or revised service models such as the one alluded to in 9.8 should include the measurement of psychosocial constructs that may be affected following a FTASD. Reinjury anxiety could be recorded with the reinjury anxiety index (Walker et al., 2010) and resilience with the brief resilience scale (Smith et al., 2008). Locus of control and self-efficacy could also be measured in people with a FTASD, and these have been examined by in people with an ACL reconstruction (Ardern et al., 2013). Correlations between these constructs and kinesiophobia should be examined at baseline and following 12 weeks of conservative treatment to examine the impact of physiotherapy treatment on these factors. The incorporation of clinical tests may help to improve the validity and accuracy of the tool.

A follow-on treatment study which stratifies people after a FTASD to high and low risk of recurrent shoulder instability could provide evidence for standard care and enhanced conservative care. For example, stratification of healthcare using the STarT Back tool has been shown to be efficacious in streamlining treatment for people with low back pain (Hill et al., 2011). Future studies could replicate this methodology in people with FTASD using the tool developed and validated in these studies. Enhanced conservative care should address increased neuromuscular treatments, as well as address adherence to strengthening programmes over a longer time frame. Regular email / clinical follow-up over 12 months following a FTASD with enhanced strength and co-ordination exercises, as well as continued regular contact with a therapist may have a positive impact of rates of recurrent shoulder instability after a FTASD.

Finally, further investigation into the use of the tool in shared-decision making should be examined. As stated above, clinical tools can facilitate shared decision-making in clinical practice by quickly and efficiently summarising the literature and enabling individualised healthcare. A mixed-methods study which investigates clinician and patient perspectives of the predictive tool needs to be undertaken to examine the clinical utility of this tool.

9.10 Conclusions

Twenty-six people (30.5%) had an episode of recurrent shoulder instability within 12 months following a FTASD.

People who have a FTASD still have decreased quality of life and increased pain and dysfunction 12 months following their injury.

People with recurrent shoulder instability have decreased quality of life, increased shoulder pain and dysfunction and higher levels of kinesiophobia compared with people who do not have recurrent shoulder instability.

The prospective tool developed in a New Zealand population used the variables of a bony Bankart lesion, aged between 16 and 25, immobilisation status, dislocation of a dominant limb, kinesiophobia, shoulder pain and disability to predict who is not going to have recurrent shoulder instability within one year of a FTASD. Further research is required to increase accuracy and sensitivity of the tool, investigate its clinical utility and its generalisability to other populations such as children or people in other countries.

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Appendix A: Letter from ACC to participant

[Date Sent]

[Name]

[Address Block]

Dear [CLIENT TITLE]. [CLIENT SURNAME]

Studies in repeated shoulder injuries after your shoulder has dislocated

(popped out of its socket)

ACC has been approached by a person (Margie Olds) who studies shoulder injuries to support a research project which examines shoulder problems after a shoulder dislocation. Margie Olds wishes to understand whether there are some things which increase or decrease the risk of more shoulder problems after a dislocation. The research study would involve completing up to five phone calls over the course of the year following your shoulder dislocation. More information about the study is contained in the attached information sheet.

From our records, we have identified you as someone who has had a shoulder dislocation.

We are writing to you to ask whether you would allow ACC to supply Margie Olds with your name and contact details. **This is entirely your choice; whether you participate or not will have no impact on your ACC claim or entitlements.** The information given to Margie Olds will be your name, address, and phone number. Data will be kept confidential at all times, stored in a secure location, ensuring only the study investigator has access to such details. Data on individuals collected as part of this study will not be shared with ACC.

What do I have to do now?

Please read through the included information sheet and think about whether you want to participate in this project or not. Whether you decide to take part in this study or not will have no effect on your relationship with ACC, your case manager or any compensation you currently receive.

If you are happy to have these details released to Margie Olds, you do not need to do anything and she will contact you by phone within the next few weeks and request additional data from ACC on:

- Your occupation
- Your diagnosis of a shoulder dislocation
- Your age
- The date of your injury
- How you hurt your shoulder
- The results of any medical assessment i.e. X-Ray or Ultrasound

When you receive the phone call, you will again have the opportunity to decline to take part in the study.

If you do not want your name and address to be given to the researcher and do not want to be contacted, **please ring 0800 956 125 within the next 14 days** from the date of this letter. Leave the **full name and reference number** on the answer-phone and the researchers will not contact you. The reference number is: [Ref No].

This project has been approved by the ACC Ethics Committee. Answers to some frequently asked questions are enclosed, but if you have any additional questions please contact Margie Olds (09-9219999 x 7156).

