CLINICAL IDENTIFIERS FOR EARLY STAGE PRIMARY/IDIOPATHIC ADHESIVE CAPSULITIS

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Statement of Originality

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968.

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Acknowledgement of Authorship

I hereby certify that this thesis is in the form of a series of published papers of which I am a joint author. I have included as part of the thesis a written statement from each co-author, endorsed by the Assistant Dean Research Training, Faculty of Health and Medicine attesting to my contribution to the joint publications (Appendix 1).

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Sarah Walmsley **Date:**

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Publications and presentations

The following publications and presentations were a direct result of the work completed in this thesis:

Published papers

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2. Walmsley S, Rivett DA, Osmotherly PG, McKiernan ST (2012). Early diagnosis of primary/idiopathic adhesive capsulitis: Can imaging contribute? *International Musculoskeletal Medicine* 34 (4): 166-174.
3. Walmsley S, Osmotherly PG, Walker, CJ, Rivett DA (2013). Power Doppler ultrasound in the early diagnosis of primary/idiopathic adhesive capsulitis: an exploratory study. *Journal of Manipulative and Physiological Therapeutics* 36 (7): 428-435.
4. Walmsley S, Osmotherly PG, Rivett DA (2014). Movement and pain patterns in early stage primary/idiopathic adhesive capsulitis: a factor analysis. *Physiotherapy.* In press, doi: 10.1016/j.physio2014.02.001.
5. Walmsley S, Osmotherly PG, Rivett DA (2014). Clinical identifiers/diagnostic criteria for primary/idiopathic adhesive capsulitis: are we seeing the real picture? *Physical Therapy* 94 (7): 968-976.

Published abstracts

1. Walmsley, S, Rivett, D, Osmotherly, P. (2007). Establishing consensus of stage one adhesive capsulitis using the Delphi technique: A pilot study. In *Proceedings of the 7th Triennial Congress of the International Federation of Shoulder and Hand Therapists*, Sydney, Australia. March 2007.
2. Walmsley S, Rivett DA, Osmotherly PG (2009). Adhesive capsulitis: establishing consensus on clinical identifiers for stage one using the Delphi technique. *Australian Journal of Physiotherapy*, supplements. 55, (4).p. 43.
3. Walmsley S, Rivett DA, Osmotherly PG (2011). Power Doppler ultrasound in the early diagnosis of primary/idiopathic adhesive capsulitis: a pilot study. *Physiotherapy*, 97. (Supplement S1): eS1320.
4. Walmsley S, Rivett DA, Osmotherly PG (2011). Power Doppler ultrasound in the early diagnosis of primary/idiopathic adhesive capsulitis. *Journal of Physiotherapy,* supplements: 027, p. 25.
5. Walmsley S, Rivett DA, Osmotherly PG (2012). Validation of a set of clinical identifiers for the early stage of primary/idiopathic adhesive capsulitis: preliminary results. In *Proceedings of the 10th Congress of the International Federation of Orthopaedic Manipulative Therapists (IFOMPT).* Quebec City, Canada, October 2012. *Journal of Orthopaedic and Sports Physical Therapy* (2012); 42(10):A41.
6. Walmsley S, Rivett DA, Osmotherly PG (2013). Movement loss patterns inpatients diagnosed with early stage primary/idiopathic adhesive capsulitis: preliminary

results. In *Proceedings of 4th International Congress of Shoulder and Elbow Therapists,* April 2013, Nagoya, Japan.

7. Walmsley S, Osmotherly PG, Rivett DA (2013). Movement and pain patterns in early stage primary/idiopathic adhesive capsulitis. In *Proceedings of Australian Physiotherapy Association Conference,* Melbourne, Australia. October 2013.
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The following conference and invited presentations were a direct result of the work completed in this thesis:

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2. Walmsley, S, Rivett, DA, Osmotherly, PG. (2007). Establishing consensus of stage one adhesive capsulitis using the Delphi technique: A pilot study. Oral presentation. *7th Triennial Congress of the International Federation of Shoulder and Hand Therapists (IFSHT)*. Sydney, Australia. March 2007.

3. Walmsley, S, Rivett, DA, Osmotherly, PG. (2008). Adhesive capsulitis: establishing consensus on diagnostic criteria for stage one using the Delphi technique. Poster presentation with two minute oral presentation. 9th *Congress of the International Federation of Manipulative Therapists (IFOMT)*. Rotterdam, The Netherlands. June 2008.
4. Walmsley, S, Rivett, DA, Osmotherly, PG. (2008). Adhesive capsulitis: establishing clinical identifiers for stage one using the Delphi technique. Oral presentation. Closed conference of *Shoulder and Elbow Physiotherapists Australia (SEPA).* Perth, Australia. September 2008.
5. Walmsley S, Rivett DA, Osmotherly PG (2009). Adhesive capsulitis: establishing consensus on clinical identifiers for stage one using the Delphi technique. Oral presentation. *Musculoskeletal Physiotherapy Australia 16th Biennial Conference.* Sydney, Australia. October 2009.
6. Walmsley S, Rivett DA, Osmotherly PG (2011). Power Doppler ultrasound in the early diagnosis of primary/idiopathic adhesive capsulitis: a pilot study Poster presentation. *World Confederation for Physical Therapy 16th International Congress (WCPT),* Amsterdam, The Netherlands. June 2011.
7. Walmsley S, Rivett DA, Osmotherly PG (2011). Power Doppler ultrasound in the early diagnosis of primary/idiopathic adhesive capsulitis. 5x5 oral presentation. *Musculoskeletal Physiotherapy Australia 17th Biennial Conference.* Brisbane, Australia. October 2011.

8. Walmsley S, Rivett DA, Osmotherly PG (2012). Early diagnosis of primary/idiopathic adhesive capsulitis: examination using power Doppler ultrasound. Poster presentation. *10th Congress of the International Federation of Manipulative Therapists (IFOMT)*, Quebec City, Canada. October 2012.
9. Walmsley S, Rivett DA, Osmotherly PG (2012). Validation of a set of clinical identifiers for the early stage of primary/idiopathic adhesive capsulitis: preliminary results. Oral presentation. *10th Congress of the International Federation of Manipulative Therapists (IFOMT)*, Quebec City, Canada. October 2012.
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presentation. *Musculoskeletal Physiotherapy Australia 18th Biennial Conference.* Melbourne, Australia. October 2013.

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List of Abbreviations

AC	Adhesive capsulitis
ADL	Activities of daily living
AR	Axillary recess
BT	Biceps tendon
CAL	Coracoacromial ligament
CDUS	Colour Doppler ultrasound
CHL	Coracohumeral ligament
CI	Confidence interval
CP	Coracoid process
CRP	C-reactive protein
ER	External rotation
ERA	External rotation in abduction
ERN	External rotation in neutral
FE	Forward elevation
GHA	Glenohumeral abduction
GHF	Glenohumeral flexion
GHJ	Glenohumeral joint
IRA	Internal rotation in abduction
HBB	Hand behind back
IR	Internal rotation
IS	Impingement syndrome

MCS	Mental component summary
MHz	Mega hertz
mm	Millimetres
mths	Months
MRA	Magnetic resonance arthrography
MRI	Magnetic resonance imaging
NSAIDs	Non steroidal anti-inflammatory drugs
OR	Odds ratio
PAR	Positive anaesthetic response
PCS	Physical component summary
PDGF	Platelet derived growth factor
PDUS	Power Doppler ultrasound
PROM	Passive range of movement
RC	Rotator cuff
RCT	Rotator cuff tear
RI	Rotator interval
ROM	Range of movement
Rx	Treatment
SCP	Subscapularis muscle
SD	Standard deviation
SF	Short form
SPADI	Shoulder pain and disability index
SSP	Supraspinatus muscle
TGF	Transforming growth factor

TSA	Total shoulder abduction
TSF	Total shoulder flexion
US	Ultrasound
VAS	Visual analogue scale
yrs	Years

Abstract

Adhesive capsulitis is a shoulder disorder commonly encountered in musculoskeletal practice. It is recognised as consisting of three stages, and is characterized initially by pain followed by a gradual loss of active and passive ranges of movement. In its early stage, confusion with other shoulder disorders with the potential to cause pain and limited range of movement is common and may result in inappropriate or untimely treatment. Musculoskeletal medicine relies on clinical findings together with medical imaging to inform the diagnosis of many disorders. These findings may be useful in contributing to a diagnosis as well excluding other potential diagnoses. The overall aim of this thesis was to identify and investigate the clinical identifiers or diagnostic criteria that may facilitate recognition of the early stage of adhesive capsulitis. Four research studies and one literature review were undertaken to meet this aim.

A correspondence-based Delphi study was initially undertaken to investigate whether consensus could be achieved among a group of experts on the diagnostic criteria/clinical identifiers that are associated with the early stage of adhesive capsulitis. This study established eight identifiers that clustered into two discrete domains of pain and movement. Secondly, a review of the diagnostic imaging literature was undertaken to determine the current and future contribution that this modality may make to the clinical diagnosis of adhesive capsulitis. As Doppler ultrasonography was identified as having potential to contribute to the early diagnosis of adhesive capsulitis, it was explored in a second study. This study demonstrated that it may be possible to visualise an area of increased vascularity in the rotator interval

area of the shoulder in patients clinically diagnosed with early stage adhesive capsulitis. A third study aimed to evaluate patients diagnosed with early stage adhesive capsulitis to determine the existence of any pattern of movement loss and associated pain that may facilitate early recognition. The limiting factor to movement was also analysed. Although pain is reportedly a characteristic in the early stage, the results of this study suggested it may be less useful than percentage loss of active range of movement in identifying patients with primary/idiopathic adhesive capsulitis. Interestingly overall, external rotation in abduction emerged as the most painful active and passive movement and the movement most frequently limited by pain rather than resistance, which may provide valuable information to both the clinician and researcher. The aim of final study was to validate the clinical identifiers established in the earlier Delphi study. This study, unexpectedly suggested the identifiers from the earlier study may not be true predictors of early stage adhesive capsulitis.

The study findings presented in this thesis provide a number of features that may facilitate identification of early stage adhesive capsulitis, as well as enable future researchers to determine more homogeneous samples. Importantly, the overall results of the studies challenge the commonly recognised clinical identifiers or diagnostic criteria for adhesive capsulitis and suggest they may not be able to adequately diagnose this disorder in its early stage. The findings also highlight the difficulty of rigorously investigating this stage of the disorder. Future directions for research and implications for clinical practice are discussed in relation to the findings of the studies in this thesis.

Chapter 1 Introduction

This chapter introduces the studies contained within this thesis. Firstly, the background and context of the research are outlined. The specific research aims to be addressed by the thesis and its constituent studies are stated, and a brief summary of the contents of each of the chapters is presented. The scope and delimitations of the thesis and collective studies are identified, and the chapter concludes with a description of the significance of the overall thesis.

1.1 Background and context

Shoulder disorders are the third most commonly presenting musculoskeletal disorder encountered after low back and neck pain (Parsons, Harding et al. 2007) and it has been estimated that as many as one in five people will experience a shoulder disorder at some stage of their lives (Lin, Jarmain et al. 2004). Accordingly, a large proportion of patients seeking physiotherapy treatment will present with a shoulder disorder (May 2003). Shoulder pain and dysfunction can result in significant disability and reduced quality of life, as well as potential inability to work (Taylor 2005). All of these factors place a burden on both the individual and society (Urwin, Symmons et al. 1998; Bongers 2001). Shoulder disorders therefore represent a significant problem for the general population, clinicians, health funding bodies and governments. The potential to reduce this burden lies with clinicians and researchers in identifying and managing the various causes of shoulder pain appropriately.

Adhesive capsulitis has been described as one of the most poorly understood shoulder disorders (Zuckerman and Rokito 2011). It is however, frequently encountered in musculoskeletal clinical practice and reportedly responsible for considerable pain and disability (Neviaser 1987). It is a disorder described as consisting of three stages (Chambler and Carr 2003; Jacobs, Smith et al. 2009; Lorbach, Anagnostakos et al. 2010) and reported to often have a protracted clinical course (Reeves 1975). Adhesive capsulitis may be difficult to diagnose in its early stage and in particular differentiate from other shoulder disorders. Many of the reported signs and symptoms that are present in various shoulder disorders overlap making differential diagnosis problematic (Hanchard, Goodchild et al. 2011). For example, sub-acromial impingement syndrome, acute bursitis, calcific tendonitis and glenohumeral osteoarthritis as well as adhesive capsulitis all present with generalised shoulder pain in the C5 dermatome (Liesdek, van der Windt et al. 1997). Night pain and pain lying on the affected shoulder are all frequently reported with these disorders as is pain with movement (Hsu, Anakwenze et al. 2011). Variable quantification of active range of movement deficit for each disorder is also present in the literature whilst passive loss is generally restricted to adhesive capsulitis and glenohumeral osteoarthritis (Carter, Hall et al. 2012). Although special tests are used frequently in musculoskeletal medicine, these tests have yet to be validated questioning their utility to confirm a diagnosis or to exclude alternate diagnoses (Hegedus, Goode et al. 2007). This overlap of characteristics and lack of validated shoulder examination procedures highlights the difficulty in establishing a correct diagnosis for early stage adhesive capsulitis.

It has been suggested that adhesive capsulitis requires a different treatment approach to other commonly presenting shoulder disorders and to date treatment strategies have demonstrated mixed results (Green 2003; Vad, Sakalkale et al. 2003; Griesser, Harris et al. 2011). Notably, most studies have generally been concerned with the later stages of adhesive capsulitis and potentially involved heterogeneous groups of patients. Recognition of the early stage of the disorder has been suggested to facilitate timely and appropriate management. In particular, reduced morbidity from adhesive capsulitis has been proposed if treatment is implemented in this stage (Hazleman 1972; Hannafin and Chiaia 2000; Marx, Malizia et al. 2007; Lorbach, Kieb et al. 2010).

The confusion over the diagnosis of adhesive capsulitis has been attributed to the poor appreciation of the aetiology and management of this disorder (Hsu, Anakwenze et al. 2011). Indeed, other shoulder disorders including rotator cuff impingement and calcific tendonitis, as well as rotator cuff tears may be responsible for the presentation of a stiff and painful shoulder with apparent limitation of active shoulder range of movement without true glenohumeral capsular contracture and restriction of passive range of movement, and are, therefore, often erroneously labelled adhesive capsulitis (Hsu, Anakwenze et al. 2011). Appropriate assessment, diagnosis and treatment associations are arguably essential to improving outcomes. The need to establish diagnostic criteria or clinical identifiers specific to adhesive capsulitis, particularly in the early stage of the disorder, is of utmost importance in achieving this result and is being increasingly recognised (Rodeo, Hannafin et al. 1997; Hannafin and Chiaia 2000; Marx, Malizia et al. 2007).

1.2 Research aims

The overall aim of this thesis is to establish diagnostic criteria or clinical identifiers that may facilitate recognition of the early stage of primary/idiopathic adhesive capsulitis.

More specifically the aims are:

1. To determine consensus of a group of experts regarding the diagnostic criteria/clinical identifiers for early stage primary/idiopathic adhesive capsulitis.
2. To review the available literature to determine the current evidence that may exist to inform the radiological diagnosis of adhesive capsulitis.
3. To explore the potential of diagnostic ultrasound to identify an area of increased vascularity in the rotator interval of patients diagnosed with early stage primary/idiopathic adhesive capsulitis.
4. To determine if a recognisable pattern of movement loss and pain is present in patients diagnosed with early stage primary/idiopathic adhesive capsulitis.
5. To validate a set of clinical identifiers for early stage primary/idiopathic adhesive capsulitis determined by consensus of a group of experts.

1.3 Outline of the thesis

This thesis is presented in publication style. Each published manuscript was written in the conventional publication style for the journal to which it was submitted. However in this thesis each manuscript is presented as a Word document and a consistent referencing style (Author – Date) has been used throughout. At the beginning of each

publication a brief overview is presented to place the chapter in the context of the thesis.

This thesis is comprised of eight chapters and begins with an overview of selected relevant aspects of the literature (Chapter 2). This chapter is presented to enable the reader to understand the context of the four studies undertaken. Review of specific relevant literature to each study is also presented in subsequent chapters. The background, methodology, results and discussion of the study findings and implications of the research conducted for this thesis are presented as a series of four research papers (Chapters 3, 5, 6 and 7). A published review paper on the current radiological evidence for the diagnosis of adhesive capsulitis providing a background to the power Doppler ultrasound study (Chapter 5) is presented in Chapter 4. The four research papers and one review paper together constitute a body of research aimed at facilitating the early diagnosis of primary/idiopathic adhesive capsulitis. The final chapter of the thesis (Chapter 8) provides an overall discussion of the findings from the collective research studies and the conclusions drawn from this body of work. It also presents the implications for future investigation on this topic and clinical practice. A more detailed description of the content of each chapter follows.

Chapter 2

A review of the literature relevant to the contents of this thesis is presented in this chapter. A general description of adhesive capsulitis, including its associations and co-morbidities is presented together with a description of the relevant shoulder anatomy

and pathophysiology. The stages of adhesive capsulitis are described and the clinical evaluation of this disorder is outlined. Current management with emphasis on early treatment is presented. The current differing schools of thought on the diagnosis of shoulder disorders are also discussed.

Chapter 3

This chapter details the Delphi study that was conducted as the initial step to establish a set of diagnostic criteria/clinical identifiers for early stage adhesive capsulitis that are then investigated in subsequent studies. This study was aimed at determining consensus that may exist among a group of experts regarding the patient reported and physical examination findings characteristic of the early stage of primary/idiopathic adhesive capsulitis. Establishing this consensus was the first step in the process of identification and validation of agreed diagnostic criteria/clinical identifiers for this disorder. This chapter has been published in a peer-reviewed scientific journal (Walmsley, Rivett et al. 2009) and has been presented at one international and four national conferences.

Chapter 4

This chapter presents a review of the published literature relevant to the medical imaging currently available and used to diagnose adhesive capsulitis. The purpose of this review was to establish the current evidence that may support the role of imaging facilitating a diagnosis of adhesive capsulitis and to discuss this in relation to the contemporary understanding of the pathology of the disorder. Notably, this chapter

highlights that medical imaging evidence is generally concerned with the later stages of the disorder. A review of the current radiological evidence that exists that may support facilitation of an early diagnosis of adhesive capsulitis is a particular focus of this chapter. The potential role of Doppler ultrasound to contribute to an early diagnosis of this shoulder disorder is proposed. This chapter has been published in a peer-reviewed scientific journal (Walmsley, Rivett et al. 2012).

Chapter 5

Chapter 5 details the power Doppler ultrasound study that was undertaken on a group of patients clinically diagnosed with early stage adhesive capsulitis. The purpose of this exploratory study was to determine if it was possible to visualise an area of increased vascularity in the rotator interval area of the glenohumeral joint capsule in early stage adhesive capsulitis. In particular, this study sought to utilise a readily available imaging modality to determine its potential contribution to the clinical picture. This chapter has been published in a peer-reviewed scientific journal (Walmsley, Osmotherly et al. 2013). It has also been presented as an oral presentation at a national conference and in poster format at two international conferences.

Chapter 6

Recognition of patterns of movement and pain underpin the diagnostic process in musculoskeletal medicine. Chapter 6 describes an exploration of movement and pain patterns that may exist in patients clinically diagnosed with early stage primary/idiopathic adhesive capsulitis using factor analysis. The aim of this study was

to determine if a detectable pattern of active or passive movement loss was present in patients diagnosed with early stage primary/idiopathic adhesive capsulitis. A second aim of this study was to determine if a detectable pattern of associated pain at the end of active or passive movements was present in these patients, as well as whether movement is typically limited by pain, inability to move or resistance at this stage of the disorder. The findings of this study have been presented at a national and an international conference and the manuscript has been published online in a peer-reviewed scientific journal.

Chapter 7

The fourth and final study in the thesis is described in Chapter 7. This study was undertaken to determine if any or all of the eight clinical identifiers established in the earlier Delphi study (Chapter 3) were predictors of early stage adhesive capsulitis. This study used the intraarticular local anaesthetic administered concurrently with a corticosteroid as the reference standard in a group of patients clinically diagnosed with early stage adhesive capsulitis. Preliminary findings of this study have been presented at an international conference. The final findings of this study have been presented at a national conference and the manuscript has been published in a peer-reviewed scientific journal, making a total of five publications arising from this thesis.