Thank you for taking the time to read this letter.

Yours sincerely

ACC Research Manager

Participant Information Sheet

Project Title

Follow-up study after a shoulder dislocation

Date Information Sheet Produced:

13 April, 2015

An Invitation

Hello.

You are invited to take part in a study on shoulder dislocations. You have been invited to this study because ACC records show that you have recently had a shoulder dislocation. This Participant Information Sheet describes the study. You don't have to decide today whether or not you will participate in this study. You may want to talk about the study with family, whānau, friends, or healthcare providers. Feel free to do this.

It is your choice whether or not you take part, and if you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you don't want to take part, please call **ACC on 0800 956 125**. If you do want to take part now, but change your mind later, you can pullout of the study at any time.

What is the purpose of this research?

This study is run by AUT University and is independent from ACC. The purpose of this study is to gain more information about what happens after a traumatic shoulder dislocation. The information learned in this research will help health professionals make decisions in the future regarding the best management for shoulder problems like yours. After this project is completed, this research will help other people like you, who have had shoulder dislocation like this, to make decisions about the type of treatment they receive. Margie Olds is a PhD student and the lead researcher on this project. This project forms part of her PhD studies.

This study will not affect your treatment in any way. This is a study that records what happens to you during your recovery. We will record different information such as the level of pain you experience, or if you have any further problems with your shoulder. The study has been granted ethical approval by the ACC Research Ethics Committee and the AUT University Ethics Committee.

How was I identified and why am I being invited to participate in this research?

You have been asked to participate in this study because this is the first-time you have had a shoulder dislocation where the arm bone has popped out the front of your shoulder as a result of an accident or some force to your shoulder. You have also been asked to take part in the study because you live New Zealand and have a claim accepted with ACC. You will be given the opportunity to ask any questions you like about the study and provide active informed consent.

What will happen in this research and what are the costs of my involvement?

This study will involve regular follow-up phone calls from a researcher at AUT University. Margie will call you to invite you to participate in the study and answer any questions you might have about the study. You will be asked if you agree to take part in this study and this part of the conversation will be recorded. The rest of the conversation and other conversations will not be recorded. Margie will ask you a number of questions about your shoulder and document any problems that you are having with your shoulder. Another researcher will then call four times over a one year period. Each phone call will take between 15-20 minutes. The researcher may also need to contact the clinics where you have had treatment for your shoulder to find out the results of clinical tests or investigations. This will give them information regarding the severity of your shoulder condition. They will not look at other information in your medical notes and your notes will not be removed from the hospital or the clinic where you presented with your shoulder dislocation. We will not look at your medical information unless you give us permission to do so and you will still be able to take part in the study. Your information will be kept securely in a locked room at AUT University. It will be stored on a database and only the researchers will know the password. In some cases, the researcher may also need to ask you other questions about your shoulder injury.

Being involved in this study will make no difference to the treatment for your shoulder injury. This study will just observe and record what happens to your shoulder following this first injury. You may also let us know if you wish to be contacted to take part in future studies about your shoulder dislocation.

What are the discomforts and risks?

The phone calls may become annoying. There is a minimal risk that your medical information will be unsafe. There is information below about how we will protect your information.

How will these discomforts and risks be alleviated?

If you no longer wish to receive the phone calls from the researcher, then you can pull-out of the study up to the end of data collection and you do not have to provide a reason.

What are the benefits?

This study gives you the opportunity to help other people like you who also have had a shoulder dislocation. This study will increase the knowledge that is available to doctors and physiotherapists about shoulder dislocations like the one that you have had. This study also forms part of a PhD qualification for Margie Olds at AUT University.

How will my privacy be protected?

We will collect information that records your age, ethnicity, the way that you injured your shoulder, your occupation and the results of any medical tests. This information will not have your name on it, and you will only be recognised by a number to ensure your privacy is maintained. This data will be password protected, locked in a cabinet at AUT University and only those researchers involved in this project will have access to this data. There will be another database which has your name and your research number on it. This database will only be accessed by the two researchers who call you and will be locked in a different cabinet, in a different room at AUT University, on a different hard drive with a different password to your other information. Only the people who call you will have access to the information about your name and number, and the other two researchers involved in this project will only have access to your medical information and will not know your name. No other person will be able to access either your name, or your medical information.

What opportunity do I have to consider this invitation?

If you do not wish to take part in this study, then please contact ACC by calling 0800 956 125 within 2 weeks of receiving this letter. Please leave your **full name and reference number** on their answer-phone and the researchers will not contact you. The reference number is: [Ref No].

How do I agree to participate in this research?

Margie Olds will call you 3 weeks after you have received this letter. She will answer any questions you may have about this study, and you can agree or decline to take part in this study over the phone.

Will I receive feedback on the results of this research?

If you would like to receive feedback about the results of this study, you will be emailed a final report at the conclusion of the study.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisors, Professor *Paula Kersten, pkersten@aut.ac.nz, 09-9219180* or *Dr Richard Ellis, rellis@aut.ac.nz, 09-9219999 ext 7612.*

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, Kate O'Connor, *ethics@aut.ac.nz* , 921 9999 ext 6038.

Whom do I contact for further information about this research?

Researcher Contact Details:

margie.olds@aut.ac.nz, 09-9219999 x7156

Project Supervisor Contact Details:

pkersten@aut.ac.nz, 09-9219180

Approved by the Auckland University of Technology Ethics Committee on 12 May 2015 Reference number 14/256

Appendix C: Consent Form

Consent Form

UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

Project title: ***Follow-up study after shoulder dislocations***

Project Supervisors: ***Professor Paula Kersten, Dr Richard Ellis***

Researcher: ***Margie Olds***

- ○ I have read and understood the information provided about this research project in the Information Sheet dated 13 April, 2015.
- ○ I have had an opportunity to ask questions and to have them answered.
- ○ I understand that notes will be taken during the interviews and that the initial consent will be recorded.
- ○ I understand that I may withdraw myself up until the end of data collection and I do not have to provide a reason.
- ○ If I withdraw myself, I can choose if information that has been provided for this project can be kept for the purpose of analysis or should be destroyed.
- ○ I agree to taking part in this research.
- ○ I agree to give the researcher permission to access medical records concerning my shoulder (if you don't provide permission you can still take part in the study)
- ○ I wish to receive a copy of the report from the research (please tick one): Yes○ No○
- ○ I would like to be contacted to take part in future studies: Yes○ No○

Date:

Approved by the Auckland University of Technology Ethics Committee on 12 May 2015 Reference number 14/256

Note: The Participant should retain a copy of this form.

Appendix D: Unable to establish phone contact

Date

Name

Address

Dear [Name],

You may have received a letter from ACC, inviting you to take part in a shoulder study on shoulder dislocations. We have tried to call you to discuss this study further, but have been unable to reach you over the phone.

If you would like to take part in this study, or find out more about what is required, please call, email or text me using the details below.

I look forward to hearing from you.

Kind Regards

Margie Olds

PhD student, Auckland University of Technology

margie.olds@aut.ac.nz 09-9219999x7156 021573422

Appendix E. Written consent letter to participant for radiology companies

[Name]

[Address 1]

[Address 2]

[Adress 3]

[Date]

Dear [Name],

Thanks for your participation in our research study on first-time traumatic shoulder dislocations. We appreciate your willingness to share your time and experiences with us.

In order to now gain access to your medical records, we now require written confirmation of your consent. Can you please sign the attached form and send it back to us in the stamped self-addressed envelope.

We appreciate your help with this.

Kind Regards

Margie Olds

PhD student, Auckland University of Technology

margie.olds@aut.ac.nz 09-9219999x7156 021573422

Radiology Consent Form

Project title: ***Follow-up study after shoulder dislocations***

Project Supervisors: ***Professor Paula Kersten, Dr Richard Ellis***

Researcher: ***Margie Olds***

I agree to give the researcher permission to access results from X-Rays and scans of my shoulder. (If you don't provide permission you can still take part in the study)

Name :

Signature : Date:

Approved by the Auckland University of Technology Ethics Committee on 12 May 2015 Reference number 14/256

Appendix F: Baseline datasheet

Shoulder Dislocation study

Please read the Information Sheet before you begin.

☐ Do you understand that you can pull out of this study at anytime and you do not have to provide a reason. If the researcher calls you, you can just say that you don't want to be involved in this anymore.

☐ Are you aware that if you pull out, you can choose the information that has already been collected from you is included in the study, or destroyed.

☐ Do you agree to taking part in this research

☐ Do you agree to give the researchers permission to access medical records such as X-Rays and Ultrasounds of your shoulder (if you don't provide permission you can still take part in the study)

Would you like to receive a copy of the report from the research? ○ Yes ○ No

☐ Would you like to be contacted to take part in future studies: (this would probably just involve a follow-up phone call in a few years' time to see how you are doing)

Date

Subject Name

Subject Number

Date of Injury

Time Since Injury

Contact number
Is there another contact number we can get you if for some reason there is a problem with this number?
(I will still need to contact you even if you lose your mobile phone. What do you suggest is the best way to do this?)