Chapter 8

Chapter 8 provides an overall discussion of the key findings of the four studies, and the conclusions which can be drawn. Limitations of the collective studies are

acknowledged and discussed. This final chapter discusses the study findings in light of the overall thesis aims and places the studies into clinical context as well as outlining the recommendations for future research and clinical practice.

1.4 Scope/de-limitations

This thesis is primarily concerned with primary or idiopathic adhesive capsulitis and the early stage of the disorder. It does not investigate secondary adhesive capsulitis or the latter stages. Although four stages of adhesive capsulitis have been previously proposed (Neviaser and Neviaser 1987; Hannafin and Chiaia 2000), this thesis has adopted the more contemporary classification into three stages. This thesis is not concerned with shoulder disorders other than adhesive capsulitis and is concerned with diagnosis rather than treatment of the disorder.

1.5 Significance

Information gained from the studies that form this thesis is intended to contribute to the recognition of early stage adhesive capsulitis. This will assist both clinicians and researchers in identifying a homogeneous group of patients with which to direct appropriate management and future research.

Chapter 2 Literature review

A review of the literature relevant to the studies described in this thesis is outlined in this chapter. Firstly, a general description of adhesive capsulitis is presented and the variable nomenclature of this disorder is introduced. A more detailed description of the incidence, classification, stages, natural history, anatomy and pathophysiology of adhesive capsulitis, along with its clinical associations and risk factors is presented. The typical clinical presentation is described and current trends in management are briefly outlined, emphasising the relevance of early treatment. An introduction to the problem of the lack of diagnostic criteria or clinical identifiers for various shoulder disorders is discussed in the context of adhesive capsulitis. Throughout the review of the literature the importance of recognising the various stages of adhesive capsulitis is highlighted. The limitations of published studies are also discussed to underline the relevance and need for the current studies.

2.1 General description of adhesive capsulitis

Adhesive capsulitis is a shoulder disorder that affects the glenohumeral joint capsule. It is characterised by a gradual onset of shoulder pain accompanied by a progressive loss of both active and passive ranges of shoulder movement (Pearsall and Speer 1998; Griesser, Harris et al. 2011). Initially labelled 'frozen shoulder' by Codman (1934) , it later became known as 'adhesive capsulitis' to better reflect the reported pathology and anatomy (Neviaser 1945). Although these remain the most frequently used terms to describe this disorder, earlier authors described it as 'peri-arthritis scapulohumerale' (Duplay 1872) and it has also been referred to as 'painful stiff shoulder' (Hazleman

1972). More recently the name 'contracture of the shoulder' has been proposed as a more accurate reflection of the presentation (Bunker 2009). However throughout this thesis the nomenclature 'adhesive capsulitis' will be adopted as it is the most commonly recognised term.

Despite the differing nomenclature, the general description of this disorder has not altered greatly since it was first described by Codman in 1934. At that time, he noted that "this is a condition which comes on slowly with pain over the deltoid insertion, inability to sleep, painful incomplete elevation and external rotation, the restriction of movement being both active and passive, with a normal radiograph, the pain being very trying and yet all patients are able to continue their daily habits and routines" (Codman 1934, p. 216). Whilst this description continues to be frequently reported, arguably it could also apply to other commonly presenting shoulder disorders.

2.2 Epidemiology

Adhesive capsulitis is generally reported to occur in 2 to 5% of the population at some stage of their life (Lundberg 1969; Wolf and Green 2002; Hand, Clipsham et al. 2008). This figure is reportedly higher in the diabetic population (Scarlat, Goldberg et al. 2000) with up to 30% of patients with type 2 diabetes mellitus afflicted at some time (Aydogan, Karan et al. 2003/2004). It most commonly affects persons aged 40 to 60 years (Neviaser 1980; Vad and Hannafin 2000) and traditionally a female predominance has been proposed with ratios of 8:2 to 6:4 noted (Binder, Bulgen et al. 1984; Wiley 1991; Shaffer, Tibone et al. 1992; Bunker and Anthony 1995). As many as

20-30% of people affected by adhesive capsulitis develop the condition in the contralateral shoulder at some point (Reeves 1975; Binder, Bulgen et al. 1984; Shaffer, Tibone et al. 1992) and it has been suggested that the non-dominant shoulder is more frequently involved (Levine, Kashyap et al. 2007; Hand, Clipsham et al. 2008). Minor preceding trauma to the shoulder has been described as occurring in 20 to 30% of people diagnosed with adhesive capsulitis (Hand, Clipsham et al. 2008).

A number of factors, including the lack of universally accepted diagnostic criteria for adhesive capsulitis, have resulted in broad estimations of the epidemiological characteristics and reported incidence of this disorder being problematic (Murnaghan 1990). The advent of arthroscopic investigation of the shoulder has recently challenged the commonly stated estimates of incidence and the assertion of a higher proportion in women, both of which have been suggested may be lower than previously reported (Bunker 2009). A further consideration of the traditional, and possibly erroneous epidemiological characteristics, is the suggestion that stiff and painful shoulders without strong evidence of capsular pathology, have been included with this diagnostic classification (Baslund, Thomsen et al. 1990; Watson, Dalziel et al. 2000). There is increasing recognition that adhesive capsulitis is a separate entity and this is necessary for correct interpretation of the incidence (Neviaser and Neviaser 1987; Bunker 2009).

2.3 Classification of adhesive capsulitis

Adhesive capsulitis is classified as either primary or secondary (Reeves 1975; Chambler and Carr 2003; Harrast and Rao 2004). Primary or idiopathic adhesive capsulitis has an insidious onset, although minor preceding trauma has frequently been noted (Nash and Hazleman 1989; Hand, Clipsham et al. 2008). Conversely, secondary adhesive capsulitis is the result of surgery, a major traumatic episode or a fracture (Hannafin and Chiaia 2000) but it is also often the name given to a collection of symptoms associated with a stiff and painful shoulder (Lundberg 1969). Some authors also include the term 'secondary' to describe any association with another condition such as diabetes or Dupytren's disease (Hand, Clipsham et al. 2008; Kelley, McClure et al. 2009). Interestingly, it has been suggested that some of the known causes of secondary adhesive capsulitis may result in concurrent isolated areas of glenohumeral capsular contracture indistinguishable from primary/idiopathic adhesive capsulitis, with frequent overlap between the two (Neviaser and Hannafin 2010). Further, extra-articular causes of shoulder stiffness, including calcific or biceps tendonitis, rotator cuff injury or glenohumeral or acromioclavicular osteoarthritis may also result in stiffness without true capsular limitation of movement, and may be grouped with this disorder (Neviaser and Hannafin 2010). Importantly, treatment of secondary adhesive capsulitis should be directed at the associated condition causing the pain and stiffness in the shoulder, rather than any proposed pathophysiological process. This thesis is generally concerned with primary/idiopathic adhesive capsulitis.

2.3.1 Stages of adhesive capsulitis

One of the most striking and potentially confusing features of adhesive capsulitis is that it is a disorder that consists of a series of stages. These stages provide a framework for clinical, arthroscopic and histological correlation (Table 2.1) and in turn require differing considerations for appropriate management.

Table 2.1 Stages of adhesive capsulitis

Stage	Examination under anaesthesia	Clinical examination	Arthroscopic findings	Histology
I	Full range of motion	Painful limitation of glenohumeral motion	Diffuse hypervascular synovitis	Hypervascular synovitis, normal underlying capsule
II	Limited range of motion	Painful limitation of glenohumeral motion	Diffuse pendunculated hypervascular synovitis	Hypervascular synovitis, fibroplastic hyperplasia and disorganised collagen deposition in the underlying capsule
III	Significant loss of motion	Mild pain at end of motion, significant loss of motion	Minimal synovitis	Minimal synovial hyperplasia, extensive scarring of the underlying capsule

Adapted from Vad and Hannafin (2000)

Whilst four stages have been described (Neviaser and Neviaser 1987; Neviaser and Hannafin 2010), adhesive capsulitis is more commonly reported as consisting of three stages (Pearsall and Speer 1998; Siegel, Cohen et al. 1999; Chambler and Carr 2003; Jacobs, Smith et al. 2009; Lorbach, Anagnostakos et al. 2010). These stages begin with the first or early stage which is frequently termed the 'painful' stage. It is generally recognised that this stage may last for up to nine months (Reeves 1975; Pearsall and Speer 1998; Griesser, Harris et al. 2011). The second stage is often referred to as the 'frozen' stage and is reported to last from four to 12 months (Reeves 1975). The third or

final stage is described as the 'thawing' or 'resolution' stage which reportedly may last from five to 26 months (Reeves 1975). Descriptions that include four stages place a stage prior to the first stage and call it the pre-adhesive stage (Neviaser and Neviaser 1987; Hannafin and Chiaia 2000). It is generally reported by these authors to last from zero to three months (Neviaser and Neviaser 1987; Hannafin and Chiaia 2000). Whilst the stages are considered a continuum of the disease process rather than discrete entities, (Figure 2.1) the length of each stage described varies throughout the literature.

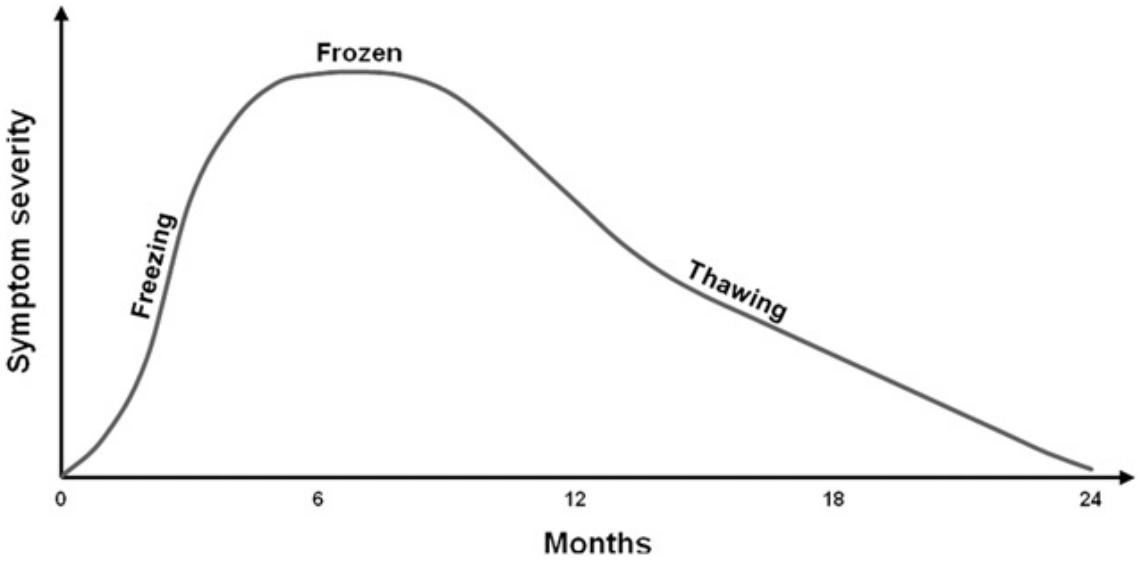

Figure 2.1 Continuum of stages in adhesive capsulitis

Image reproduced with permission from Elsevier (Hsu, Anakwenze et al. 2011)

Perhaps reflecting the difficulty in early identification, the traditional description of the stages of adhesive capsulitis has recently been challenged with the recommendation that the stages be simply classified as 'pain-predominant' and 'stiffness-predominant' (Hanchard, Goodchild et al. 2012). Throughout this thesis the description of three stages will be adopted and it is concerned with the first or early stage of the disorder.

2.3.2 Natural history

The natural history of primary/idiopathic adhesive capsulitis remains controversial. Traditionally, it has been accepted that the disorder slowly progresses towards spontaneous resolution (Brue, Valentin et al. 2007). However, it has been recently proposed that there are no true natural history studies as most include some form of treatment (Neviaser and Hannafin 2010). Although it has been widely accepted that adhesive capsulitis is a self-limiting disorder, a number of long term studies have indicated that pain and loss of movement or function may still be present in persons at long term follow-up (Reeves 1975; Binder, Bulgen et al. 1984; Shaffer, Tibone et al. 1992; Vecchio, Kavanagh et al. 1995; Griggs, Ahn et al. 2000; Hand, Clipsham et al. 2008). As outcome measures vary between studies, determining residual symptoms is problematic and it has been suggested that the use of patient reported outcomes may provide more favourable results than physical examination findings (Neviaser and Hannafin 2010). Notably, external rotation has been proposed as the predominant restricted movement, which may not be apparent in patient reported outcome measures (Hsu, Anakwenze et al. 2011).

Addressing the lack of true natural history studies, a very recent long term study of patients with idiopathic adhesive capsulitis that analysed non-operative and untreated participants using both range of movement and patient reported scores, concluded that most patients would experience complete resolution without any treatment (Vastamaki, Kettunen et al. 2012). An important consideration in determining the natural history of adhesive capsulitis however, also relates to the heterogeneity of

selection criteria of participants included in studies, which in turn may potentially influence the recovery. This lack of consistent diagnostic criteria or clinical identifiers adversely affects the ability to accurately determine the natural history of the disorder.

2.4 Anatomy and pathophysiology of adhesive capsulitis

An appreciation of shoulder anatomy and the pathophysiology of adhesive capsulitis may assist in recognition of the disorder and provides a framework for interpreting the clinical presentation. It may also provide a rationale for the selection of appropriate management strategies. Adhesive capsulitis primarily affects structures of the glenohumeral joint. This joint is enclosed within a capsule lined with a synovial membrane that attaches to bone at the borders of the articulating surfaces of both the head of the humerus and the glenoid fossa. The capsule is lax and forms a redundant axillary fold inferiorly and has a normal volume of 25-30 ml (Dias, Cutts et al. 2005). The tendons of the rotator cuff muscles (supraspinatus, infraspinatus, subscapularis and teres minor) merge with the glenohumeral joint capsule and with each other, with the exception of the area between supraspinatus and subscapularis where the rotator interval is formed. This triangular area contains glenohumeral joint capsule and is reinforced by the coracohumeral and superior glenohumeral ligaments and is traversed by the biceps tendon (Figure 2.2). The middle and inferior glenohumeral ligaments also form part of the glenohumeral joint capsule and lie inferior to the superior glenohumeral ligament.

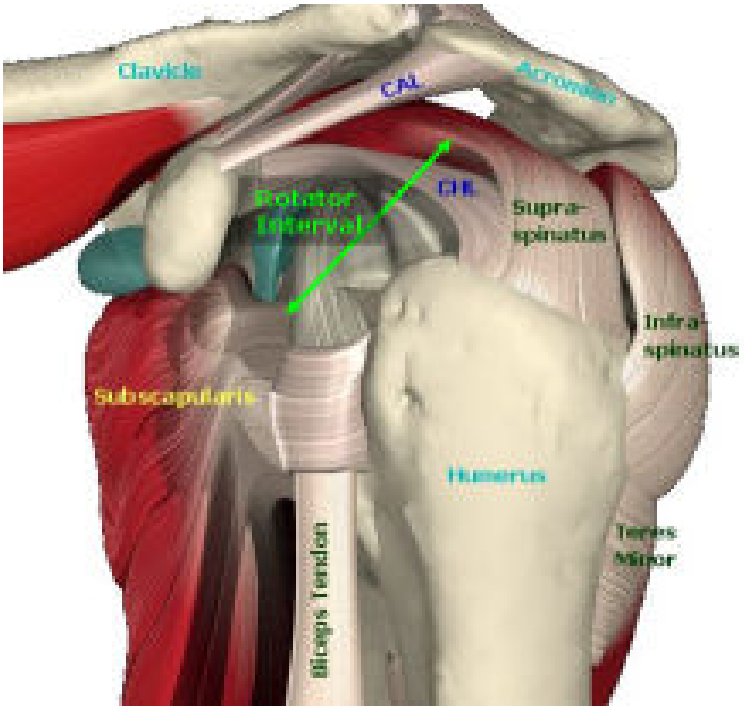

Figure 2.2 The rotator interval area of the shoulder

CAL = coracoacromial ligament, CHL = coracohumeral ligament.

(http://www.shoulderdoc.co.uk/education/rotator_cuff_mechanics.pdf)

Many of the anatomical structures that comprise the shoulder, as well as referral from the cervical spine, may be responsible for shoulder pain. It is therefore important to be able to differentiate these potential sources of pain through recognition of sets of diagnostic criteria or clinical identifiers that reflect the underlying anatomical structures and pathophysiological processes. Interestingly, mechanical stress between the subacromial space and the coracohumeral ligament as well as partial thickness rotator cuff tears have been suggested as a precursor to adhesive capsulitis (Kanbe, Inoue et al. 2009). This may provide an explanation for the reported difficulty in

differentiating early stage adhesive capsulitis from shoulder impingement which also primarily presents as a painful shoulder (Kelley, McClure et al. 2009).

A description of the pathogenesis of adhesive capsulitis helps provide an explanation for the stages of the disorder and informs the clinical characteristics that are reported to characterise each stage. It is important to note that although surgery has allowed both direct observation and histological assessment of the anatomical structures involved in adhesive capsulitis, most of the studies reported to date have involved recalcitrant presentations or patients in the later stages of the disorder (Hsu, Anakwenze et al. 2011). Generalisations about the pathophysiology of adhesive capsulitis may therefore be limited. Nonetheless a description of the macroscopic, histological and biochemical findings identified to date provide relevant insights into recognition of this disorder.

Despite the recent advances made possible through surgical appraisal, controversy about the exact pathophysiology of adhesive capsulitis has been present for some time. Whether the disorder is an inflammatory or fibrotic process (Ozaki, Nakagawa et al. 1989; Bunker and Anthony 1995; Hannafin and Chiaia 2000) or an inflammatory process with subsequent reactive fibrosis (Bunker, Reilly et al. 2000; Hand, Athanasou et al. 2007), has generated considerable debate. Given the presentation of pain followed by stiffness, the latter suggestion would seem the most plausible and is now most generally recognised. The controversy regarding the exact pathogenesis of adhesive capsulitis has been suggested to be a result of the lack of consistency of inclusion criteria in published studies in considering the stages of adhesive capsulitis, which

may influence diagnosis and therefore treatment outcomes (Hannafin and Chiaia 2000).

The term 'adhesive capsulitis' originated when it was noted during open surgery that there was evidence of capsular and synovial inflammation and adhesions, resulting in adherence of the axillary fold both to itself and to the neck of the humerus (Neviaser 1945). More recently, macroscopic changes including contraction of the coracohumeral ligament within the rotator interval area have been recognised (Ozaki, Nakagawa et al. 1989), as well as thickness and contracture of the inferior aspect of the glenohumeral joint capsule (Wiley 1991) and axillary pouch (Connell, Padmanabhan et al. 2002). The rotator interval area which contains the coracohumeral ligament is now generally recognised as the predominant site involved in adhesive capsulitis (Ozaki, Nakagawa et al. 1989; Wiley 1991; Omari and Bunker 2001; Uhthoff and Boileau 2006). As will be outlined in more detail in Chapter 4, radiological investigation has reported differences in the dimensions of this area suggesting contracture (Omari and Bunker 2001; Kim, Rhee et al. 2009). Loss of joint volume has also been identified as a characteristic of the later stages of the disorder (Bunker 2009) also suggesting capsular contraction, and arthroscopic scrutiny of the glenohumeral joint has identified synovitis and histological findings consistent with inflammation (Neviaser 1980; Neviaser and Neviaser 1987; Hannafin and Chiaia 2000; Watson, Dalziel et al. 2000; Neviaser and Hannafin 2010)(Figure 2.3). Focal vascularity and increased papillary growth (angiogenesis), rather than synovitis, have also been reported (Wiley 1991; Bunker and Anthony 1995). Nonetheless, at least in the early stage of the disorder, it would appear that

inflammation is present, given the reported pain at this stage (Hannafin and Chiaia 2000) and the positive short term effect of corticosteroid injections (Bulgen, Binder et al. 1984; van der Windt, Koes et al. 1998; Arslan and Celiker 2001; Carette, Moffet et al. 2003; Ryans, Montgomery et al. 2005; Buchbinder, Green et al. 2009).

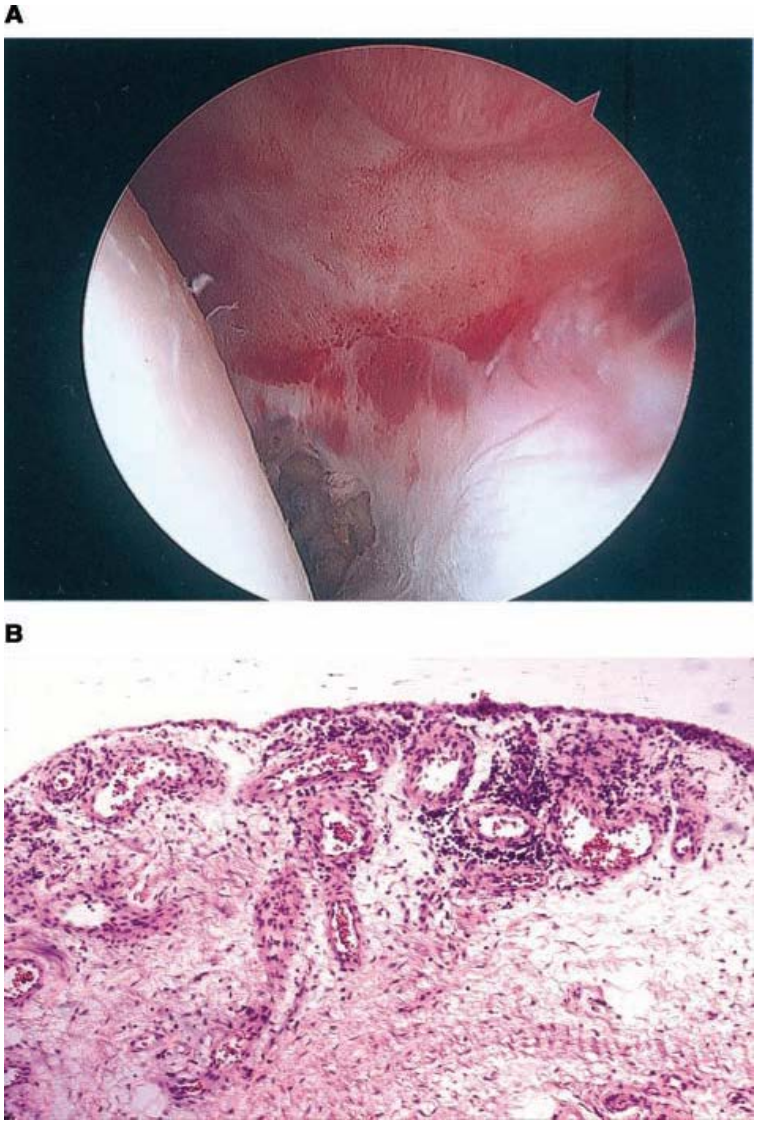

Figure 2.3 A. Fibrous synovial inflammatory reaction. B. Histologic findings of early stage adhesive capsulitis

Note: Histological findings demonstrate rare inflammatory cell infiltrate; hypervascular, hypertropic synovitis; and normal capsular tissue.

Image reproduced with permission from SAGE Publications Inc (Neviaser and Hannafin 2010)

Histological and immunochemical scrutiny of glenohumeral capsular tissue has demonstrated vascular, collagenous tissue comprised mainly of fibroblasts and myofibroblasts similar to that identified in Dupytren's disease (Bunker and Anthony 1995). Evidence of neovascularisation has also been reported (Bunker and Anthony 1995; Ryu, Kirpalani et al. 2006; Hand, Athanasou et al. 2007). Further evidence of an inflammatory process is the presence of elevated cytokine levels, including transforming growth factor (TGF) ß, platelet-derived growth factor (PDGF), interleukin-1ß, tumour necrosis factor α and hepatocyte growth factor (Rodeo, Hannafin et al. 1997; Bunker, Reilly et al. 2000). These cytokines have been suggested to be involved in the mechanism of sustained inflammation and fibrosis and have been previously demonstrated to increase fibroblast activity in other musculoskeletal disorders (Gharaee-Kermani and Phan 2001). Although it is unknown what triggers these elevated cytokine levels, it has been suggested that minor trauma may be responsible for the initial inflammation which may subsequently lead to the accumulation of fibroblasts and release of type I and type III collagen in adhesive capsulitis (Bunker, Reilly et al. 2000). It has been suggested (Bunker, Reilly et al. 2000) that an imbalance between the aggressive fibrosis and an inability for the collagen to remodel may result in stiffening of the glenohumeral joint capsule and associated ligaments.

In summary, the pathology of adhesive capsulitis has recently become more clearly understood as a progressive process of initial inflammation followed by fibrosis. This

has provided an explanation for the differing clinical presentations at each stage of the disorder.

2.5 Risk factors

A number of risk factors have been described for adhesive capsulitis and some of these may have links to the current understanding of pathophysiology of the disorder, and thus may facilitate recognition. The most frequently reported risk factors include diabetes (Bridgeman 1972; Thomas, McDougall et al. 2007; Tighe and Oakley 2008), Dupytren's disease (Smith, Devaraj et al. 2001) and thyroid disease (Cakir, Samanci et al. 2003) as well as female gender (Binder, Bulgen et al. 1984; Sheridan and Hannafin 2006). A genetic predisposition for adhesive capsulitis has also been suggested but is yet to be verified in large studies (Hakim, Cherkas et al. 2003). Less frequently reported risk factors include hyperlipidemia (Bunker and Esler 1995; Hand, Clipsham et al. 2008), Parkinson's disease (Riley, Lang et al. 1989) and cardiac disease (Boyle-Walker, Gabbard et al. 1997), Whilst there may be some evidence for the various reported factors listed above, diabetes and Dupytren's disease have recently been suggested as the only two that withstand robust scrutiny (Bunker 2009). As risk factors have the potential to influence diagnosis, a brief outline of those more commonly reported is presented.

2.5.1 Diabetes

Both insulin and non-insulin dependent diabetes mellitus have been strongly linked to adhesive capsulitis, with the incidence in diabetics reported to be two to four times

higher than in the normal population (Hannafin and Chiaia 2000; Milgrom, Novack et al. 2008). The pathological basis for the strong association of this systemic disorder with adhesive capsulitis has been suggested to be linked to microvascular disease and abnormalities of collagen repair (Stam 1994). It has been reported that diabetic patients with adhesive capsulitis follow a more protracted course and tend be more resistant to various treatment options (Ogilvie-Harris and Myerthall 1977; Shaffer, Tibone et al. 1992; Massoud, Pearce et al. 2002). Clinical differences observed in diabetic patients, in contrast to non-diabetic patients, include a younger age group and increased frequency of bilateral involvement (Stam 1994).

The number of people with diabetes is increasing globally due to population growth, aging, urbanization, and the increasing prevalence of obesity (Wild, Roglic et al. 2004). It has been suggested that if age-specific prevalence remains constant, the number of people with diabetes in the world is expected to double between 2000 and 2030 (Wild, Roglic et al. 2004). It may therefore be expected that the prevalence of adhesive capsulitis may similarly increase. It has been proposed patients diagnosed with adhesive capsulitis should be evaluated for the presence of a diabetic condition as its effect on management and prognosis is marked (Tighe and Oakley 2008).

2.5.2 Dupytren's disease

The association between Dupytren's disease and adhesive capsulitis was first recognised in 1936 (Smith, Devaraj et al. 2001). Since that time the association has been explored further (Lundberg 1969; Bunker and Anthony 1995; Smith, Devaraj et al. 2001). Although the aetiology of Dupytren's disease and adhesive capsulitis remain

unknown, there are a number of similarities between the two disorders. Histologically both demonstrate dense type III collagen in nodules and bands, as well as a comparable distribution of fibroblasts and myofibroblasts (Lundberg 1969; Bunker and Anthony 1995). From a clinical perspective, it has been noted that both adhesive capsulitis and Dupytren's disease may follow trauma and progress towards joint contracture (Smith, Devaraj et al. 2001). Further, both diabetes and hyperlipidemia are metabolic conditions that have been reported to have a significantly increased incidence in patients with Dupytren's disease and adhesive capsulitis (Bunker and Esler 1995).

Interestingly, despite the pathological links between the two diseases, the clinical course differs, with adhesive capsulitis reported to resolve over time, whilst Dupytren's disease is progressive (Smith, Devaraj et al. 2001). However, as discussed earlier, the natural history of adhesive capsulitis may not in fact be towards full resolution.

2.5.3 Thyroid dysfunction

Previous studies have reported a link between thyroid dysfunction and adhesive capsulitis (Cakir, Samanci et al. 2003). A recent study has however challenged this association as the prevalence of thyroid disease in patients diagnosed with adhesive capsulitis as well as the control group was 13% (Milgrom, Novack et al. 2008). Whilst the exact pathogenesis of any association has yet to be confirmed, it remains one of the more commonly reported associations (Nash and Hazleman 1989; Gumina, Carbone et al. 2011; Hsu, Anakwenze et al. 2011).

2.5.4 Female gender

Females have been described as having a greater risk of developing adhesive capsulitis than males (Reeves 1975; Binder, Bulgen et al. 1984; Sheridan and Hannafin 2006). Earlier studies reported the ratio of females to males ranged from 8:2 to 6:4 (Wiley 1991; Shaffer, Tibone et al. 1992; Bunker and Anthony 1995). However, the advent of arthroscopic investigation more recently has challenged the historical perspective and suggested that a ratio of 1:1 may be a more accurate representation (Bunker 2009). No causative link has yet been described that may support the reported higher prevalence in the female gender, although it has been proposed that the female 40 to 60 year age group coincides with menopause and possible hormonal influences at that time (Hannafin and Chiaia 2000; Vad and Hannafin 2000).

2.5.5 Genetic factors

A genetic predisposition for adhesive capsulitis remains controversial (Hsu, Anakwenze et al. 2011). A female twin study described that the disorder occurred two to three times more frequently in these individuals than by chance (Hakim, Cherkas et al. 2003). It has been proposed however that this occurrence may be multifactorial with individual specific environmental factors responsible, rather than a common genetic susceptibility (Hakim, Cherkas et al. 2003). Interestingly, Dupytren's disease is also believed to have a genetic basis (Hsu, Anakwenze et al. 2011).

2.6 Clinical evaluation of adhesive capsulitis

Patient reported symptoms and physical examination findings are the cornerstones of diagnosis in musculoskeletal medicine, and recognition of presentation 'patterns' underpins the clinical reasoning process to inform diagnosis and management decisions. Despite this, early diagnosis of adhesive capsulitis is frequently made on the basis of exclusion of other causes of pain and range of movement loss (Sheridan and Hannafin 2006). As it is recognised the pathology of this disorder progresses through stages (Chambler and Carr 2003), it is arguably appropriate to consider the clinical evaluation of each of the stages as differing entities. Accordingly, the commonly reported names of the stages provide an indication of the predominant clinical features, with the first stage often referred to as the 'painful' stage, the second stage the 'adhesive' stage and the third stage the 'resolution' stage. An important consideration is that while some authors identify the stage of adhesive capsulitis in their description of patient characteristics (Kelley, McClure et al. 2009), many diagnostic and treatment studies fail to be specific about the stage involved when describing inclusion criteria for participants. Arguably, the later stages of adhesive capsulitis may be more easily recognised and the early stage may be more difficult to differentiate from other painful shoulder disorders.

2.6.1 Patient reported findings

There are a number of patient reported findings described that may facilitate the diagnosis of early stage primary/idiopathic adhesive capsulitis. Consistent with the early stage being referred to as 'the painful' stage, pain is reportedly the most

predominant feature (Dudkiewicz, Oran et al. 2004). It is described as a gradual onset over the deltoid insertion, with an ache at rest and sharp pain with movement (Hannafin and Chiaia 2000; Sheridan and Hannafin 2006; Neviaser and Hannafin 2010). Night pain, or the inability to sleep due to pain, is also commonly reported as present in the early stage (Bulgen, Binder et al. 1984; Sandor 2000; Vad and Hannafin 2000), together with pain when lying on the affected shoulder (Siegel, Cohen et al. 1999; Vermeulen, Oberman et al. 2000; Le, Sheperd et al. 2004; Hsu, Anakwenze et al. 2011). Pain with rapid or unguarded movement has also been reported (Bunker 2009; Kelley, McClure et al. 2009). These reported characteristics, however, could arguably be applied to other commonly presenting shoulder disorders.

Although a stiff shoulder as a result of major trauma is referred to as secondary adhesive capsulitis, some authors acknowledge that primary or idiopathic adhesive capsulitis may follow a minor trauma (Ogilvie-Harris and Myerthall 1977). Indeed it is considered by some authors that a minor trauma is the precursor to developing the disorder (Ogilvie-Harris and Myerthall 1977). Conversely, it has been suggested that a reported minor traumatic event may merely coincide with the onset of symptoms (Kelley, McClure et al. 2009). Whilst a minor trauma or strain may be common (Nash and Hazleman 1989), a recent study reported minor trauma in only 22% of participants (Hand, Clipsham et al. 2008). Notwithstanding, consideration of minor trauma in the presentation is clinically common, but to date has not been specifically linked to the onset of adhesive capsulitis.

2.6.2 Physical examination findings

Varying descriptions of physical examination findings for adhesive capsulitis have been described (Nash and Hazleman 1989; Harrast and Rao 2004; Lin, Jarmain et al. 2004). Notably however, these findings generally describe the latter stages of the disorder when the restriction of movement is obvious or indeed a prerequisite for diagnosis (van der Windt, Koes et al. 1998). A clinical diagnosis of adhesive capsulitis is generally made if patients demonstrate painful restriction of both active and passive ranges of movement of the shoulder in more than two planes (Buchbinder, Green et al. 2008). However, global loss of range of movement has been noted as the primary factor distinguishing adhesive capsulitis from many of the conditions that may be responsible for secondary adhesive capsulitis (Siegel, Cohen et al. 1999). Despite reported loss of range of movement, there is no consensus regarding the quantification of movement loss required to define adhesive capsulitis (Harrast and Rao 2004).

Whilst there is no single reliable or validated clinical test by which to diagnose adhesive capsulitis, painful limitation of external rotation in neutral abduction (Wolf and Cox 2010) and pain with palpation of the coracoid process (Carbone, Gumina et al. 2009) have both been proposed as pathognomic signs. Pain at the end of range of movement is a further physical examination finding frequently described (Fareed and Gallivan 1989; Nash and Hazleman 1989; Stam 1994; Lin, Jarmain et al. 2004). Notably, validated physical examination findings in the early stage have not been reported to date. It would therefore be useful for early recognition if valid clear signs could be identified.

The 'capsular pattern'

It has been proposed that if a joint capsule is inflamed all or most of the passive movements of that joint will be painful and limited in a recognisable pattern that varies from joint to joint (Cyriax and Cyriax 1993). This 'capsular' pattern for adhesive capsulitis as described by James Cyriax (Cyriax and Cyriax 1993), whereby passive external rotation is proportionally more limited than abduction which is proportionally more limited than internal rotation, is widely regarded as characteristic of the latter stages of adhesive capsulitis (Reeves 1975; Ozaki, Nakagawa et al. 1989; Boyle-Walker, Gabbard et al. 1997). The presence of this pattern in the early stage of the disorder is discussed in more detail in Chapter 6.

2.7 Treatment of adhesive capsulitis

Despite a number of management strategies being investigated, the treatment of adhesive capsulitis remains controversial and studies of interventions have produced variable and often confusing conclusions. An important consideration in drawing conclusions across studies is not only the differing inclusion criteria or definitions of adhesive capsulitis used in research, but also the heterogeneity of the treatment regimes and outcome measures (Kelley, McClure et al. 2009). Nonetheless, numerous management options for adhesive capsulitis have been investigated, including oral steroid medications (Buchbinder, Green et al. 2006) corticosteroid injections (Bulgen, Binder et al. 1984; Rizk, Pinals et al. 1991; van der Windt, Koes et al. 1998; Carette, Moffet et al. 2003; Ryans, Montgomery et al. 2005; Bal, Eksioglu et al. 2008), exercise and physiotherapy (Griggs, Ahn et al. 2000; Green, Buchbinder et al. 2003; Diercks and

Stevens 2004), capsular distension (Quraishi, Johnston et al. 2007), manipulation under anaesthetic (Dodenhoff, Levy et al. 2000; Farrell, Sperling et al. 2005; Kivimaki, Pohjolainen et al. 2007), and arthroscopic and open capsular release (Ozaki, Nakagawa et al. 1989; Omari and Bunker 2001).

Treatment of musculoskeletal conditions is traditionally directed at the underlying pathology and this has been considered the case for adhesive capsulitis. (Neviaser and Hannafin 2010). More recently the suggestion that rotator cuff tendinopathy/sub acromial impingement syndrome should be assessed and managed by modifying the symptoms has however been proposed (Lewis 2009) and this may be considered for adhesive capsulitis in the future. Importantly however, it has become increasingly recognised that treatment needs to be tailored to the stage of adhesive capsulitis to optimize results (Neviaser and Hannafin 2010). Despite this, that few intervention studies report the duration of the symptoms or stage of the disorder as a variable, thus confounding the interpretation of outcomes and making comparison across studies difficult (Sheridan and Hannafin 2006; Neviaser and Hannafin 2010). It has recently been suggested that up to 90% of patients with adhesive capsulitis may be successfully managed conservatively (Levine, Kashyap et al. 2007) but that arguably correct identification is necessary. The lack of uniformity in the labelling of shoulder disorders has been highlighted in several systematic reviews (Green, Buchbinder et al. 1998; Buchbinder, Green et al. 2003; Blanchard, Barr et al. 2010) and a criticism of many studies of treatment effect is that both painful and stiff shoulders or both secondary

and primary capsulitis cases have been grouped together which may have influenced outcomes (Bunker 2009).

In conclusion, inconsistent labelling, heterogeneous samples and ill defined duration and quantification of symptoms have resulted in confusion determining appropriate management strategies. The need to establish a validated set of diagnostic criteria/clinical identifiers that are stage specific for adhesive capsulitis is highlighted by a review of current treatment options.

2.7.1 Early treatment

It is necessary to acknowledge that adhesive capsulitis is comprised of stages with different pathophysiological characteristics, when considering appropriate management strategies. With the growing understanding of the pathology and recognition of the early inflammatory component of adhesive capsulitis, there is increasing evidence that intra-articular corticosteroid injections may be of benefit in the early stage (Hazleman 1972; Sheridan and Hannafin 2006; Neviaser and Hannafin 2010). It has been suggested that this management in the early, inflammatory stage would be most effective as opposed to when fibrous contracture is more apparent (Blanchard, Barr et al. 2010). Further, treatment in the early stage has been proposed to minimise the overall morbidity of the disorder (Hazleman 1972; Hannafin and Chiaia 2000). However in order for this treatment to be appropriately administered, correct identification of adhesive capsulitis in its early stage is essential. Indeed, a recent systematic review on the effectiveness of corticosteroid injections compared with physiotherapeutic interventions reported that in the short term, injections are superior

(Blanchard, Barr et al. 2010). Notably this review highlighted that certain treatments would be more effective depending on the stage of the disorder but that none of the reported studies identified this as a consideration in interpretation of the results.

The role of corticosteroid injections to reduce pain and allow an increase in shoulder range of movement has not only been suggested as useful in the treatment of adhesive capsulitis, but has also been suggested to contribute to differential diagnosis in confusing presentations of shoulder pain (Sheridan and Hannafin 2006).

2.8 Diagnosis of shoulder disorders

Diagnostic labels have been traditionally used both in the musculoskeletal clinical setting to inform patient management, as well as in research to identify homogeneous study populations. These labels are typically based on a set of patient reported symptoms and physical examination findings or identifiable pathophysiologic characteristics (Binkley, Finch et al. 1993). Labels applied to shoulder disorders may describe symptoms such as 'stiff and painful shoulder' or 'painful arc syndrome', whilst others have a more pathophysiological origin eg. 'bursitis', 'adhesive capsulitis' or 'supraspinatus tendinopathy'. However the absence of a consistent set of diagnostic criteria or clinical identifiers, frequently results in a variety of names being applied to a particular disorder, many of which have multiple meanings (Buchbinder, Goel et al. 1996). As noted earlier, adhesive capsulitis may be referred to as 'peri-arthritis', 'frozen shoulder', 'painful stiff shoulder' and more recently 'contracture of the shoulder' (Bunker 2009), resulting in confusion in the identification of this disorder. Indeed this

lack of uniformity in defining shoulder disorders in general, including adhesive capsulitis, has been highlighted in a systematic review of interventions for shoulder pain where conflicting criteria often defined the same condition in different trials (Green, Buchbinder et al. 1998). Clearly these inconsistencies result in difficulty in determining appropriate management strategies, as well as drawing conclusions across studies.