Date of Birth:

Sex

Height

Weight

Ethnicity

Some people identify with more than on ethnicity. Do you identify with any other ethnicities? YES/NO

If yes, what are they?

Are you right or left handed? (which hand do you use to write with?) RIGHT / LEFT

Which shoulder did you dislocate? RIGHT / LEFT

Describe what your occupation is / what you do during the day?

Would you consider this job manual or sedentary? MANUAL / SEDENTARY

Does this job require you to work above shoulder height (with your arms raised above your head)?

YES ABOVE SHOUDLER HEIGHT / NO, AT SHOULDER HEIGHT OR BELOW

Are there any other members in your family that have also dislocated their shoulder?

Do you consider yourself to be double jointed (overly flexible or bendy) i.e. can you easily put your hands flat on the floor? YES/NO

Describe what happened to your shoulder? How did you dislocate it?

Which of the following best describes how you got injured?

FALL < 1M / FALL > 1M / MOTOR VEHICAL ACCIDENT / SPORTS INJURY / ASSAULT OR FIGHT / SEIZURE / OTHER

Was your arm in a sling or immobilised after your dislocation? YES/NO

If yes, how long for?

Have you had any physiotherapy? YES/NO

If yes, how many sessions?

If Sport, can you name the sport?

Would you consider this sport to be a collision sport? YES/NO

Would you consider this sport to be an overhead sport? YES/NO

What position were you playing when you got injured?

Is this your usual position? YES/NO

Comments?

What level of sport to you play? SCHOOL / CLUB / SEMI-PROFESS / PROFESSIONAL

How many hours per week were you in practice or competition before the injury?

Have you returned to sport? YES/NO

If yes, what is the length of time from dislocation?

How many hours per week are you in practice or competition now?

Out of 100%, how good are you now compared to before your dislocation?

These next set of questions relate do your typical level of shoulder activity prior to your injury. I am interested in how often you have done these activities in the last month. There are five different answers. Never or less than once a month, Once a month, Once a week, More than once a week, Daily

1. Carrying objects 4kg or heavier by hands (such as a bag of groceries, or four block of cheese/two 2l milk containers)

2. Handling objects overhead

3. Weight lifting or Weight training with arms

4. Swinging motion (as in hitting a tennis ball, golf ball, baseball or similar object)

5. Lifting objects 12.5kgs or heavier (NOT INCLUDING WEIGHT LIFTING)

6. Do you participate in contact sport?

7. Do you participate in sports that involve hard overhand throwing (e.g. baseball or cricket), or overhead serving (e.g. tennis, volleyball) or lap distance swimming?

8. Do you participate regularly in other sports? (Please name them)

This next set of questions asks about your level of pain on a scale from 0 to 10 where 10 is your worst pain ever.

1. How much pain did you have initially on a scale of 0 to 10?

2. How much pain do you have now?

3. At its worst?

4. When lying on the involved side?

5. Reaching for something on a high shelf?

6. Touching the back of your neck?

7. Pushing with the involved arm?

This next set of questions asks about how much difficulty you have doing things, on a scale from 0 to 10 where 0 is unable and 10 is 100%, no problem

How much difficulty do you have:

8. Washing your hair?

9. Washing your back?

10. Putting on an undershirt or pullover sweater/jersey?

11. Putting on a shirt that buttons down the front?

12. Putting on your pants?

13. Placing an object of a high shelf?

14. Carrying a heavy object of 5 kg?

15. Removing something from your back pocket?

This next set of questions asks about any fear that you may have related to your injury. There are four possible answers, statement 1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree

1. I'm afraid that I might injury myself if I exercise

2. If I were to try to overcome it (push through your pain), my pain would increase

3. My body is telling me I have something dangerously wrong

4. People aren't taking my medical condition seriously enough

5. My accident has put my body at risk for the rest of my life

6. Pain always means I have injured my body

7. Simply being careful that I do not make an unnecessary movements is the safest thing I can do to prevent my pain from worsening

8. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body

9. Pain lets me know when to stop exercising so that I don't injure myself

10. I can't do all the things normal people do because it's too easy for me to get injured

11. No one should have to exercise when he/she is in pain

The final set of questions ask you to rate these answers on a scale of 0-10

1. How much pain do you experience in your shoulder with overhead activities? (0 no pain, 10 extreme pain)

2. How much aching or throbbing do you experience in your shoulder? (0 none, 10 extreme aching)

3. How much weakness or lack of strength do you experience in your shoulder? (0 no weakness, 10 Extreme weakness)

4. How much fatigue or lack of stamina do you experience in your shoulder? (0 not at all, 10 Extreme fatique)

5. How much clicking, cracking, or snapping do you experience in your shoulder? (0 no clicking, 10 extreme clicking)

6. How much stiffness do you experience in your shoulder? (0 not at all, 10 extreme stiffness)

7. How much discomfort do you experience in your neck muscles as a result of your shoulder? (0 not at all, 10 extreme discomfort)