Musculoskeletal assessment by physiotherapists aims to gather information to determine appropriate treatment and prognosis, rather than simply applying a diagnostic label (van der Heijden 1999). Identifying sets of diagnostic criteria or clinical identifiers may not represent a single pathological entity, but it could identify a sub-group of patients who may benefit from a particular management strategy, as well as ensure consistency of participants in randomised clinical trials. Whilst some authors consider the specific localisation of the anatomical origin of a lesion is essential for effective treatment (Green, Buchbinder et al. 1998), others note the difficulty in identifying a source of shoulder pain (Larson, O'Connor et al. 1996; de Winter, Jans et al. 1999). Interestingly, despite the large number of clinical tests currently used for the examination of the shoulder, acceptable reliability and validity has not been established for any of these tests (Hegedus, Goode et al. 2007; Green, Shanley et al. 2008; May, Chance-Larsen et al. 2010). This may suggest that determining identifiable sets of clinical characteristics, or sub-groups of patients, may be a better approach to diagnosis and management.

The importance of diagnostic sub-grouping is being recognised in musculoskeletal physiotherapy in recent years to help address the limitations of randomised clinical trials that lack evidence for particular interventions. As a means of addressing the challenge of heterogeneity of patient presentation, sub-grouping patients with prescribed criteria has been proposed to achieve improved, consistent and predictable treatment outcomes (Jull 2012). To date, such classification systems for low back pain have been reported in the physiotherapy literature and this potential application to neck pain has been discussed (Jull 2012). Similarly, it has been suggested that the identification of sub-groups of shoulder pain based on common clinical characteristics that are easily and reliably reproduced would be a more effective strategy to determine prognosis or treatment outcomes than the use of diagnostic labels (Schellingerhout, Verhagen et al. 2008; May, Chance-Larsen et al. 2010). Correct diagnosis through history and physical examination (thereby leading to appropriate treatment) has been highlighted previously in a study of inter observer agreement on the diagnostic classification of shoulder disorders (de Winter, Jans et al. 1999).

2.8.1 Diagnosis of adhesive capsulitis

It has been recently proposed that the confusion over the definition of adhesive capsulitis has been reflected in the poor understanding of not only the aetiology, but also the diagnosis and management of this disorder (Hsu, Anakwenze et al. 2011) as well as a complication of treatment choices (Mitchell, Adebajo et al. 2005). Notably, a recent review of 21 randomised clinical trials failed to derive a consistent description of the disorder (Schellingerhout, Verhagen et al. 2008). Published literature has described

inconsistent nomenclature and diagnostic criteria for adhesive capsulitis, and there is minimal consensus regarding the specific symptoms or range of motion restrictions (Pearsall and Speer 1998). A specific criticism of many reported studies of adhesive capsulitis is that they may have included participants with shoulder disorders other than adhesive capsulitis (Bunker 2009). It has been suggested that greater care needs to be exercised in the use of the term adhesive capsulitis which is over used, often incorrectly, and that adhesive capsulitis needs to be recognised as a separate pathological entity (Neviaser and Neviaser 1987). However adhesive capsulitis does not have a single, agreed diagnostic reference standard (Wolf and Cox 2010), making identification difficult. Observational studies (Rundquist, Anderson et al. 2003; Rundquist and Ludewig 2004), cadaveric investigations (Harryman, Sidles et al. 1992) and expert opinion (Bunker 2009; Hanchard, Goodchild et al. 2011) have proposed that restriction of external rotation is the most recognisable characteristic, although this remains to be validated. It is apparent that there is not currently a set of validated diagnostic criteria or clinical identifiers for adhesive capsulitis. As this disorder consists of stages, arguably each of these stages, should have criteria specific to it.

The most common causes of shoulder pain and loss of movement are reportedly rotator cuff disease and adhesive capsulitis. These two disorders may present similarly, thereby resulting in a diagnostic dilemma which is important because the appropriate management of these disorders is quite different (Lin, Jarmain et al. 2004). It has been widely reported that adhesive capsulitis, particularly in its early stage, may be difficult to differentiate from other commonly presenting shoulder disorders (Manske and

Prohaska 2008; Kelley, McClure et al. 2009). Moreover, adhesive capsulitis is often regarded as a diagnosis of exclusion, when other disorders have been ruled out (Fareed and Gallivan 1989). Recognition that a number of disorders affecting the shoulder may result in a stiff and painful shoulder is essential to an understanding of adhesive capsulitis because throughout the literature adhesive capsulitis is often confused with or at least not well differentiated from these other disorders (Neviaser 1987; Watson and Dalziel 1993). In particular, other shoulder disorders including calcific tendonitis, rotator cuff tears and tendonitis, bicipital tendonitis and glenohumeral arthrosis may mimic adhesive capsulitis and result in a stiff and painful shoulder. The need for correct diagnosis has been suggested because of the differing treatment approaches needed for these other diagnoses (Neviaser and Neviaser 1987; Hsu, Anakwenze et al. 2011).

In subjects suspected of having adhesive capsulitis, injection of local anaesthetic into the glenohumeral joint has been used to demonstrate a decrease in pain and muscle guarding resulting in an increase in range of motion (Baslund, Thomsen et al. 1990; Sheridan and Hannafin 2006; Marx, Malizia et al. 2007). In particular, pain relief in the early stage has been described as a means of confirming diagnosis. As well as potentially confirming a diagnosis of adhesive capsulitis, local anaesthetic has also been recommended to eliminate other sources of pain and movement loss including disorders of the rotator cuff, thereby facilitating diagnosis (Baslund, Thomsen et al. 1990). However this is not a readily available diagnostic tool in the physiotherapy clinical setting.

Importantly, because of the difficulty in diagnosis and the lack of a single clinical test or investigation distinguishing primary/idiopathic adhesive capsulitis from other causes of shoulder pain and stiffness, practitioners must rely on salient aspects of the patient reported and physical examination findings (Lin, Jarmain et al. 2004; Neviaser and Hannafin 2010). As adhesive capsulitis comprises a continuum of stages with differing pathological processes at each stage, arguably there is a need to determine a set of diagnostic criteria/clinical identifiers based on patient reported and physical examination findings for each stage, and this thesis will address this issue for the early stage where diagnosis is the most difficult.

2.9 Summary

Adhesive capsulitis is a commonly occurring shoulder disorder that remains inconsistently defined and poorly recognised, particularly in its early stage. This chapter has reviewed the current evidence regarding adhesive capsulitis with respect to epidemiology, classification and clinical presentation in order to provide a rationale for the studies that comprise this thesis. It has highlighted the need to better recognise the stages of the disorder when considering diagnosis. The rationale for early recognition to facilitate effective treatment has also been presented.

This thesis aims to address the lack of a defined set of diagnostic criteria or clinical identifiers for early stage adhesive capsulitis. Determining a set of criteria may not only assist clinicians to appropriately direct management, but will also facilitate identification of homogeneous samples to be included in future research and enable

meaningful conclusions to be drawn across studies. The review highlights that no previous studies have been conducted to establish diagnostic criteria or clinical identifiers for the early stage of adhesive capsulitis. Not only is a clear set of diagnostic criteria for early or indeed any stage of adhesive capsulitis currently unavailable, but notably any proposed criteria are yet to be validated and importantly do not adequately consider the stages of the disorder.

The following chapter describes the first study that was conducted in order to determine the consensus of a group of experts on a set of diagnostic criteria/clinical identifiers for early stage adhesive capsulitis. This study was the first step in the process of determining a set of diagnostic criteria or clinical identifiers for the early stage of adhesive capsulitis.

Chapter 3 Adhesive capsulitis: establishing consensus on clinical identifiers for stage one using the Delphi technique

This chapter has been published in a peer-reviewed scientific journal:

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The work presented in this manuscript was completed in collaboration with the co-authors (Appendix 1). The ethics approval and supporting documents for the study reported in this chapter appear in Appendix 2.

Overview

As the overall aim of this thesis was to establish diagnostic criteria or clinical identifiers for the early stage of adhesive capsulitis, it was determined that gathering the opinion of experts would be an appropriate first step. Where there is a lack of empirical evidence on diagnosis of musculoskeletal disorders, previous studies have utilised the Delphi technique to achieve a similar aim. This technique is a means for systematically collecting the opinion of a selected group of experts on a particular topic, and as such was determined a suitable methodology for the first study. This chapter describes the correspondence based Delphi study that was conducted as the initial step to gather the opinion of experts on a set of diagnostic criteria or clinical identifiers for the early stage of adhesive capsulitis. The published paper that constitutes this chapter is preceded by

a more detailed explanation of the Delphi technique, its advantages and disadvantages and previous applications in determining diagnostic criteria or clinical identifiers.

3.1 The Delphi technique

The Delphi technique takes its name from the Greek oracle Apollo at Delphi who was renowned for his ability to be able to forecast future events (Baretta 1996). Developed and named by the Rand Corporation in the 1950s to assist the decision making process, though minimise the effect of personal interaction, the technique has recently gained popularity in a number of settings including the health sciences. The Delphi technique is considered an established and recognised method of deriving expert opinion to determine the degree of consensus on a given topic (Powell 2003; Brown, O'Connor et al. 2005). It is useful in situations where a lack of agreement or incomplete state of knowledge may exist (Powell 2003). The Delphi technique is a multi-stage process that uses a panel of experts and a series of sequential questionnaires or rounds linked by feedback to achieve consensus by the final round. Each round builds on the results of the previous round to achieve consensus. The first round is generally idea generation with the subsequent rounds providing feedback to participants to achieve increasing consensus of opinion. The feedback may be in the form of exclusion or inclusion of items or alternatively ranking items on a scale. The Delphi technique has been used in a variety of forms and may commence with an open-ended set of questions designed to generate ideas or start with a small focus group that generates the initial questionnaire. Examples of its use include developing practice guidelines and clinical protocols, policy making, curriculum development and definition of professional roles, as well as

establishing diagnostic criteria or clinical identifiers (Graham, Regeher et al. 2003; Cook, Brismee et al. 2005; Cook, Brismee et al. 2006).

3.1.1 Advantages and disadvantages

Selection of the Delphi technique requires consideration of its advantages and disadvantages and its applicability to the situation at hand. The Delphi technique has been highlighted as having a number of advantages that make it attractive to researchers where the opinion of experts is required. Maintaining anonymity amongst respondents, allowing time for participants to consider their response, not being influenced by dominant individuals and enabling recruitment from diverse geographical locations and clinical backgrounds are some of the advantages that have been described (McKenna 1994; Sumsion 1998). The need for participants not to meet face to face avoids personality influences and the possibility of domination of an influential or more senior individual.

Whilst there are many advantages of the Delphi technique, several authors have questioned the reliability of the results obtained (Baretta 1996; Hasson, Keeney et al. 2000; Keeney, Hasson et al. 2001; Ferguson, Davis et al. 2005). Further, the technique has also received criticism for the potential lack of panellist accountability and responsibility, as well as the loss of the dynamics that may be achieved in a face-to-face situation (Ferguson, Davis et al. 2005). Panellists potentially being limited in their ability to elaborate on their thoughts in this structured setting has also been suggested as a weakness of the technique (Walker and Selfe 1996). Whilst the Delphi technique aims to achieve consensus on a given topic, it has been stated that the existence of

consensus does not mean that the correct answer has been found (Keeney, Hasson et al. 2001). Nevertheless, it has been suggested that the reliability of the group judgment will increase in consensus techniques with a larger group of participants (Black, Murphy et al. 1999). The potential for a high attrition rate with successive rounds and the reliance on high participant motivation have also been proposed as further disadvantages (Baretta 1996; Cleary 2000) as well as researcher bias in interpretation of the responses (Sumsion 1998; Cleary 2000).

3.1.2 Use in establishing diagnostic criteria/clinical identifiers

In the absence of a gold standard for diagnosis it has been proposed that formal consensus techniques including the Delphi technique may be useful in reducing bias and minimising the judgmental approach frequently necessary to develop diagnostic criteria or clinical identifiers (Ferguson, Davis et al. 2005). This technique has been widely used in establishing consensus on various diagnostic descriptors and clinical identifiers, including cervical and lumbar spine instability (Cook, Brismee et al. 2005; Cook, Brismee et al. 2006), the development of a diagnostic classification of low back pain (Binkley, Finch et al. 1993), carpal tunnel syndrome (Graham, Regeher et al. 2003) and zygapophyseal joint pain (Wilde, Ford et al. 2007).

In summary, the Delphi technique is a consensus method that has been used with increasing frequency in healthcare research. It brings together expert opinion of a diverse group of people and it is possible to include participants over a wide geographical area. Selection of the technique requires consideration of its advantages

and disadvantages for each given situation, and the interpretation is strengthened with the use of rigorous statistical analysis.

3.2 Abstract

Background: Adhesive capsulitis is often both difficult to diagnose in its early stage and to differentiate from other commonly presenting shoulder disorders with the potential to cause pain and limited range of movement.

Objectives: the purpose of this study was to establish consensus among a group of experts regarding the clinical identifiers for the first or early stage of primary (idiopathic) adhesive capsulitis.

Design: A correspondence based Delphi technique was used in this study

Methods: Three sequential questionnaires, each building on the results of the previous round, were used to establish consensus.

Results: A total of 70 experts from Australia and New Zealand involved in the diagnosis and treatment of adhesive capsulitis completed the three rounds of questionnaires. Following round three, descriptive statistics were used to screen the data into a meaningful subset. Cronbach alpha and factor analysis were then used to determine agreement among the experts. Consensus was achieved on eight clinical identifiers. These identifiers clustered into two discrete domains of pain and movement. For pain, the clinical identifiers were a strong component of night pain, pain with rapid or unguarded movement, discomfort lying on the affected shoulder,

and pain easily aggravated by movement. For movement, clinical identifiers included a global loss of active and passive range of movement, with pain at the end of range in all directions. Onset of the disorder was at greater than 35 years of age.

Conclusion: This is the first study to use the Delphi technique to establish clinical identifiers indicative of the early stage of primary (idiopathic) adhesive capsulitis. Although limited in differential diagnostic ability, these identifiers may assist the clinician in recognizing early stage adhesive capsulitis and may inform management, as well as facilitate future research.

3.3 Introduction

Adhesive capsulitis of the shoulder is a disorder frequently encountered by primary health care professionals. It is often difficult to identify and correctly diagnose in its early stage. Labelled 'frozen shoulder' by Codman in 1934 (Codman 1934) but subsequently termed adhesive capsulitis by Neviaser (Neviaser 1945) to better describe the pathology, this condition is generally characterised by pain and a gradual progressive loss of shoulder active and passive range of motion (Pearsall and Speer 1998). It has been reported that its prevalence is 2% to 3% in the general population (Pearsall and Speer 1998; Siegel, Cohen et al. 1999; Hannafin and Chiaia 2000). This figure is higher in the diabetic population (Scarlat, Goldberg et al. 2000) with a prevalence of 30% reported in patients with type 2 diabetes mellitus (Aydogan, Karan et al. 2003/2004). It is also reported to be more common in women, especially between the ages of 40-60 years (Neviaser and Neviaser 1987; Pearsall and Speer 1998; Siegel,

Cohen et al. 1999; Dias, Cutts et al. 2005). The condition usually very slowly progresses towards spontaneous resolution; however several long term studies suggest ongoing impairment may persist in some patients (Reeves 1975; Binder, Bulgen et al. 1984; Shaffer, Tibone et al. 1992; Vecchio, Kavanagh et al. 1995; Hand, Clipsham et al. 2008).

Adhesive capsulitis is described as being either primary or secondary (Reeves 1975; Chambler and Carr 2003; Harrast and Rao 2004). Primary adhesive capsulitis is due to an unknown cause (i.e. it is idiopathic), whereas secondary adhesive capsulitis results from a known cause or surgical event (Hannafin and Chiaia 2000). Published descriptions of the condition commonly further subdivide it into three or four stages. Following arthroscopic evaluation, Neviaser and Neviaser (Neviaser and Neviaser 1987) identified four stages of involvement. These four stages have been correlated with clinical examination findings and histological appearance of the tissues (Hannafin and Chiaia 2000). The more recent literature however, generally describes adhesive capsulitis as consisting of three stages (Pearsall and Speer 1998; Siegel, Cohen et al. 1999; Chambler and Carr 2003). These stages have been identified as the painful stage (first), adhesive stage (second) and resolution stage (third). The painful stage in this nomenclature includes both stage one (the pre-adhesive stage) and stage two as described by Neviaser and Neviaser (Neviaser and Neviaser 1987). The current study was concerned with identifying primary adhesive capsulitis and the painful or first stage of the condition.

Although 'textbook' descriptions of diagnostic criteria for adhesive capsulitis including variable pain and movement characteristics, are present in the literature, validation of

these descriptions is lacking. Currently the diagnosis of primary adhesive capsulitis is based on the findings of the patient history and physical examination. No specific clinical test or definitive investigation has been reported in the literature, and there remains no gold standard to diagnose this disorder. A varying range of 'typical' signs and symptoms such as pain aggravated by shoulder movement (Siegel, Cohen et al. 1999; Hannafin and Chiaia 2000), pain at night (Neviaser and Neviaser 1987) and multi-directional limitation of active and passive joint movement accompanied by pain at the extremes of range (Pearsall and Speer 1998) have been proposed instead. To date, however, there are no agreed upon or validated diagnostic criteria for the disorder.

The lack of validity and reliability of the diagnostic classification of shoulder pain has been a topic of controversy for some time (Buchbinder, Goel et al. 1996; Winters, Groenier et al. 1997; de Winter, Jans et al. 1999; Groeiner, Winters et al. 2003; Walker-Bone, Palmer et al. 2003; Schellingerhout, Verhagen et al. 2008). In a study of inter-observer agreement between general practitioners and physical therapists this deficit has been particularly highlighted (Liesdek, van der Windt et al. 1997). However, the need for diagnostic labels for shoulder disorders has been questioned as there is some evidence that the outcomes of treatment may be similar for heterogeneous groups of patients with shoulder pain lacking a specific diagnosis (Ginn, Herbert et al. 1997; Hay, Thomas et al. 2003; Ginn and Cohen 2004; Thomas, van der Windt et al. 2005). Conversely other authors suggest that a uniform method of defining shoulder disorders is necessary (Green, Buchbinder et al. 1998; Buchbinder, Green et al. 2006). In a systematic review of randomised controlled trials of interventions for the painful

shoulder, the authors commented that, in the studies sampled, no standard diagnostic definitions were used and indeed conflicting criteria were used to define the same condition in various trials (Green, Buchbinder et al. 1998). These limitations make drawing conclusions across studies difficult. Although a set of diagnostic criteria may not exclusively represent a single pathological entity, it may represent a subgroup of patients to which randomised controlled trials may be directed.

Similarly, early and accurate identification of diagnostic criteria is recommended in determining prognosis as well as for optimizing treatment outcomes in the clinic (van der Heijden 1999). Early presentation of shoulder disorders has been associated with favourable outcome (Bulgen, Binder et al. 1984). Some authors, recommend that treatment and prognosis for adhesive capsulitis should be tailored to the stage of the disorder (Neviaser and Neviaser 1987; Hannafin and Chiaia 2000). Consequently, it is arguably appropriate to establish diagnostic criteria for each stage rather than the disease process as a whole.

The difficulty faced by clinicians in the diagnosis of shoulder disorders has recently been addressed by Mitchell and colleagues (Mitchell, Adebajo et al. 2005). They proposed a simple model to assist in the diagnosis of rotator cuff, glenohumeral and acromioclavicular joint disorders, as well as referred cervical spine pain. Although potentially facilitating aspects of the clinical reasoning process, this model fails to recognise the various stages of adhesive capsulitis. Agreed upon diagnostic criteria for early stage adhesive capsulitis therefore remain to be established.

The aim of this study was to reveal such consensus that may currently exist among a group of experts regarding the clinical signs and symptoms indicative of the first stage of primary adhesive capsulitis. The establishment of such consensus is the first step in the process of identification and validation of agreed upon diagnostic criteria for this disorder.