8. How much feeling of instability or looseness do you experience in your shoulder? (0 not at all, 10 extreme instability)

9. How much do you compensate for your shoulder with other muscles? (0 not at all, 10 extreme compensation)

10. How much loss of range of motion do you have in your shoulder? (0 not at all, 10 extreme loss)

11. How much has your shoulder limited the amount you can participate in sports or recreational activities? (0 not at all, 10 extremely limited)

12. How much has your shoulder affected your ability to perform the specific skills required for your sport or work? (If your shoulder affects both sports and work, consider the area that is most affected.) (0 not at all affected, 10 extremely affected)

13. How much do you feel the need to protect your arm during activities? (0 not at all, 10 extremely)

14. How much difficulty do you experience lifting heavy objects below shoulder level? (0 not at all, 10 extreme difficulty)

15. How much fear do you have of falling on your shoulder? (0 not at all, 10 extreme fear)

16. How much difficulty do you experience maintaining your desired level of fitness? (0 not at all, 10 extreme difficulty)

17. How much difficulty do you have "roughhousing or horsing around" with family or friends? (0 not at all, 10 extreme difficulty)

18. How much difficulty do you have sleeping because of your shoulder? (0 not at all, 10 extreme difficulty)

19. How conscious are you of your shoulder? (0 not at all, 10 extremely conscious)

20. How concerned are you about your shoulder becoming worse? (0 not at all, 10 extremely concerned)

21. How much frustration do you feel because of your shoulder? (0 not at all, 10 extreme frustration)

General Comments

Don't forget to submit this data!

Thanks for your time in answering these questions. There is another physio that will call you in three months to see how you are and how you are getting on with your shoulder. The follow-up questions won't take as long

Section A: Physical Symptoms (0-10)	

Appendix G: Western Ontario Shoulder Instability Index (WOSI)

1. How much pain do you experience in your shoulder with overhead activities?	
2. How much aching or throbbing do you experience in your shoulder?	
3. How much weakness or lack of strength do you experience in your shoulder?	
4. How much fatigue of lack of stamina do you experience in your shoulder?	
5. How much clicking, cracking, or snapping do you experience in your shoulder?	
6. How much stiffness do you experience in your shoulder?	
7. How much discomfort do you experience in your neck muscles as a result of your shoulder?	
8. How much feeling of instability or looseness do you experience in your shoulder?	
9. How much do you compensate for your shoulder with other muscles?	
10. How much loss of range of motion do you have in your shoulder?	
Section B: Sports/Recreation/Work	
11. How much has your shoulder limited the amount you can participate in sports or recreational activities?	
12. How much has your shoulder affected your ability to perform the specific skills required for your sport or work? (If your shoulder affects both sports and work, consider the area that is most affected.)	
13. How much do you feel the need to protect your arm during activities?	
14. How much difficulty do you experience lifting heavy objects below shoulder level?	
Section C: Lifestyle	
15. How much fear do you have of falling on your shoulder?	
16. How much difficulty do you experience maintaining your desired level of fitness?	
17. How much difficulty do you have "roughhousing or horsing around" with family or friends?	
18. How much difficulty do you have sleeping because of your shoulder?	
Section D: Emotions	
19. How conscious are you of your shoulder?	
20. How concerned are you about your shoulder becoming worse?	
21. How much frustration do you feel because of your shoulder?	

Appendix H: Shoulder Activity Score

Carrying objects 4kg or heavier by hands (such as a bag of groceries) Handling objects overhead	Never or less than once a month Once a month Once a week More than once a week Daily
Weight lifting or Weight training with arms	Never or less than once a month Once a month Once a week More than once a week Daily
Swinging motion (as in hitting a tennis ball, golf ball, baseball or similar object	Never or less than once a month Once a month Once a week More than once a week Daily
Lifting objects 25lbs or heavier (NOT INCLUDING WEIGHT LIFTING)	Never or less than once a month Once a month Once a week More than once a week Daily
Do you participate in contact sport	No Yes without organised officiating Yes with organised officiating Yes at a professional level (e.g. paid to play)
Do you participate in sports that involve hard overhand throwing (e.g. baseball or cricket), or overhead serving (e.g. tennis, volleyball) or lap distance swimming?	No Yes without organised officiating Yes with organised officiating Yes at a professional level (e.g. paid to play)

Appendix I: Shoulder Pain and Disability Index (SPADI)

Pain: How severe is your pain:	
1. At its worst?	
2. When lying on the involved side?	
3. Reaching for something on a high shelf?	
4. Touching the back of your neck?	
5. Pushing with the involved arm?	
Disability scale: How much difficulty do you have:	
1. Washing your hair?	
2. Washing your back?	
3. Putting on an undershirt or pullover sweater?	
4. Putting on a shirt that buttons down the front	
5. Putting on your pants	
6. Placing an object of a high shelf?	
7. Carrying a heavy object of 5 kg?	
8. Removing something from your back pocket?	

Appendix J: Tampa Scale of Kinesiophobia

1. I'm afraid that I might injury myself if I exercise	1 strongly disagree 2 disagree 3 agree 4 strongly agree	(Miller , Kori and Todd 1991)
2. If I were to try to overcome it, my pain would increase	1 strongly disagree 2 disagree 3 agree 4 strongly agree	
3. My body is telling me I have something dangerously wrong	1 strongly disagree 2 disagree 3 agree 4 strongly agree	
4. People aren't taking my medical condition seriously enough	1 strongly disagree 2 disagree 3 agree 4 strongly agree	
5. My accident has put my body at risk for the rest of my life	1 strongly disagree 2 disagree 3 agree 4 strongly agree	
6. Pain always means I have injured my body	1 strongly disagree 2 disagree 3 agree 4 strongly agree	
7. Simply being careful that I do not make an unnecessary movements is the safest thing I can do to prevent my pain from worsening	1 strongly disagree 2 disagree 3 agree 4 strongly agree	

8. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1 strongly disagree 2 disagree 3 agree 4 strongly agree
9. Pain lets me know when to stop exercising so that I don't injure myself	1 strongly disagree 2 disagree 3 agree 4 strongly agree
10. I can't do all the things normal people do because it's too easy for me to get injured	1 strongly disagree 2 disagree 3 agree 4 strongly agree
11. No one should have to exercise when he/she is in pain	1 strongly disagree 2 disagree 3 agree 4 strongly agree

1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree

Appendix K: Data from Follow-up phone call.

In order to enable a standardised form that could be used by several research assistants at one time, in a wide variety of places, an online version of the follow-up data form was built at the URL (http://www.shoulderresearch.co.nz/shoulder-dislocation-followup.php). The print version of this follow-up data form is displayed below.

Shoulder Dislocation Follow-up study

Fields marked with a * are compulsory

Date

Subject Name *

Subject Number (if known)

Date of Birth:

Date of Injury

Time Since Injury

Have you had anymore problems with your shoulder such as another dislocation or episode of instability? *

If so, when did this happen?

How did this happen?

Did it go back in by itself?

Did you require someone else to put it back in its socket?

Who waas this person?

Please describe any other problems you have had with your shoulder

Have you returned to sport?

If so, what sport do you play?

Have you had any physiotherapy?

If yes, how many sessions?

These next set of questions relate do your typical level of shoulder activity in the last week. There are five different answers. (Never or less than once a month, Once a

month, Once a week, More than once a week, Daily) I am interested in how often you do the following activities

1. Carrying objects 4kg or heavier by hands (such as a bag of groceries, or four block of cheese/two 2l milk containers)

2. Handling objects overhead

3. Weight lifting or Weight training with arms

4. Swinging motion (as in hitting a tennis ball, golf ball, baseball or similar object)

5. Lifting objects 12.5kgs or heavier (NOT INCLUDING WEIGHT LIFTING)

6. Do you participate in contact sport?

7. Do you participate in sports that involve hard overhand throwing (e.g. baseball or cricket), or overhead serving (e.g. tennis, volleyball) or lap distance swimming?

This next set of questions asks about your level of pain on a scale from 0 to 10 where 10 is your worst pain ever.