3.4 Method

The Delphi technique was chosen to explore this issue as it is an established and recognised method of deriving the opinion of experts to determine the degree of consensus where there is a lack of empirical evidence (Powell 2003; Brown, O'Connor et al. 2005). This technique has the advantages of maintaining anonymity amongst respondents, allowing time for participants to consider their response, not being influenced by dominant individuals and enabling recruitment from diverse geographical locations and clinical backgrounds (McKenna 1994; Sumsion 1998). Using a panel of experts, the Delphi technique is a multi-stage process using a series of sequential questionnaires or rounds linked by feedback. Each round of the process builds on the results of the previous one and results in consensus by the final round. This technique has been widely used in establishing consensus on various diagnostic descriptors and clinical identifiers (Graham, Regeher et al. 2003; Cook, Brismee et al. 2005; Ferguson, Davis et al. 2005; Cook, Brismee et al. 2006; McCarthy, Rushton et al. 2006; Wilde, Ford et al. 2007).

3.4.1 Participants

The participants were a group of experts involved in the diagnosis and treatment of adhesive capsulitis and were recruited from several disciplines. These disciplines included rehabilitation medicine, physical medicine, orthopaedic surgery, physical therapy, chiropractic and osteopathy. Medical practitioners invited to participate in the study were required to hold postgraduate qualifications in a relevant specialty or be members of a special interest group in a discipline relevant to the study. Rehabilitation medicine physicians were recruited from the Musculoskeletal Medicine and Pain Special Interest Group, a sub-group of the Australasian Faculty of Rehabilitation Medicine. Members of the Australasian Faculty of Musculoskeletal Medicine were also included, as were Members of the College of Physical Medicine. As a special interest group of the Australian Orthopaedic Association, members of the Shoulder and Elbow Society of Australia were approached. Physical therapist participants were members of Shoulder and Elbow Physiotherapists Australia (a physical therapy sub-group of the Shoulder and Elbow Society of Australia), as well as coordinators of postgraduate musculoskeletal physical therapy programs at Australian and New Zealand universities. In addition, specialist musculoskeletal physical therapists recognized by the Australian Physiotherapy Association and the Australian College of Physiotherapists were included. Australian and New Zealand authors who had published on the topic of adhesive capsulitis in peer reviewed journals or texts in the past ten years also were invited to participate. These potential participants were identified through searching Medline and CINAHL databases using the search terms

'adhesive capsulitis' and 'frozen shoulder'. Only articles published in the English language between February 1996 and February 2006 were identified. The reference lists of identified articles were also scrutinised in an attempt to identify any texts or other references that may have been published during this period. Where contact details indicated the authors were located in Australia or New Zealand, these individuals were included in the expert group. Finally, chiropractors and osteopaths who were coordinators of postgraduate musculoskeletal programs offered at Australian and New Zealand universities were approached. A total of 185 potential participants were contacted in the first round.

3.4.2 Pilot Study

A pilot study, using a sample of convenience comprising six participants representative of the overall sample, was performed prior to the commencement of the main study to determine if the instructions to participants were clear and to identify any improvements to the method. Following the pilot study, it was determined that two reminders should be issued to non-responding participants to maximise the response rate. It was also determined that documents should be highlighted to more clearly indicate that it was stage one of adhesive capsulitis being investigated, not the later, more easily recognisable stages.

3.4.3 Procedure

The study was correspondence based, and the questionnaires were distributed by the researchers to the participants' work addresses. Addresses were obtained from the appropriate organisations and all contact details were available in the public domain

with the exception of the rehabilitation medicine physicians whose members were approached through the chairperson of the Musculoskeletal Medicine and Pain Special Interest Group. In this case, the letter of invitation was sent to the chairperson of the group requesting it be forwarded to members. Those members who were potentially interested in participating asked to contact the researchers directly. Members of the Faculty of Musculoskeletal Medicine were also approached through the chairperson of the Faculty, who provided names and contact details of members. All of the participants who were clinicians were approached at their private clinics.

Experts were asked to participate in three rounds of questionnaires. For the first round, potential participants were posted a letter of invitation together with the first questionnaire, and were given two weeks to reply. Participants were given the opportunity to receive the subsequent questionnaires electronically and to supply a contact telephone number. A reminder was sent if a response was not received in the specified time, and if necessary, a second reminder was issued after a further two weeks. The same approach and timeframe for reminders was used for the two subsequent rounds. Telephone contact was used in the second and third rounds for the second reminder if a telephone number was made available by the participant.

3.4.4 Round 1

The first questionnaire requested participants to list as many or as few diagnostic criteria they considered necessary and sufficient to diagnose stage one primary adhesive capsulitis. Respondents were given the opportunity to provide a rationale for their criteria if they felt this appropriate. The responses were independently reviewed

and collated by each of the three researchers using a series of operational rules. These rules involved listing all the criteria (individual responses) proposed, grouping the criteria into relevant clinical categories, eliminating single responses, merging repeated responses and discarding unclear responses. Responses clearly inconsistent with the literature or responses obviously relating to secondary adhesive capsulitis or the later stages of the target disorder were also discarded. Following initial independent review the researchers met and reached a consensus on the criteria to constitute the second round.

3.4.5 Round 2

The second round used the criteria identified in round one by all participants. In this round, participants were asked to score the importance of each criterion in the diagnosis of stage one adhesive capsulitis using the following five point Likert scale adapted from Cook et al.(Cook, Brismee et al. 2006).

1. *Strongly Agree:* the selected criterion is extremely important in the diagnosis of stage one of primary adhesive capsulitis
2. *Agree:* the selected criterion is important in the diagnosis of stage one of primary adhesive capsulitis
3. *Undecided:* uncertainty of the importance of the selected criterion in the diagnosis of stage one of primary adhesive capsulitis
4. *Disagree:* the selected criterion is not important in the diagnosis of stage one of primary adhesive capsulitis

5. *Strongly Disagree:* there is absolutely no importance whatsoever of the selected criterion in the diagnosis of stage one of primary adhesive capsulitis.

3.4.6 Round 3

The third round provided feedback to the participants in the form of the percentages for each of the five response options as to how all participants rated each criterion in round two. In the light of this information, participants were requested to rescore each criterion on the same Likert scale used in round two.

3.4.7 Data analysis

The data was analysed initially using simple descriptive statistics. The Cronbach coefficient alpha then was used as a measure of the level of consistency of opinion among the respondents of the agreed upon criteria. Finally, to determine the underlying structure of the criteria, a factor analysis was performed.

3.5 Results

From the 185 potential participants approached in the first round 89 responses (48.1%) were received. From the 89 respondents from round one, 75 responses (84.3%) were received following round two. Seventy (93.3%) of these respondents completed the final round. Overall, 37.8% of the original sample completed all three rounds. The response rate of participants in each discipline is indicated in Table 3.1 and the flow of participants through the study is depicted in Figure 3.1.

Table 3.1. Composition and response rate of participants in Delphi study

Group	Participants approached N (%)	Respondents Round 1 N (%)	Respondents Round 2 N (%)	Respondents Round 3 N (%)
Member of the Musculoskeletal and Pain Special Interest Group of The Australasian Faculty of Rehabilitation Medicine	3 (1.6)	2 (2.2)	1 (1.3)	1 (1.4)
Member of the Australasian Faculty of Musculoskeletal Medicine	28 (15.1)	11 (12.4)	9 (12)	7 (10)
Member of the Australian College of Physical Medicine	28 (15.1)	10 (11.2)	7 (9.3)	6 (8.6)
Member of the Shoulder and Elbow Society of Australia	81 (43.8)	36 (40.4)	28 (37.3)	27 (38.6)
Member of Shoulder and Elbow Physiotherapists Australia	12 (6.5)	10 (11.2)	10 (13.3)	9 (12.9)
Coordinator of a post-graduate musculoskeletal physiotherapy program	11 (5.9)	11 (12.4)	11 (14.7)	11 (15.7)
Specialist musculoskeletal physiotherapist	4 (2.2)	3 (3.4)	3 (4)	3 (4.3)
Author of publication on adhesive capsulitis in the past 10 years	11 (5.9)	3 (3.4)	3 (4)	3 (4.3)
Coordinator of a post-graduate chiropractic program	5 (2.7)	3 (3.4)	3 (4)	3 (4.3)
Coordinator of a post-graduate osteopathic program	2 (1.1)	0 (0)	0 (0)	0 (0)
Total	185	89	75	70

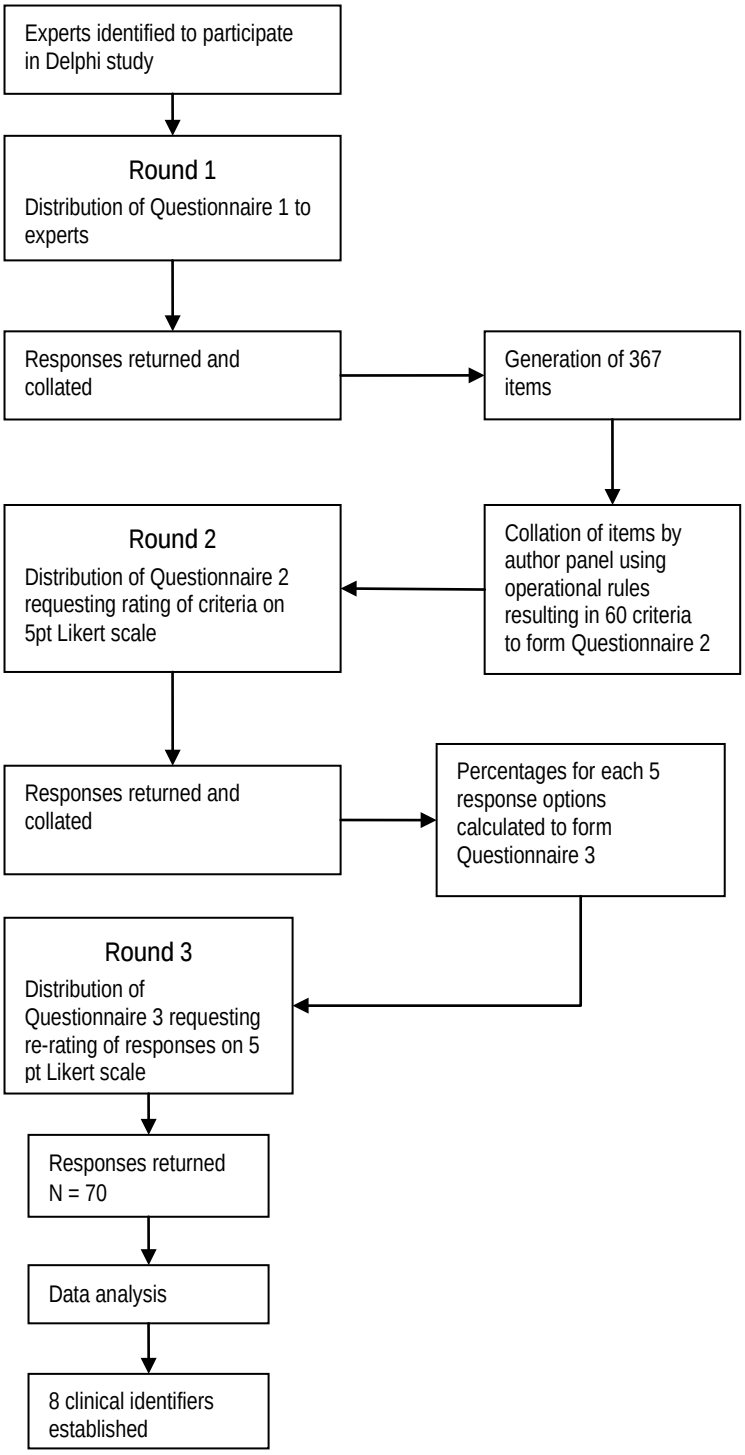


Figure 3.1 Flow of participants through the study

Following the first round, 367 criteria were generated. Collation of the data resulted in 60 diagnostic criteria structured into six sections to form round two. These criteria are outlined in Table 3.2.

Table 3.2 Items generated following round one

Category	Criterion/descriptor
Patient reported findings	1. Pain is generally located over the upper arm
	2. Pain is predominantly over the lateral shoulder/deltoid region
	3. Pain is predominately over the anterior shoulder
	4. Pain may be referred distally into the forearm
	5. Pain is diffuse or poorly localized
	6. The pain is described as deep
	7. The intensity of the pain is described as severe
	8. The pain is constant or unrelenting in nature
	9. The pain is described as an ache
	10. The level of pain is progressively increasing
	11. There is an intermittent catching or pinching pain
	12. There is a strong component of night pain
	13. There is a marked increase in pain with rapid or unguarded movements
	14. It is uncomfortable to lie on the affected shoulder
	15. The patient reports the pain is easily aggravated by movement
	16. Once aggravated the patient reports the pain is slow to settle
	17. Function is limited by increasing stiffness in this stage
	18. The history of onset of pain is spontaneous
	19. Symptoms have been present for greater than 4 weeks
	20. There is often a history of a minor trauma/precipitating event
	21. The onset of the condition is sudden
Demographic factors	22. The onset is generally in people greater than 35 years of age
	23. The onset is generally in people less than 60 years of age
	24. The condition more commonly presents in females
Physical examination findings	25. On examination there is a global loss of active and passive range of movement
	26. On examination there is pain at the end of range in all directions
	27. On examination there is no painful arc with shoulder elevation
	28. There is protective muscle guarding with movement
	29. The loss of movement in any direction is minor
	30. The greatest loss of movement is in external rotation
	31. There is painful limitation of active external rotation range performed in supine at 90° shoulder abduction
	32. There is marked pain during isometric external rotation strength testing performed in supine at 90° shoulder abduction
	33. The patient's range of movement is progressively decreasing due to pain
	34. There is a global loss of passive glenohumeral joint movement
	35. The loss of movement is in a glenohumeral joint capsular pattern i.e.: external rotation >abduction> internal rotation
	36. Resisted isometric muscle testing is painfree
	37. If pain is not inhibiting, muscle strength testing will be normal
	38. There is diffuse tenderness to palpation around the shoulder
	39. There is tenderness to palpation specifically over the anterior joint
	40. The scapula position is elevated at rest or with movement

Category	Criterion/descriptor
	41. Provocative tests for tendonitis do not inform the diagnosis
Associated factors	42. There can be an association with diabetes
	43. There may be a co-existing history of a thyroid condition
	44. The onset of the condition is more common in spring and autumn
	45. A minor viral illness may precede the onset
	46. There is often a past history of adhesive capsulitis of the opposite shoulder
	47. There is frequently a history of impingement syndrome in the same shoulder
	48. The thoracic spine is kyphotic or hypomobile
Response to treatment	49. There is a non-response or an exacerbation of pain with treatment involving physical therapies
	50. There is minimal or no response to usual analgesic medication
	51. There is minimal or no response to non steroidal anti-inflammatory drugs (NSAIDs)
	52. There is no response to subacromial steroid injection
	53. There is a favourable response to a steroid injection into the glenohumeral joint
Investigations	54. A thickened joint capsule will be evident on magnetic resonance imaging (MRI)
	55. A decreased joint volume will be evident on MRI
	56. Ultrasound investigation does not inform the diagnosis
	57. X-Ray examination only excludes osteoarthritis and calcific tendonitis
	58. There is a mild elevation of erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP)
	59. Blood factors exclude an infective or systemic inflammatory state
	60. Arthroscopy reveals synovitis and inflammation of the joint capsule

Following round three, the data were analysed initially using descriptive statistics. As the purpose of the study was to seek strongly held views by experts, and the initial request had been for necessary and sufficient criteria, it was determined that only the 'strongly agree' response would be analysed. Therefore, the number of respondents scoring 'strongly agree' was calculated and is graphically represented in Figure 3.2

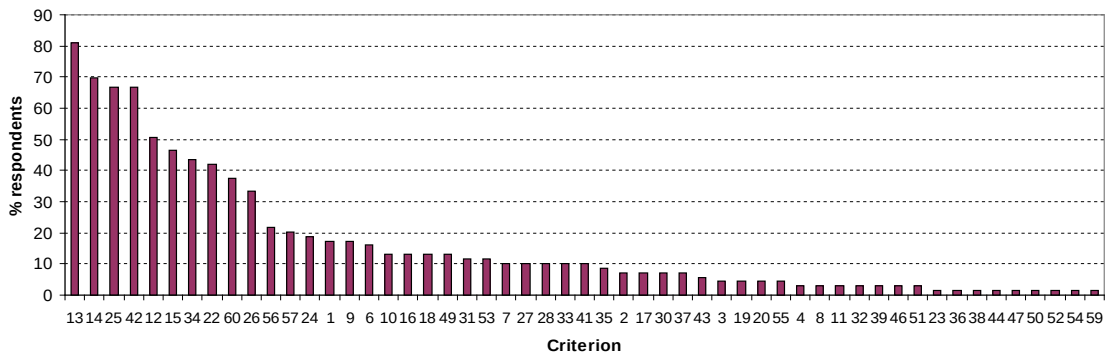


Figure 3.2 Percentage of respondents scoring a criterion as 'strongly agree' (N = 70)

In order to determine the criteria to be used in further analysis, several principles were applied. First, the Pareto principle (Rao, Carr et al. 1996) which suggests that 20% of the items would determine 80% of the value or benefit in deciding what is important in diagnosis was used to commence analysis. By applying this principle, 12 criteria were identified. Second, the pattern of drop off of frequency for these items resulted in a delineation at ten criteria. As this was in reasonable agreement with the Pareto principle, it was considered that this was an appropriate cut-off to select. As a result, ten criteria (in descending order, criteria 13, 14, 25, 42, 12, 15, 34, 22, 60, 26) were selected for further analysis.

In order to measure the internal consistency of the criteria Cronbach alpha was used. Using SPSS version 15 (SPSS Inc., 233 Wacker Dr, Chicago, IL 60606), an analysis of the ten selected criteria resulted in a Cronbach alpha value of 0.63. Stepwise removal of items whose inclusion reduced the alpha value was performed (criteria 42 and 60). Removal of these two criteria maximised Cronbach alpha to 0.71. Eight criteria were established as a result of this analysis and are presented in Table 3.3

Table 3.3 Diagnostic criteria achieving consensus

Criterion	Descriptor
12	There is a strong component of night pain
13	There is a marked increase in pain with rapid or unguarded movements
14	It is uncomfortable to lie on the affected shoulder
15	The patient reports the pain is easily aggravated by movement
22	The onset is generally people greater than 35 years of age
25	On examination there is global loss of active and passive range of movement
26	On examination there is pain at the end of range in all directions
34	There is global loss of passive glenohumeral joint movement

As the underlying structure of these criteria was of interest and factor analysis was proposed, a Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) was performed to determine whether this would be of benefit. The value of this test was 0.661. A value above 0.60 indicates that it is worthwhile proceeding with factor analysis (Tabachnick and Fiddell 1996). A factor analysis using Varimax rotation, was therefore, performed on the remaining eight criteria to examine their underlying structure.

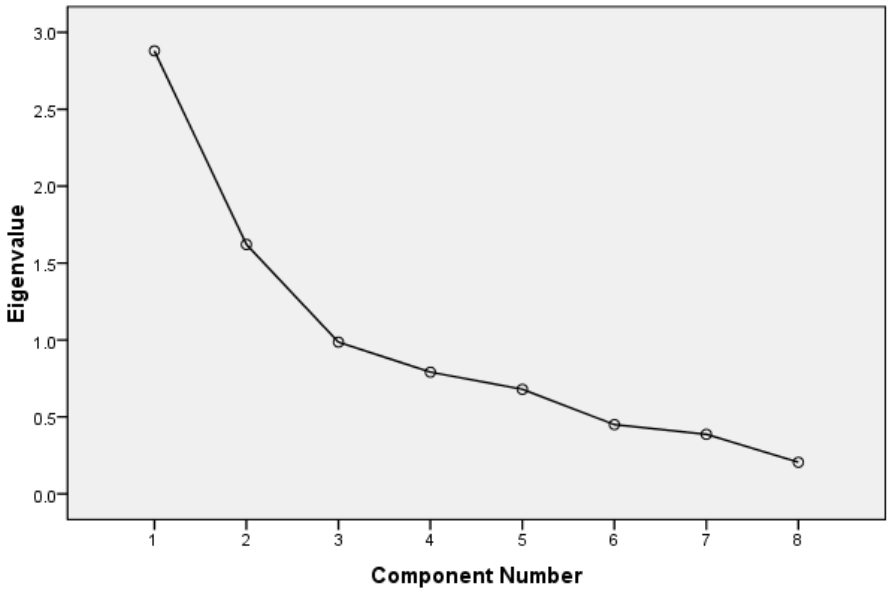


Figure 3.3 Scree plot of final components selected

Figure 3.3 demonstrates the scree plot for this calculation. The result of this factor analysis determined two discrete dimensions of pain and movement into which the criteria clustered. This is represented in Figure 3.4.