1. How much pain did you have initially on a scale of 0 to 10?

2. How much pain do you have now?

3. At its worst?

4. When lying on the involved side?

5. Reaching for something on a high shelf?

6. Touching the back of your neck?

7. Pushing with the involved arm?

This next set of questions asks about how much difficulty you have doing things, on a scale from 0 to 10 where 0 is unable and 10 is 100%, no problem

How much difficulty do you have:

8. Washing your hair?

9. Washing your back?

10. Putting on an undershirt or pullover sweater/jersey?

11. Putting on a shirt that buttons down the front?

12. Putting on your pants?

13. Placing an object of a high shelf?

14. Carrying a heavy object of 5 kg?

15. Removing something from your back pocket?

This next set of questions asks about any fear that you may have related to your injury. There are four possible answers, statement 1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree

1. I'm afraid that I might injury myself if I exercise

2. If I were to try to overcome it (push through your pain), my pain would increase

3. My body is telling me I have something dangerously wrong

4. People aren't taking my medical condition seriously enough

5. My accident has put my body at risk for the rest of my life

6. Pain always means I have injured my body

7. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening

8. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body

9. Pain lets me know when to stop exercising so that I don't injure myself

10. I can't do all the things normal people do because it's too easy for me to get injured

11. No one should have to exercise when he/she is in pain

The final set of questions ask you to rate these answers on a scale of 0-10

1. How much pain do you experience in your shoulder with overhead activities?

(0 no pain, 10 extreme pain)

2. How much aching or throbbing do you experience in your shoulder?

(0 none, 10 extreme aching)

3. How much weakness or lack of strength do you experience in your shoulder?

(0 no weakness, 10 Extreme weakness)

4. How much fatigue of lack of stamina do you experience in your shoulder?

(0 not at all, 10 Extreme fatigue)

5. How much clicking, cracking, or snapping do you experience in your shoulder?

(0 no clicking, 10 extreme clicking)

6. How much stiffness do you experience in your shoulder?

(0 not at all, 10 extreme stiffness)

7. How much discomfort do you experience in your neck muscles as a result of your shoulder? (0 not at all, 10 extreme discomfort)

8. How much feeling of instability or looseness do you experience in your shoulder? (0 not at all, 10 extreme instability)

9. How much do you compensate for your shoulder with other muscles? (0 not at all, 10 extreme compensation)

10. How much loss of range of motion do you have in your shoulder? (0 not at all, 10 extreme loss)

11. How much has your shoulder limited the amount you can participate in sports or recreational activities? (0 not at all, 10 extremely limited)

12. How much has your shoulder affected your ability to perform the specific skills required for your sport or work? (If your shoulder affects both sports and work, consider the area that is most affected.) (0 not at all affected, 10 extremely affected)

13. How much do you feel the need to protect your arm during activities? (0 not at all, 10 extremely)

14. How much difficulty do you experience lifting heavy objects below shoulder level? (0 not at all, 10 extreme difficulty)

15. How much fear do you have of falling on your shoulder? (0 not at all, 10 extreme fear)

16. How much difficulty do you experience maintaining your desired level of fitness? (0 not at all, 10 extreme difficulty)

17. How much difficulty do you have “roughhousing or horsing around” with family or friends? (0 not at all, 10 extreme difficulty)

18. How much difficulty do you have sleeping because of your shoulder? (0 not at all, 10 extreme difficulty)

19. How conscious are you of your shoulder? (0 not at all, 10 extremely conscious)

20. How concerned are you about your shoulder becoming worse? (0 not at all, 10 extremely concerned)

21. How much frustration do you feel because of your shoulder? (0 not at all, 10 extreme frustration)

General Comments

Don't forget to submit this data! OR Thank you for your submission

Appendix L: AUT Ethics Approval

AUT UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

AUTEC
SECRETARIAT

12 May 2015

Paula Kersten

Faculty of Health and Environmental Sciences

Dear Paula

Re Ethics Application: 14/256 Recurrent instability following a first-time traumatic anterior shoulder dislocation: A tool to predict recurrence.

Thank you for providing evidence as requested, which satisfies the points raised by the Auckland University of Technology Ethics Committee (AUTEC).

Your ethics application has been approved for three years until 12 May 2018.

As part of the ethics approval process, you are required to submit the following to AUTEC:

- A brief annual progress report using form EA2, which is available online through http://www.aut.ac.nz/researchethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 12 May 2018;
- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/researchethics. This report is to be submitted either when the approval expires on 12 May 2018 or on completion of the project.

It is a condition of approval that AUTEC is notified of any adverse events or if the research does not commence. AUTEC approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to obtain this. If your research is undertaken within a jurisdiction outside New Zealand, you will need to make the arrangements necessary to meet the legal and ethical requirements that apply there.

To enable us to provide you with efficient service, please use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

All the very best with your research,

Kate O’Connor

Executive Secretary

Auckland University of Technology Ethics Committee

Cc: Margie Olds

Appendix M: ACC Ethics Approval

8 May 2015

Margie Olds

Auckland University of Technology

AUCKLAND

Dear Margie

ACC Research Ethics Committee Decision Notification

Re: Recurrent instability following a first-time traumatic anterior shoulder dislocation: a tool to predict recurrence, #272

Thank you for your response to the Committee which was considered at its meeting on 6 May 2015.