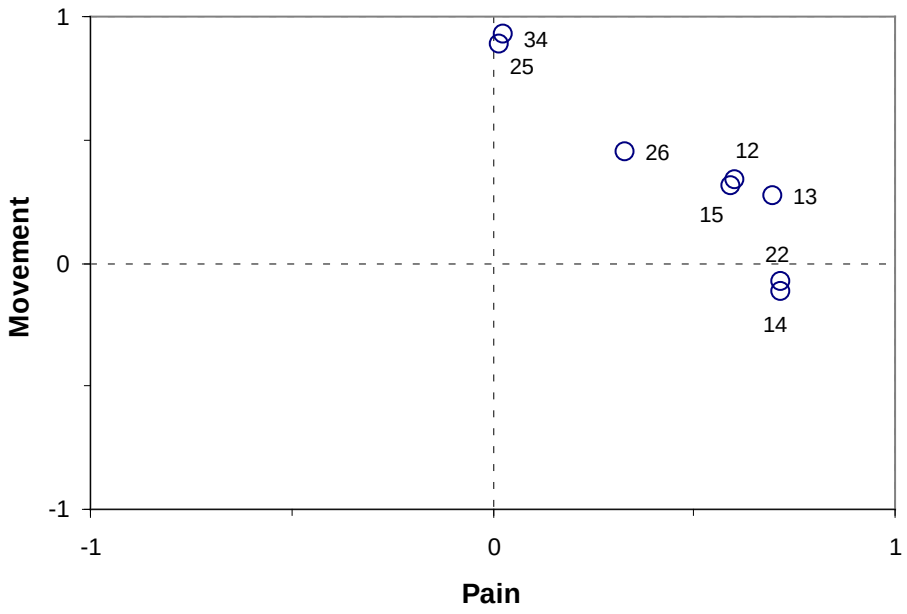


Figure 3.4 Component plot of diagnostic criteria following factor analysis

These factors together accounted for 56.3% of the total variance of the expert responses, with the pain factor accounting for 36% and the movement factor 20.3%. The relative weights of the eight criteria are shown in Table 3.4, which provides factor loadings for each criterion in the two factor solution.

Table 3.4 Factor loadings following principal components factor analysis of clinical criteria

	Factor	
Criterion	Pain Eigenvalue = 2.88	Movement Eigenvalue = 1.62
14	0.719	
22	0.717	
13	0.695	
12	0.604	
15	0.595	
34		0.928
25		0.888
26		0.447

3.6 Discussion

The Delphi technique was used successfully in this study to establish consensus among a group of musculoskeletal professionals on eight clinical identifiers for the first stage of primary (idiopathic) adhesive capsulitis. Although the initial aim of the study had been to establish diagnostic criteria and instructions to participants had been to respond as such, following data analysis it was considered more appropriate to alter the nomenclature of the set of resultant criteria to clinical identifiers. In a recent Delphi study of lumbar zygapophyseal joint pain (Wilde, Ford et al. 2007) a similar dilemma was encountered, with experts in medical disciplines applying different definitions to the term 'diagnostic criteria'. Following the first round of that study it was decided to replace the phrase 'diagnostic criteria' with 'criteria indicative' of lumbar zygapophyseal joint pain to more appropriately reflect the responses received. At the conclusion of the current study, the term 'clinical identifiers' was similarly determined to be more appropriate for the set of criteria established, as they could not be regarded as a gold standard for diagnosis or provide a differential diagnosis, but rather are a set of clinical identifiers that may assist the clinician in diagnosis, as well help form the basis for further research.

Unlike many earlier published studies using the Delphi technique, the application of rigorous statistical analysis, rather than only simple descriptive statistics, was used to determine consensus in this study. Notably, factor analysis in this study has resulted in identifiers clustering into two discrete domains of pain and movement.

Clinically, diagnosis of adhesive capsulitis is made through the history and physical examination. Textbook descriptions of the clinical characteristics of adhesive capsulitis identify a number of features present in each of the various stages of the disorder (Murnaghan 1990). These features encompass onset and description of pain, as well as effect on movement. Similarly, in published studies such as a recent systematic review of physical therapy for adhesive capsulitis, many of the clinical identifiers proposed by respondents in the present study are described (Cleland and Durall 2002), despite a lack of validation. Whilst these identifiers (including descriptions of pain and movement) are commonly proposed they have not previously been subjected to formal evaluation. Using the Delphi technique, the present study is the first to subject these descriptors to scrutiny and begin the process of validation.

To date, there has been no agreement on the necessary criteria or clinical identifiers required for diagnosing adhesive capsulitis in its early stage (Murnaghan 1990; Groeiner, Winters et al. 2003; Smidt and Green 2003; Dudkiewicz, Oran et al. 2004). However, it has been suggested that whilst the exact identifiers are poorly defined, pain is a significant feature in this stage (Hannafin and Chiaia 2000). Our study supports this premise, with several dimensions of pain being qualified and achieving consensus. A strong component of night pain; a marked increase of pain with rapid or unguarded movements; discomfort lying on the affected shoulder; and pain easily aggravated by movement, were the four descriptors of pain on which consensus was achieved. Although not validated, night pain or sleep disturbance has previously been commonly described as a feature of this disorder in the early stage (Reeves 1975;

Neviaser and Neviaser 1987; Cleland and Durall 2002; Dudkiewicz, Oran et al. 2004). There are also descriptions in the literature of pain easily aggravated by movement (Siegel, Cohen et al. 1999; Hannafin and Chiaia 2000). Although probably not exclusive to adhesive capsulitis, these descriptors of pain may reflect the pathology of inflammatory synovitis that has been demonstrated at this stage (Neviaser and Neviaser 1987; Hannafin, DiCarlo et al. 1994). The panel of experts in this study concur that these identifiers are necessary to diagnose early stage primary adhesive capsulitis. Although the identifiers describing location and intensity of pain did not reach consensus, the pain identifiers described and for which consensus was reached, may assist the clinician in the diagnosis of early stage adhesive capsulitis.

The exact characteristics of movement dysfunction in the early stage of adhesive capsulitis are not clearly described in the literature. Although the effect on movement in the later stages of the disorder is usually described and even quantified, description of any movement deficit in the early stage is generally minimal. Nonetheless, general restriction of movement in all directions at this early stage has been described previously (Reeves 1975; Pearsall and Speer 1998; Siegel, Cohen et al. 1999). This study achieved consensus on the clinical identifiers of global loss of both active and passive ranges of movement, accompanied by pain at the end-range in all directions. Although no specific quantification of the loss at this stage has been determined, the fact that loss is global, rather than related to a specific direction is the key feature in this clinical descriptor. Unlike many other shoulder pathologies, adhesive capsulitis is a disorder mainly affecting the glenohumeral joint capsule (Neviaser and Neviaser 1987). Global

loss of active and passive range of motion is consistent with pathology of this structure. In addition, pain at the end-range in all directions is a feature that may also raise the level of clinical suspicion of adhesive capsulitis and is also consistent with capsular pathology (Pearsall and Speer 1998).

Demographic factors of adhesive capsulitis, including the age of onset, are considered a relevant clinical feature important in diagnosis. Generally, it is suggested in the literature that patients affected by this disorder are over 40 years of age (Neviaser and Neviaser 1987; Pearsall and Speer 1998; Hannafin and Chiaia 2000; Dias, Cutts et al. 2005). Following round one, a variety of responses quantifying age were received from the expert panel, such as "not seen less than 30 years of age"; "middle aged 45 – 60"; "age 50's". The most frequent response was captured in criterion 22 "the onset is generally in people greater than 35 years of age". Interestingly, criterion 23 ("The onset is generally in people less than 60 years of age"), which was descriptive of the upper age limit for this disorder, did not achieve consensus. Therefore, in this study, there was consensus that the age of onset of the disorder generally is greater than 35 years. This finding is consistent with previous published literature, although no explanation was offered (Neviaser and Neviaser 1987; Pearsall and Speer 1998; Hannafin and Chiaia 2000; Dias, Cutts et al. 2005). The higher incidence of women in the 40-60 year age group, which failed to reach consensus, has been hypothesised to coincide with menopause and perimenopause (Vad and Hannafin 2000) but as yet this hypothesis remains unproven. The factor analysis determined that those respondents who regarded clinical identifiers in the pain dimension as diagnostically important,

consistently reported age (criterion 22) alongside the pain identifiers. As pain behaviour and age are generally considered patient reported data and not physical examination findings, it is appropriate that the clinical identifier describing age clustered with identifiers describing pain rather than with movement findings.

Interestingly, the eight clinical identifiers established in this study did not include any negative findings. Instructions to participants were not to limit responses to positive findings, and indeed negative findings were solicited; however they failed to reach consensus. This finding is relevant, as the presence of pathology in structures other than the glenohumeral joint capsule may elicit differing clinical characteristics that would raise doubts about a diagnosis of adhesive capsulitis. Acute cervical radiculopathy or rotator cuff tendonitis, for example, may be recognised by other clinical features that would contribute to a differential diagnosis. As such features did not reach consensus in the current study, the limitation of the results in assisting differential diagnosis is acknowledged. A further consideration of the identifiers established is whether the resultant group should be regarded as a set or as individual items. Instructions to participants had been to give a 'set of necessary and sufficient diagnostic criteria'; however it remains to be determined whether all or only some are necessary in diagnosis. This is particularly relevant as some of the identifiers may also be present in other acutely presenting shoulder disorders of differing pathology.

The recent suggestion that attempting to place diagnostic labels on groups of patients in clinical research trials is of little value (Schellingerhout, Verhagen et al. 2008) may overstate the case. Arguably, one of the aims of establishing diagnostic criteria is to

identify a homogenous subgroup of patients with which to evaluate treatment outcomes and make comparisons across trials more meaningful. Although there is some evidence that the outcomes of treatment may be similar in heterogeneous groups (Ginn, Herbert et al. 1997; Hay, Thomas et al. 2003; Ginn and Cohen 2004; Thomas, van der Windt et al. 2005), it remains to be seen if subgroups of patients with common clinical features experience greater benefits with particular interventions.

The Delphi technique, and its application in this study, has a number of limitations. However it was chosen as it enabled the engagement of a large number of - musculoskeletal experts from a range of relevant professions and across a wide geographical area. One limitation often described is that there may be a poor response rate to the questionnaires (McKenna 1994; Sumsion 1998). In this study, the initial round had a moderate response rate of 48.1%, whereas the second and third rounds had high response rates of 84.3% and 93.3% respectively. It has been suggested that a poor response rate may characterise the final rounds (McKenna 1994); however this did not occur in the current study. The overall response rate for this study was 37.8%, which compares favourably with recent studies that also had a large sample but achieved a response rate of only 8.4% (Cook, Brismee et al. 2005; Cook, Brismee et al. 2006). Researcher bias has also been proposed as a weakness of the Delphi technique. The use of an open initial response in round one achieved a richness of collected data; however, this required care in reducing data to a more manageable volume for the subsequent rounds. Strict operational definitions were used by the three researchers to minimise bias. Furthermore, following round three, rather than just using simple

descriptive statistics as in many earlier studies, a more rigorous analysis was used to provide a more independent insight into the data.

Composition and size of the expert panel in Delphi studies vary across the literature. In an article discussing the methodology of the Delphi technique, Williams and Webb (Williams and Webb 1994) note that there is no agreement regarding the optimal size of an expert panel. They commented that the panel size of studies reported in the earlier literature varied from 10 to 1685 participants. In the current study, the inclusion criteria for potential participants determined the size of the expert panel. These inclusion criteria were established to recruit musculoskeletal practitioners and leaders in several fields with expertise in clinical, research and educational facets of shoulder pain. Although medical practitioners were represented, omission of rheumatologists, who may assess and treat musculoskeletal disorders, could be regarded as a limitation of this study. This omission occurred as it was not possible to identify a defined special interest group in musculoskeletal medicine or orthopaedics within the Australian Rheumatology Association. Regional differences in prevalence or characteristics of adhesive capsulitis are not described in the literature. However, as the participants in this study were recruited from Australian and New Zealand experts the results may only reflect views held in this region.

The present study has not only addressed the difficulty faced by clinicians in the diagnosis of shoulder disorders as described by Mitchell and colleagues (Mitchell, Adebajo et al. 2005), but is the first of its kind to establish a set of clinical identifiers for the early stage of primary adhesive capsulitis. Although a specific diagnostic test or

negative findings that may contribute to differential diagnosis have not achieved consensus in this study, several parameters of patient presentation have been established. These agreed clinical identifiers should assist in the clinical decision-making process and aid in the early recognition of this disorder. They also represent the first step in the longer process of identification and validation of the agreed diagnostic criteria for this disorder.

3.7 Conclusions

The results of this study provide a framework for the validation of clinical identifiers for early primary adhesive capsulitis in further studies, as well as potentially facilitating comparisons across future clinical trials. Although the identifiers established in this study do not constitute an exclusive or discriminatory set of diagnostic criteria, they may be of assistance to the clinician confronted with the diagnostic dilemma of recognising the early stage of primary adhesive capsulitis.

Chapter 4 Early diagnosis of primary/idiopathic adhesive capsulitis: Can imaging contribute?

This chapter has been published in a peer-reviewed scientific journal:

Walmsley S, Rivett DA, Osmotherly PG (2012). Early diagnosis of primary/idiopathic adhesive capsulitis: Can imaging contribute? International Musculoskeletal Medicine 34, (4): 166-174.

The work presented in this manuscript was completed in collaboration with the co-authors (Appendix 1).

Overview

The Delphi study described in the preceding chapter proposed a set of clinical identifiers determined by expert consensus necessary and sufficient to achieve a diagnosis of early stage adhesive capsulitis. Although musculoskeletal medicine frequently relies on diagnostic imaging to confirm or exclude a diagnosis, inclusion of a diagnostic imaging finding in the set of clinical identifiers was notably lacking. Despite this, a number of studies have investigated the role of imaging in the diagnosis of adhesive capsulitis, and a review of the relevant literature is presented in this chapter. The potential future role of power Doppler ultrasonography to identify patients with early stage adhesive capsulitis is identified and suggestions for further research proposed.

4.1 Abstract

Adhesive capsulitis is a frequently presenting shoulder disorder in musculoskeletal medicine. It is recognized as consisting of three stages, and is often difficult to diagnose in its early stage and differentiate from other shoulder disorders. Treatment of this disorder has been proposed to be dependant on the stage, with early treatment suggested to decrease the overall morbidity. Arguably therefore, recognition in this early stage is desirable. The purpose of this paper is to review the current evidence that may support the role of imaging facilitating a diagnosis of adhesive capsulitis and to discuss this in relation to the contemporary understanding of the pathology of this disorder. The emerging role of Doppler ultrasound in the diagnosis and management of inflammatory arthropathies is discussed, and in particular its potential to contribute to the early diagnosis of adhesive capsulitis. While the diagnosis of adhesive capsulitis is presently largely based on clinical examination, this review outlines the current and future role that radiology may be able to contribute to the clinical presentation.

Key words: Adhesive capsulitis, diagnosis, shoulder, ultrasonography, magnetic resonance imaging,

4.2 Introduction

Adhesive capsulitis is a disorder of the shoulder which is frequently encountered in the primary health care setting. This disorder is characterised by gradually worsening pain and stiffness of the glenohumeral joint (Neviaser and Neviaser 1987; Hannafin and Chiaia 2000). Traditionally, it has been reported to affect 2-5% of the normal population

though, with advancing understanding of the pathology through arthroscopic examination it has been recently suggested that incidence may actually be as low as 0.75% (Bunker 2009). Adhesive capsulitis is generally described as primary or secondary (Reeves 1975; Chambler and Carr 2003). Primary or idiopathic adhesive capsulitis results from an unknown cause, whereas secondary adhesive capsulitis is due to a known cause such as trauma or surgery. It is recognised that adhesive capsulitis progresses through three stages and the natural history is towards resolution (Pearsall and Speer 1998; Siegel, Cohen et al. 1999; Chambler and Carr 2003). The three stages have been described as the painful stage (first) lasting between three and nine months, the adhesive stage (second) lasting between four to 12 months, and the resolution stage (third) lasting from five to 26 months (Pearsall and Speer 1998). While various treatment options have been reported with variable results, it has been proposed that treatment implemented in the first or early stage may decrease the overall morbidity of the disorder (Hazleman 1972; Hannafin and Chiaia 2000). Arguably, therefore, diagnosis and treatment in this early stage are most important.

The diagnosis of adhesive capsulitis is clinical and often one of exclusion (Hannafin and Chiaia 2000; Hand, Athanasou et al. 2007; Manske and Prohaska 2008; Kelley, McClure et al. 2009). It is acknowledged that diagnosis of adhesive capsulitis in its early stage can be difficult as the symptoms may be non-specific and easily confused with other pathologies, such as rotator cuff tendinopathy or subacromial bursitis (Manske and Prohaska 2008; Kelley, McClure et al. 2009). Whilst the diagnosis of established adhesive capsulitis is straightforward and essentially clinical, it is likely

that confusion with coexisting impingement syndrome is common as features of both conditions may be present. In an attempt to address the lack of clearly defined diagnostic criteria for the early stage of adhesive capsulitis a Delphi study was conducted resulting in eight clinical identifiers being established for this early stage (Walmsley, Rivett et al. 2009). These identifiers remain to be validated and currently there is no definitive test or investigation for the early diagnosis of this disorder. The use of radiology as an adjunct to diagnosis in musculoskeletal medicine is well established, however its role in the recognition of early stage adhesive capsulitis has yet to be determined. The current and potential future contribution of radiology in the diagnosis of adhesive capsulitis will be discussed in the light of the contemporary understanding of the anatomical and pathological evidence for the disorder.

4.2.1 Pathology of adhesive capsulitis

An appreciation of the pathology of adhesive capsulitis provides a rationale behind the selection and timing of appropriate radiological investigation. While there has been controversy as to whether the disorder primarily represents an inflammatory or fibrotic process, it is now largely recognized that a mechanism involving capsular inflammation followed by fibrosis is responsible for the symptoms (Hand, Athanasou et al. 2007). Historically both inflammation (Wiley 1991; Rodeo, Hannafin et al. 1997; Hand, Athanasou et al. 2007) and fibrosis (Bunker and Anthony 1995) have been microscopically described in adhesive capsulitis. Although histological examination has not identified inflammatory cells in the glenohumeral joint capsule in some studies, (Bunker and Anthony 1995; Bunker, Reilly et al. 2000) others describe a visual

appearance of synovitis consistent with inflammation (Neviaser and Neviaser 1987; Hannafin and Chiaia 2000; Watson, Dalziel et al. 2000).

The surgical examination of patients believed to have adhesive capsulitis has identified the rotator interval area of the glenohumeral joint capsule as the anatomical location predominantly involved in this disorder (Ogilvie-Harris and Myerthall 1977; Ozaki, Nakagawa et al. 1989; Wiley 1991). As seen in Figure 4.1, the rotator interval is a triangular space bounded superiorly by the anterior aspect of the supraspinatus tendon and inferiorly by the superior aspect of the subscapularis tendon. It is bordered medially by the lateral margin of the coracoid process and laterally by the transverse humeral ligament. Its contents include the coracohumeral and superior glenohumeral ligaments, together with the long head of biceps tendon (Fitzpatrick, Powell et al. 2003).