The Committee were satisfied that the issues raised with the information sheet and consent form had been addressed. However it was noted that the AUT Ethics Committee approval letter which had given approval to the study for six months had expired. It was queried whether a parental consent and parental consent and participant assent had been developed as per the AUT committee's requirements.

The Committee gave provisional approval to the proposal subject to assurance that the issues raised by the AUT committee had been addressed and that the correspondence with the AUT Ethics Committee has been appropriately concluded.

Please do not hesitate to contact me if you have any queries.

Yours sincerely

Fiona Conlon, Secretary

PP Hilary Stace, Co-Chair

ACC Research Ethics Committee

ACC Research Ethics Committee

Research/Data Request Monitoring Form

Institution:		
Principal Investigator:		
Title of proposal:		
Date approval given by ACC:		
Status of research. If withheld or an extension of time is required please provide details.	Withdrawn ☐ In progress ☐ Extension required ☐ Completed ☐	Details
Date of study closure: (actual or expected)		
During the course of the research how were ethical issues that arose addressed?		
If the study included the involvement of claimants please provide the details in the adjacent cell as appropriate.	Intended number of claimants in study - Number of claimants involved to date – Number of claimants yet to be involved -	
If number of participants involved is less than planned will this adversely affect the research outcome? Please give details?		
Since ethics approval was obtained has there been changes made to the, research protocols, research design, sample size, duration, protocols for security and storage of data, or in the key investigators?		

ACC Research Ethics Committee

Research/Data Request Monitoring Form

If the researchers received data from ACC that identified claimants has the identifiers now been removed or the data destroyed or returned to ACC? Please give details. If the data has not been so processed when is this expected to take place? Please give details.	
If the study has been completed or is expected to be completed, will the results be published? If yes, briefly describe what and where it has been published or is expected to be published:	
Have the researchers submitted a report to ACC or do they intend to do so? Please give details.	
Has any aspect of the research been the subject of complaints and/or adverse events? If so please give details.	
Have the researchers any additional comments to make, issues they would like addressed etc?	
Summary of findings?	
Signature of Principal Investigator :	
Date form completed:	

From: Fiona Conlon [mailto:Fiona.Conlon@acc.co.nz]
Sent: Wednesday, 13 May 2015 7:48 a.m.
To: Margie Olds
Subject: RE: Ethics Application #272

As the Committee gave provisional approval to the proposal subject to assurance that the issues raised by the AUT committee had been addressed and that the correspondence with the AUT Ethics Committee has been appropriately concluded, your proposal is now fully approved.

All the best with your research.

Kind regards

Fiona.

Fiona Conlon, Senior Research Advisor, ACC
Tel (04) 816-6387 / Ext 46387

Appendix N: Amendment to ethics

AUTEC Secretariat

Auckland University of Technology

D-89, WA505F Level 5 WA Building City Campus

T: +64 9 921 9999 ext. 8316

E: ethics@aut.ac.nz

www.aut.ac.nz/researchethics

3 August 2015

Paula Kersten
Faculty of Health and Environmental Sciences

Dear Paula

Re: Ethics Application: 14/256 Recurrent instability following a first-time traumatic anterior shoulder dislocation: A tool to predict recurrence.

Thank you for your request for approval of an amendment to your ethics application.

I have approved the minor amendment to your ethics application allowing a change to the recruitment protocol.

I remind you that as part of the ethics approval process, you are required to submit the following to the Auckland University of Technology Ethics Committee (AUTEC):

- A brief annual progress report using form EA2, which is available online through http://www.aut.ac.nz/researchethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 12 May 2018;
- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/researchethics. This report is to be submitted either when the approval expires on 12 May 2018 or on completion of the project.

It is a condition of approval that AUTEC is notified of any adverse events or if the research does not commence. AUTEC approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to obtain this. If your research is undertaken within a jurisdiction outside New Zealand, you will need to make the arrangements necessary to meet the legal and ethical requirements that apply there.

To enable us to provide you with efficient service, please use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

All the very best with your research,

Kate O'Connor

Executive Secretary

Auckland University of Technology Ethics Committee

Cc: Margie Olds, Richard Ellis

Appendix O: STROBE

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with 1 a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Particpants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Participants 6 (b) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources

		of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed Statistical methods 12 (e) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage Participants 13* (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest Descriptive data 14* (c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations		Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
		Other information
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.