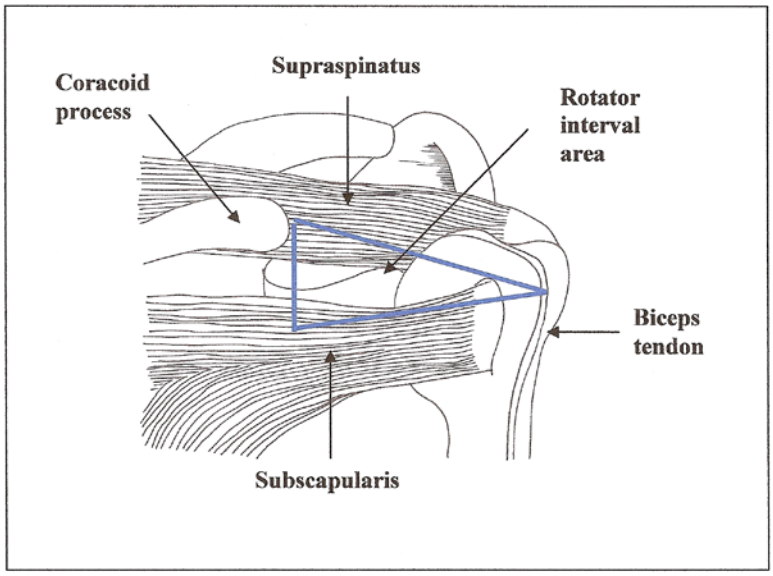


Figure 4.1 The rotator interval area of the shoulder

Both arthroscopic (Wiley 1991; Bunker and Anthony 1995; Watson, Dalziel et al. 2000) and open surgical studies (Ozaki, Nakagawa et al. 1989; Omari and Bunker 2001) assessing the role of the rotator interval in adhesive capsulitis have demonstrated inflammation of the extra-articular tissue in this area, synovitis of the anterosuperior glenohumeral joint capsule and thickening of the coracohumeral ligament. Histologically, the rotator interval has also been demonstrated to be an area of pathological significance (Bunker and Anthony 1995). Arthroscopic findings of adhesive capsulitis have also described the presence of red, inflamed synovium in the rotator interval, surrounding and in some instances indistinguishable from the intra-articular portion of the biceps tendon and coracohumeral ligament (Lee, Sykes et al. 2005). Macroscopic appraisal of the tissue in this study suggested the presence of chronic inflammation as demonstrated by high vascularity (Lee, Sykes et al. 2005).

The controversy and confusion regarding the exact pathogenesis of adhesive capsulitis has been proposed by Hand et al (Hand, Athanasou et al. 2007) to stem from the fact that many published studies have examined groups of patients who were resistant to conservative treatment, and thus in the later stages of the disorder. It does, however also appear from the surgical evidence that the pathology in the early stage of the disorder is inflammatory and this is supported by the clinical observation that intra-articular corticosteroid injections provide short term improvement in symptoms (Bulgen, Binder et al. 1984; van der Windt, Koes et al. 1998; Arslan and Celiker 2001; Carette, Moffet et al. 2003; Diercks and Stevens 2004; Ryans, Montgomery et al. 2005; Lorbach, Anagnostakos et al. 2010). In summary, the pathological evidence suggests

that adhesive capsulitis in the early stage involves inflammatory changes of the glenohumeral joint capsule associated with increased vascularity in the synovium initiating at the rotator interval area, which then progresses to thickening and fibrosis of the capsular tissue.

4.3 Current radiology in the diagnosis of adhesive capsulitis

The radiological investigations most commonly performed for patients presenting with shoulder pain in the primary health care setting are X-ray and ultrasound examinations. These imaging investigations may confirm a diagnosis or be useful to eliminate other various possible pathologies (Kelley, McClure et al. 2009). While the various imaging modalities have described numerous findings in adhesive capsulitis, no one investigation to date is regarded as superior to clinical examination for the diagnosis of this disorder. Although invasive, conventional arthrography has been suggested as the preferred imaging investigation for adhesive capsulitis as it is able to demonstrate reduced glenohumeral joint volume (Binder, Bulgen et al. 1984; Neviaser and Neviaser 1987). Arthrographic evaluation of glenohumeral joint volume has however been suggested to provide misleading information in the presence of full-thickness rotator cuff tears which allow contrast material to flow into the subacromial space (Hsu, Anakwenze et al. 2011).

While becoming increasingly more common and potentially providing superior diagnostic capabilities for shoulder pain, magnetic resonance imaging (MRI) continues to remain a less accessible and expensive imaging modality and is therefore used less

frequently, though it is regarded by some as the gold standard for shoulder imaging (McNally and Rees 2007). Magnetic resonance arthrography (MRA) has been reported to demonstrate enhancement of the rotator interval and thickening and enhancement of the axillary recess (Song, Kwon et al. 2011). Nuclear medicine bone scans are less frequently used and their contribution to the diagnosis of adhesive capsulitis is not regarded as significant (Binder, Bulgen et al. 1984). Although the early stage of adhesive capsulitis has not received particular attention in most reported radiological investigations, findings later in the course of the disorder may provide valuable information.

4.3.1 Ultrasound imaging

Ultrasound investigation of the shoulder has become increasingly utilised over recent years with the introduction of better imaging equipment, more advanced understanding of ultrasound anatomy and a more defined examination technique (Beggs 2006). This imaging modality is attractive as it has the advantages of being safe, non-invasive and using non ionising radiation, (Backhaus, Burmester et al. 2001) as well as being fast, inexpensive and well-tolerated by the patient (Read and Perko 1998; Delle Sedie, Riente et al. 2008).

The use of gray-scale ultrasound imaging in the assessment of rotator cuff tendons is widely accepted (Read and Perko 1998). Conversely, only a small number of published studies report its application in assisting the diagnosis of adhesive capsulitis (Ryu, Lee et al. 1993; Lee, Sykes et al. 2005; Homsi, Bordalo-Rodrigues et al. 2006). Indeed, it has been suggested that with the use of ultrasound there is no single finding that may be

regarded as diagnostic or consistently present in all cases of adhesive capsulitis (Anderson and Read 2008). Using arthrography as the gold standard for diagnosis against which the sonographic findings were compared, Ryu et al (Ryu, Lee et al. 1993) described limitation of movement of the supraspinatus tendon as a reliable criteria for diagnosis of this disorder. While the duration of the symptoms of participants in this study was not reported, it is unlikely that they were in the early stage of adhesive capsulitis, and probably were at the stage when limitation of range of movement facilitated clinical diagnosis. As a means of assisting the diagnosis of adhesive capsulitis, the coracohumeral ligament was assessed by Homsi et al (Homsi, Bordalo-Rodrigues et al. 2006) with ultrasound to determine if it was thickened in patients with arthrographic evidence of the disorder. They concluded that a thickened coracohumeral ligament may be suggestive of adhesive capsulitis, but it was recognised that further studies are needed to validate these results. However the patients examined were likely at a later stage of the disorder when a clinical diagnosis may be more apparent and arthrography was utilised as the diagnostic reference which, may have lead to an incorrect interpretation in some cases (Hall 2005). A further recent suggestion that may assist in the diagnostic dilemma in early diagnosis has been a proposal that dynamic ultrasound assessment of posterior shoulder capsular compliance and joint synovial proliferation may correlate well with the various stages of adhesive capsulitis (Cairns 2009). The ability of ultrasound to assess dynamically has been highlighted by this author together with the importance of early diagnosis.

Colour Doppler ultrasound has also been sporadically reported to provide valuable information in the diagnosis of adhesive capsulitis (Lee, Sykes et al. 2005). Enhanced vascularity and hypoechoic change in the rotator interval have been correlated with vascular synovial fronds visualized with arthroscopic investigation (Lee, Sykes et al. 2005). Though an unblinded assessment, ultrasound appraisal of the rotator interval compared with arthroscopic findings suggested that colour Doppler ultrasound was able to provide an early and accurate diagnosis of adhesive capsulitis by assessing for hypoechoic vascular soft tissue (Lee, Sykes et al. 2005). In contrast to the previous studies, this study examined a group of patients who had experienced symptoms for less than 12 months, therefore reflecting the earlier stage of the disorder. Colour Doppler ultrasound has also been proposed by other authors to show capsulosynovial hyperaemia at the rotator interval early in the disorder, as well as tenderness to probing over the glenohumeral joint capsule (Anderson and Read 2008).

4.3.2 Magnetic resonance imaging

Unlike ultrasound, the use of MRI and MRA has received wide attention in the literature in the diagnosis of adhesive capsulitis. A summary of studies using MRI is given in Table 4.1 and a summary of MRA studies is provided in Table 4.2. Comparison of these studies demonstrates that inclusion criteria for subjects vary and may not always include subjects in the early stage of adhesive capsulitis, but rather more likely in the later stages when the clinical presentation may be more apparent. Further, individual studies describe differing endpoints and as a result it has been suggested that drawing conclusions on the role of these radiological investigations in

the diagnosis of this disorder may be difficult (Petchprapa, Beltran et al. 2010). Despite these limitations, however, the reported studies using MRI and MRA provide consistent findings and therefore valuable diagnostic indicators.

Table 4.1 Summary of MRI studies on adhesive capsulitis

Study	Number of shoulders	Inclusion criteria	Duration of symptoms (mean)	Investigation	Summary of findings
Emig 1994	10 AC 15 asymptomatic	9 subjects diagnosed by arthrography, 1 confirmed at surgery.	Not stated	MRI measuring thickness of capsule, synovium and CHL, volume of articular fluid	Capsule and synovium thickness > 4mm was specific (95%) and sensitive (70%) for AC. No significant difference in volume of fluid or thickness of CHL. RI not useful for assessing AC.
Tamai 1997	18 AC 8 IS 3 healthy volunteers	> 1 month history of shoulder pain and stiffness, < 135º forward elevation, recognizable limitation of IR and ER. Monitored until pain free and near normal ROM.	1-18 months (7 months)	Dynamic gadolinium enhanced MRI assessment of the synovium in AC subjects.	Obvious enhancement of the GHJ synovium in AC subjects clearly distinguishable from that of normal shoulders.
Carrillon 1999	25 AC 15 with RCT's	Gradually increasing shoulder pain at least 1 month duration, anterior elevation < 135º, ER < 20º, normal X rays.	2-10 months (6 months)	MRI involving two spin-echo T2 weighted sequences with fat saturation and two spin-echo T1 weighted postgadolinium sequences	Post gadolinium enhancement of the GHJ capsule and synovium was seen in the RI in all 25 AC subjects (in only 1 of the RCT subjects) and in the AR in 22 out of 25.
Connell 2002	24 AC 22 RC pathology	Insidious onset of shoulder pain and dysfunction. Pain and stiffness >15 weeks, increasing in nature, most severe at rest, restriction of PROM > 30° in 2 or more planes.	15 weeks – 26 months (10.2 months)	MRI prior to arthroscopic capsulotomy. Routine intravenous gadolinium.	Presence of enhancing fibrovascular scar tissue in the RI, soft tissue thickening around the biceps anchor and thickening of the axillary pouch on MRI are suggestive signs of AC.
Lefevre-Colau 2005	26 AC 14 contralateral pain free, non restricted shoulders	Gradually increasing shoulder pain more severe at rest, for at least one month, limitation of PROM mainly in forward elevation and ER, normal X ray, non responsive to normal Rx.	At MRI 3-26 months (9.5 ± 5.4 months)	MRI with gadolinium enhancement measuring GHJ capsule and synovial thickness in the RI and AR.	Mean thickness of AR and RI greater in AC shoulders compared to controls.

Study	Number of shoulders	Inclusion criteria	Duration of symptoms (mean)	Investigation	Summary of findings
Sofika 2008	46 AC (47 shoulders)	Presumptive clinical diagnosis or MRI findings suggestive of AC. Pts with MRI's and detailed clinical information that allowed stage to be determined	Clinical diagnosis of stage 1 (0-3 mths), 8 subjects; stage 2 (3-9 mths), 23 subjects; stage 3 (9-15 mths), 8 subjects; stage 4 (15-24 mths), 8 subjects	MRI measuring capsular and synovial thickness at the AR, scarring in the RI, signal intensity in the capsule.	All subjects demonstrated scarring of the RI; 29 subjects had hyperintensity of the GH capsule; capsular and synovial thickening measured in the AR correlated with clinical stage of AC; hyperintense capsular signal correlated with stage 2

Legend: AC, adhesive capsulitis; ADL activities of daily living; AR, axillary recess; CHL, coracohumeral ligament; ER, external rotation; FE, forward elevation, GHJ, glenohumeral joint; h/o, history of; IR, internal rotation; IS, impingement syndrome; MRA, magnetic resonance arthrography; MRI, magnetic resonance imaging; mths, months; PROM, passive range of movement; RC, rotator cuff; RCT, rotator cuff tear; RI, rotator interval; ROM, range of movement; Rx, treatment; VAS, visual analogue scale

Table 4.2 Summary of MRA studies on adhesive capsulitis

Study	Number of shoulders	Inclusion criteria	Duration of symptoms (mean)	Investigation	Summary of findings
Manton 2001 (47)	9 AC 19 without signs of AC	Retrospective arthrographic diagnosis based on having 2 or more of the following: joint volume <10ml, poor or absent filling of the AR of the joint or biceps tendon sheath, irregularity of the capsule insertion, pain after injection of <10ml of contrast, or extravasation of contrast prior to injection ≥10ml	Not stated	MRA assessing relative amount of fluid in the biceps tendon sheath and AR, corrugation at the margin of the capsule, capsule synovium thickness, abnormalities of the RI, and the presence of RCT's	Concluded no useful MRA signs of AC. Capsule/synovium thickness, static fluid, and the presence of corrugation are inconclusive signs distinguishing shoulders with AC from those without.
Lee 2003 (46)	16 AC 11 controls	Arthroscopically proven AC with at least two of the following: vascular synovitis, capsular contracture, tightness of the humeral head against the glenoid, difficult penetration of the GHJ capsule with the arthroscope. Excluded AC diagnosed clinically.	Not stated	MRA measuring thickness of GHJ capsule and synovium, filling ratio of AR to determine relative volume, width of the RI.	Thickening of the GHJ capsule and synovium and diminished filling ratio of the AR to posterior joint cavity appeared to be useful diagnostic criteria for AC

Study	Number of shoulders	Inclusion criteria	Duration of symptoms (mean)	Investigation	Summary of findings
Mengiardi 2004 (51)	22 Rx arthroscopic capsulotomy for AC 22 age and sex matched controls	Surgical confirmation of AC (thickened GHJ capsule and synovitis in the area of the RI) and treatment with arthroscopic capsulotomy < 3 months after MRA.	3-24 months (11 months)	Pre operative MRA compared with age and sex matched control subjects without AC.	Thickening of the CHL and joint capsule in the RI. Synovitis-like abnormalities at the superior border of the subscapularis tendon significantly more common in AC subjects than in controls.
Jung 2006 (45)	14 AC 14 controls	Injected GHJ volume < with pain. Pain and stiffness >15 weeks, restriction of PROM of >30° in 2 or more planes, normal X ray.	Not stated	MRA measuring mean thickness of GHJ capsule and synovium, width of the AR and RI.	In the absence of a full thickness RCT, thickness of the GHJ capsule and synovium >3mm at the level of the AR is a practical MR criterion for the diagnosis of AC on oblique coronal T2 weighted MRA without fat suppression.
Kim 2009 (44)	26 AC 47 controls	Painful stiff shoulder for at least 4 weeks, severe pain interfering with ADL, night pain, painful restriction of active and passive elevation to < 100°, 50% restriction of ER. AC confirmed arthroscopically in 11 shoulders.	Not stated	Retrospective review of patients undergoing MRA. Estimated the height, base RI area, width, RI index and RI ratio.	Shoulders with AC differed significantly in height, base, RI area, RI index and RI ratio from those without AC.
Song 2011 (33)	35 AC 45 controls	Painful stiff shoulder for at least 4 weeks, severe shoulder pain that interfered with ADL, night pain, painful restriction of active and passive elevation < 100º, 50% restriction of ER, normal X ray	Not stated	Indirect MRA comparison with control subjects. Measured joint capsule thickness in AR; thickness of enhancing portion of the AR and RI.	AC subjects had significantly thickened joint capsule in the AR and a thickened enhancing portion in the AR and RI

Legend: AC, adhesive capsulitis; ADL activities of daily living; AR, axillary recess; CHL, coracohumeral ligament; ER, external rotation; FE, forward elevation, GHJ, glenohumeral joint; h/o, history of; IR, internal rotation; IS, impingement syndrome; MRA, magnetic resonance arthrography; MRI, magnetic resonance imaging; PROM, passive range of movement; RC, rotator cuff; RCT, rotator cuff tear; RI, rotator interval; ROM, range of movement; Rx, treatment; VAS, visual analogue scale

Consistent with the surgical and histological findings, the area of most interest in both MRI and MRA investigations has been the rotator interval (Wiley 1991; Bunker and Anthony 1995). Some studies report a difference in rotator interval dimensions visualized with MRA, (Jung, Jee et al. 2006; Kim, Rhee et al. 2009) while other authors

were unable to demonstrate statistically significant differences (Manton, Schweitzer et al. 2001; Lee, Ahn et al. 2003). Enhancement of tissue in this area has also been reported in both MRI and MRA investigations, indicating the presence of inflammation Figure 4.2 (Carrillion, Noel et al. 1999; Connell, Padmanabhan et al. 2002; Lefevre-Colau, Drape et al. 2005; Jung, Jee et al. 2006; Song, Kwon et al. 2011).

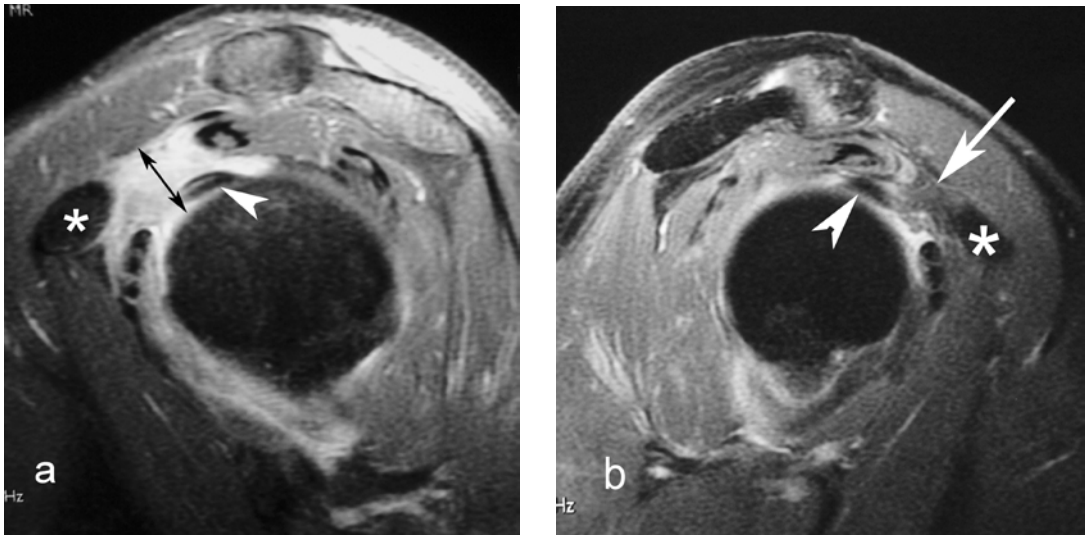


Figure 4.2 Magnetic resonance image of a 61 year old woman with clinical evidence of right adhesive capsulitis and a contra lateral healthy shoulder. Sagittal fat-suppressed T1-weighted spin-echo sequence after IV Gd-chelate enhancement (TR/TE=600 ms/15ms).

Note the marked enhancement of the joint capsule and synovial membrane in the rotator cuff interval (*black opposed arrow*) in the right AC shoulder (a) and the lack of enhancement in the contralateral healthy shoulder (*white double arrow*) (b). Biceps tendon (*arrowhead*) and coracoid process (*asterisk*) are shown. (Image reproduced with permission from: Lefevre-Colau M, Drape J, Fayad F et al. Magnetic resonance imaging of shoulders with idiopathic adhesive capsulitis: reliability of measures. *European Radiology* 2005; 15: 2415-2422).

Interestingly, Connell et al (Connell, Padmanabhan et al. 2002) surgically correlated rotator interval and synovial inflammation using MRI with respect to the various stages of adhesive capsulitis. Thickening of the joint capsule and the coracohumeral ligament in the rotator interval area have also been reported Figure 4.3 (Carrillion,

Noel et al. 1999; Mengiardi, Pfirrmann et al. 2004). Obliteration of the subcoracoid fat between the coracoid process and the coracohumeral ligament has further been described as a useful MRA finding (Mengiardi, Pfirrmann et al. 2004). Using a variety of methods including both enhanced and unenhanced MRI and direct (intraarticular) and indirect (intravenous) MRA, capsular thickening of the axillary recess has been suggested by several authors as a useful sign of adhesive capsulitis (Emig, Schweitzer et al. 1995; Lee, Ahn et al. 2003; Lefevre-Colau, Drape et al. 2005; Jung, Jee et al. 2006; Sofka, Ciavarra et al. 2008; Song, Kwon et al. 2011). However, conflicting results have also been reported (Carrillion, Noel et al. 1999; Manton, Schweitzer et al. 2001; Mengiardi, Pfirrmann et al. 2004).

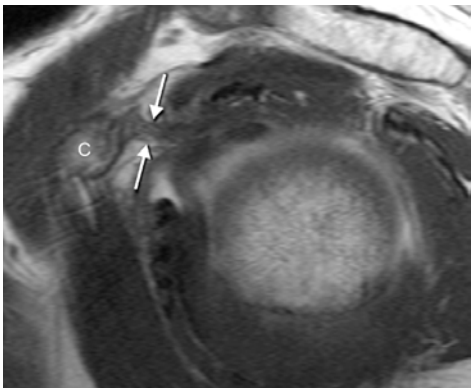


Figure 4.3 Sagittal oblique T1-weighted (700/12) image shows thickened CHL (arrows) in a 57-year-old patient with adhesive capsulitis.

C = coracoid process (Image reproduced with permission from: Mengiardi B, Pfirrmann C WA, Gerber C et al. Frozen shoulder: MR arthrographic findings. *Radiology* 2004; 233: 486-492).

Despite the findings reported in the literature, Petchprapa et al (Petchprapa, Beltran et al. 2010) have recently suggested that the clinical role of MRI may be limited due to the

variability of methodology in the studies reported to date. While some authors may draw certain conclusions from their studies, they are not always supported by others using differing methodologies. Further, as adhesive capsulitis is a disorder that progresses through a series of stages, reported results should be considered within the context of the duration of symptoms of the subjects. Some authors acknowledge the various stages of adhesive capsulitis in their studies, (Tamai and Yamato 1997; Connell, Padmanabhan et al. 2002; Sofka, Ciavarra et al. 2008) however it should be noted that generalized conclusions where the stage of the disorder has not been identified may need to be drawn with caution. Although findings have been described that may be useful indicators of adhesive capsulitis, plain MRI and MRA are not investigations routinely utilised in the primary health care setting and therefore their practical application to this disorder may be limited (Hsu, Anakwenze et al. 2011). Nonetheless the diagnosis of adhesive capsulitis is essentially clinical, and while not routinely performed in the early stage of adhesive capsulitis, MRI may facilitate a diagnosis at that stage which may be subsequently confirmed clinically (Petchprapa, Beltran et al. 2010).

4.4 The future of ultrasound in the diagnosis of adhesive capsulitis

As discussed earlier there is evidence that various radiological investigations have identified several features that may assist in the diagnosis of adhesive capsulitis. Other imaging modalities, notably power Doppler ultrasound, with the potential to assist

diagnosis, have received little attention. Two of these will be discussed in light of the current pathological understanding and existing radiological evidence.

4.4.1 Power Doppler ultrasound

The radiological assessment of vascularity has been made possible with technological improvements and, in particular, with both colour and power Doppler ultrasound. In contrast to colour Doppler ultrasonography, which is better suited to evaluate high velocity flow in large blood vessels, power Doppler ultrasound is better suited to detect low velocity blood flow in small vessels as in the synovium (Wakefield, Brown et al. 2003). Although power Doppler ultrasound has its origins in cardiac investigations, it has since been applied to other diagnostic situations including musculoskeletal medicine (Newman, Adler et al. 1994; Wamser, Bohndorf et al. 2003). In musculoskeletal inflammatory disease, power Doppler ultrasound has the potential to detect soft tissue hyperemia (Newman, Adler et al. 1994). Power Doppler has also been described as an efficient tool to measure and monitor disease activity and progression (Agrawal and Dasgupta 2008).

While most musculoskeletal ultrasound is performed using gray-scale ultrasound alone, the detection of hyperemia with both colour and power Doppler is reported to be becoming increasingly common (Boesen, Boesen et al. 2010). Power Doppler ultrasound has been demonstrated to provide a reliable and accurate method for visualizing blood flow in the synovial tissue of patients with osteoarthritis and rheumatoid arthritis of the knee joint (Walther, Harms et al. 2001). With respect to the shoulder, several studies that assessed biceps tendon pathology give evidence that this

modality provides important diagnostic information (Strunk, Lange et al. 2003; Wamser, Bohndorf et al. 2003; Chang, Wu et al. 2010). Notably power Doppler ultrasound has been able to distinguish between inflammatory and non-inflammatory shoulder pain through assessment of the biceps tendon sheath in patients with rheumatoid arthritis, compared with patients with degenerative diseases of the shoulder (Strunk, Lange et al. 2003). However, Wamser et al (Wamser, Bohndorf et al. 2003) conclude that while power Doppler ultrasonography is able to detect active inflammatory changes in the soft tissues of the shoulder, it is less capable than MRI in determining the degree of synovitis and distinguishing synovitis from fluid. The suggestions that a negative Doppler signal does not exclude the possibility of synovitis, but rather a positive signal is an indication of active synovitis has also been proposed (Koski, Saarakkala et al. 2006). Histopathologically, a minor colour signal in the synovium has been shown to be an important marker for synovitis, though the amount of colour may not correlate strongly with the severity of the histopathological synovitis (Koski, Saarakkala et al. 2006).

Both the current pathological and surgical evidence, together with findings on ultrasound and MRI imply the rotator interval is the area of initial synovial hyperaemia in adhesive capsulitis. It has been proposed that increased signal intensity of the joint capsule and synovium in the early stage is likely to reflect the active synovial and capsular response at this stage of the disorder (Sofka, Ciavarra et al. 2008). It would appear logical therefore that an imaging modality with the ability to detect synovitis may have potential to identify the early stage of adhesive capsulitis.

Figure 4.4 illustrates a power Doppler examination of a patient with clinically diagnosed adhesive capsulitis showing an area of increased vascularity in the rotator interval area. Evidence of enhanced vascularity in the rotator interval using colour Doppler ultrasound (Lee, Sykes et al. 2005) has been demonstrated, however the role of power Doppler ultrasound in the diagnosis of adhesive capsulitis remains to be investigated.

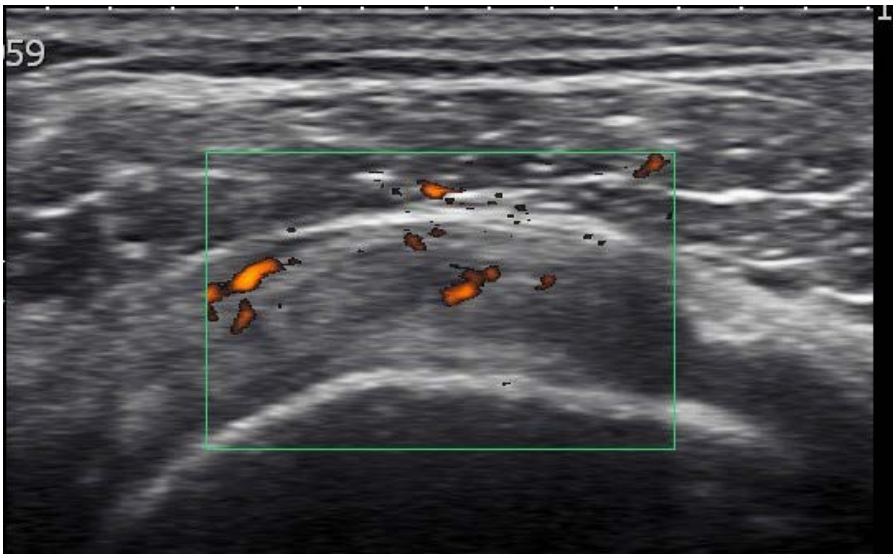


Figure 4.4 Power Doppler ultrasound of 54 year old female with a 6 month history of adhesive capsulitis demonstrating increased vascularity at the rotator cuff interval.

Although the use of Doppler ultrasound is promising in musculoskeletal medicine, a number of limitations require consideration. Application of Doppler ultrasound is influenced by the skill of the examiner, sensitivity of the machine, as well as technical artefacts (Walther, Harms et al. 2001). The technique is highly motion sensitive and even minimal soft tissue motion can make differentiation of blood flow from motion

difficult to discern (Rubin 1999). Further, excessive pressure from the transducer may also result in vessel occlusion, although a stand-off gel pad may minimize this issue (Wakefield, Brown et al. 2003). It has also been demonstrated that the selection of the ultrasound machine used for investigation is important as an inability to detect a signal at the capillary flow level may be due to flow in synovium being under the detection threshold of some machines (Koski, Saarakkala et al. 2006).

As ultrasound is safe, inexpensive, non-invasive and relatively accessible it may contribute in the future in diagnostically combining clinical signs and symptoms with objective radiological findings (Walther, Harms et al. 2001). Power Doppler is an emerging technology that may, by measurement of vascularity of the musculoskeletal system provide an indication of disease processes and progression (Joshua, Edmonds et al. 2006). Arguably therefore, there is merit in assessing the shoulders of patients with acute pain with respect to vascularity of the capsule and particularly the rotator interval to determine whether an increase in vascularity may be present, potentially assisting in the early diagnosis of adhesive capsulitis.

4.5 Conclusion

Ultrasound and MRI findings in adhesive capsulitis have been described and may be useful diagnostically, most notably demonstrating increased vascularity in the rotator interval (Lee, Sykes et al. 2005; Lefevre-Colau, Drape et al. 2005). Despite reports of radiological examinations potentially being of some value in the diagnosis of adhesive capsulitis, it has also been argued that to date these investigations do not provide any

real contribution over that of standard clinical assessment (Beggs 2006). Notably however, most studies have involved severe cases or those at a later stage of the disorder. With this imaging modality becoming increasingly popular in the clinical setting (Wakefield, Brown et al. 2003) power Doppler ultrasound may enable the clinician to combine imaging with the history and examination findings to facilitate early diagnosis of adhesive capsulitis. Future studies are required to explore these potential benefits.

Acknowledgements

We thank Dr Mariola Wierna for reviewing the manuscript prior to submission and Mariken Osmotherly for the artwork.

Chapter 5 Power Doppler ultrasound in the early diagnosis of primary/idiopathic adhesive capsulitis: an exploratory study

This chapter has been published in a peer-reviewed scientific journal:

Walmsley S, Osmotherly PG, Walker CJ, Rivett DA (2013). Power Doppler ultrasonography in the early diagnosis of primary/idiopathic adhesive capsulitis: an exploratory study. Journal of Manipulative and Physiological Therapeutics 36 (7): 428-435.

The work presented in this manuscript was completed in collaboration with the co-authors (Appendix 1).The ethics approval and supporting documents for the study reported in this chapter appear in Appendix 3.

Overview

A review of the current evidence that may support the role of diagnostic imaging in the diagnosis of adhesive capsulitis was outlined in the preceding chapter. The review identified that most of the studies published to date have been concerned with the later stages of the disorder when imaging's contribution to the clinical picture may add little over clinical examination. The review identified that power Doppler ultrasonography may have the potential to facilitate the early diagnosis of adhesive capsulitis and warranted further investigation. This chapter describes an exploratory study that was undertaken to determine the potential of power Doppler ultrasonography to identify the early stage of adhesive capsulitis. In particular, this study explores a method that

may be possible to use in the clinical setting as an adjunct to clinical diagnosis utilising common clinically available equipment.

5.1 Abstract

Objective: The purpose of this exploratory study was to determine if increased vascularity in the rotator interval area of the glenohumeral joint capsule could be visualised with power Doppler ultrasonography (PDUS) in patients with a clinical diagnosis of early stage adhesive capsulitis.

Methods: Demographic and clinical characteristics from a consecutive series of 41 patients diagnosed with early stage adhesive capsulitis were recorded and examination with PDUS was undertaken. Images were reviewed by three musculoskeletal radiologists, and consensus was determined on the presence of increased signal in the rotator interval area.

Results: Consensus was achieved on the presence of increased signal in 12 (29%) of the 41 cases. Participants with an increased PDUS signal did not demonstrate a characteristic set of identifying features, suggesting that those with increased vascularity may not constitute a distinct sub-group.

Conclusion: This study found that some patients diagnosed with early stage adhesive capsulitis demonstrated increased vascularity in the rotator interval area when examined with PDUS. These findings suggest that PDUS may have the potential to assist in the identification of increased vascularisation in the early stages of this

disorder. Further research in the use of PDUS in diagnosing early stage adhesive capsulitis is warranted.

5.2 Introduction

Shoulder pain commonly presents in the musculoskeletal primary care setting and may arise from many potential sources. Differential diagnosis frequently poses a dilemma as many disorders may present with similar symptoms and physical examination findings. Adhesive capsulitis of the shoulder has been typically reported to have an incidence of 2 - 5% (Hannafin and Chiaia 2000; Hand, Clipsham et al. 2008) and is described as being either primary or secondary (Hannafin and Chiaia 2000). Primary or idiopathic adhesive capsulitis has an unknown cause in contrast to secondary which results from a known event including trauma and surgery (Hannafin and Chiaia 2000). This disorder has been described as consisting of three stages (Pearsall and Speer 1998). The first or early stage is generally described as the painful stage and is considered to last up to nine months (Pearsall and Speer 1998). Adhesive capsulitis has been reported to be characterised by pain and progressive restriction of both active and passive shoulder movement as the patient progresses to the later stages (Pearsall and Speer 1998). It has also been reported to occur more commonly in women (Stam 1994) and in up to 30% of the diabetic population, and has also been associated with thyroid disorders, autoimmune diseases (Aydogan, Karan et al. 2003/2004) and Dupytren's disease (Bunker and Anthony 1995). The age at which this disorder is reported to most frequently occur is between 40 and 60 years (Hannafin and Chiaia 2000; Hand, Clipsham et al. 2008). The early stage of adhesive capsulitis is acknowledged as the

most difficult to diagnose as the clinical presentation at this stage may be confused with other shoulder disorders (Walmsley, Rivett et al. 2009).

It has been contended that treatment of adhesive capsulitis in its early stage may minimise the morbidity of the disorder (Hannafin and Chiaia 2000). In order that treatment may optimally be implemented, accurate and timely diagnosis is therefore required. The pathology of adhesive capsulitis has recently become better understood and it is now acknowledged that the process involved is initial inflammation followed by subsequent fibrosis of the glenohumeral joint capsule (Hand, Athanasou et al. 2007). The site at which the process is predominantly involved has been identified as the rotator interval area of the glenohumeral joint capsule (Ogilvie-Harris and Myerthall 1977; Ozaki, Nakagawa et al. 1989; Wiley 1991).

Musculoskeletal health care frequently relies on diagnostic imaging, together with clinical findings to inform the diagnosis of many conditions. Diagnostic imaging may be useful in contributing to a diagnosis, as well as to rule out other potential diagnoses. Although there is no clear criterion standard for diagnosis of early stage adhesive capsulitis, diagnostic imaging using ultrasonography (US) (Ryu, Lee et al. 1993; Lee, Sykes et al. 2005; Homsi, Bordalo-Rodrigues et al. 2006) and magnetic resonance imaging (MRI) (Emig, Schweitzer et al. 1995; Torstensen and Hollinshead 1999; Manton, Schweitzer et al. 2001; Connell, Padmanabhan et al. 2002; Lee, Ahn et al. 2003; Mengiardi, Pfirrmann et al. 2004; Lefevre-Colau, Drape et al. 2005; Jung, Jee et al. 2006; Yilmaz, Kantarci et al. 2007) have recently been suggested to assist the diagnosis of this disorder. Notably enhancement or hypervascularity of the rotator interval area has

been demonstrated with MRI in adhesive capsulitis (Connell, Padmanabhan et al. 2002; Lefevre-Colau, Drape et al. 2005; Sofka, Ciavarra et al. 2008; Song, Kwon et al. 2011). However most of the imaging findings that have been reported in these reports are in patients in the later stages of adhesive capsulitis when the clinical presentation more clearly indicates the diagnosis.

Assessment of the vascularity of soft tissues may also be achieved using both colour (CDUS) and power Doppler ultrasound (PDUS) (McNally 2011). There is preliminary evidence that CDUS has the potential to identify characteristics of early stage adhesive capsulitis (Lee, Sykes et al. 2005; Anderson and Read 2008). With more sensitivity to detect low blood flow such as occurs in inflammation of synovial tissue, PDUS has more recently gained popularity in the diagnosis and management of diseases of the musculoskeletal system (Joshua, Edmonds et al. 2006). Its use is becoming more widespread in the clinical setting as unlike some other imaging modalities, Doppler ultrasonography is a non invasive, generally accessible and relatively inexpensive non-ionising imaging modality. Nonetheless, the use of PDUS in the diagnosis of early stage adhesive capsulitis remains unexplored. Therefore, the aim of this study was to examine the rotator interval area of the shoulder with PDUS in a series of consecutive patients clinically diagnosed with early stage primary adhesive capsulitis to explore its potential use as a tool to assist clinicians. The goals of this study included assessing if it were possible to visualise with PDUS an area of increased vascularity in the rotator interval area of patients in the early stage of adhesive capsulitis and if there is an

association between clinical presentation or demographic variables and a reported increase in vascularity in the rotator interval as seen with PDUS in these patients.

5.3 Materials and Methods

5.3.1 Design

A consecutive case series of 41 patients diagnosed with early stage primary adhesive capsulitis on the basis of clinical presentation and attending an orthopaedic clinic specialising in upper limb disorders in New South Wales, Australia was invited to participate in the study. Power Doppler US examination was performed, and clinical measures of pain and shoulder range of movement and demographic information were collected in the clinic.

5.3.2 Participants

Potential participants were referred to the clinic by various medical practitioners with the clinical diagnosis of early stage adhesive capsulitis. In the absence of a validated set of clinical identifiers or diagnostic criteria for early stage adhesive capsulitis (de Winter, Jans et al. 1999; Walmsley, Rivett et al. 2009), the clinical decision of the referring medical practitioner was pragmatically considered appropriate. However, to ensure a homogeneous sample, and consistent with the diagnosis often being one of exclusion (Hannafin and Chiaia 2000; Manske and Prohaska 2008), strict inclusion and exclusion criteria were used. As the study was investigating the early stage of primary or idiopathic adhesive capsulitis, potential participants were required to have a history of less than nine months of shoulder pain that did not result from significant trauma,

fracture, dislocation or surgery. Potential participants were excluded if they either had not undergone recent radiographic and US investigation to exclude other pathologies, or these investigations revealed other pathologies including osteoarthritis, calcific tendonitis or a full thickness rotator cuff tear. The presence of a neurological disorder, rheumatoid arthritis and any systemic inflammatory joint disease, or an injection into the glenohumeral joint in the preceding six weeks, was a further exclusion criterion. The Human research Ethics Committee of The University of Newcastle granted ethical approval for this study. All participants provided written informed consent before the examination procedure.

5.3.3 Measurement

Participants first had a standard clinical history taken including recording of various pain descriptors relevant for adhesive capsulitis such as current level of pain and night pain measured on a visual analogue scale (0-100mm). Further recorded descriptors included presence of pain aggravated by movement, pain with rapid or unguarded movement, a feeling of nausea with movement, pain settling quickly after movement and pain worse towards the end of range, as well as waking due to pain (Rizk, Pinals et al. 1991; Stam 1994; Lin, Jarmain et al. 2004; Bunker 2009; Kelley, McClure et al. 2009). The Shoulder Pain and Disability Index (SPADI) (Staples, Forbes et al. 2010) was also administered before the scanning procedure.

The rotator interval of all participants was examined using a 12 MHz linear transducer with a commonly clinically used diagnostic US system (Model M5; Shenzhen Mindray Bio-medical Electronics Co., Ltd., China). Although more sophisticated US systems

may be available in specialist radiology practices, the system chosen was considered appropriate and sufficiently sensitive enough for this study, as the aim was to determine whether a tool commonly found in the primary care setting was of clinical utility in the diagnosis of early stage adhesive capsulitis. The examination was performed in the clinic by one of the researchers who had been individually trained in the use of the machine by both a musculoskeletal sonographer and an experienced musculoskeletal radiologist.

The participant was seated for the examination with the affected arm relaxed. The elbow was flexed with the forearm of the affected shoulder held in supination beside the patient's thigh, as has been previously described (Lee, Sykes et al. 2005; Stegbauer, Rump et al. 2008) (Figure 5.1).

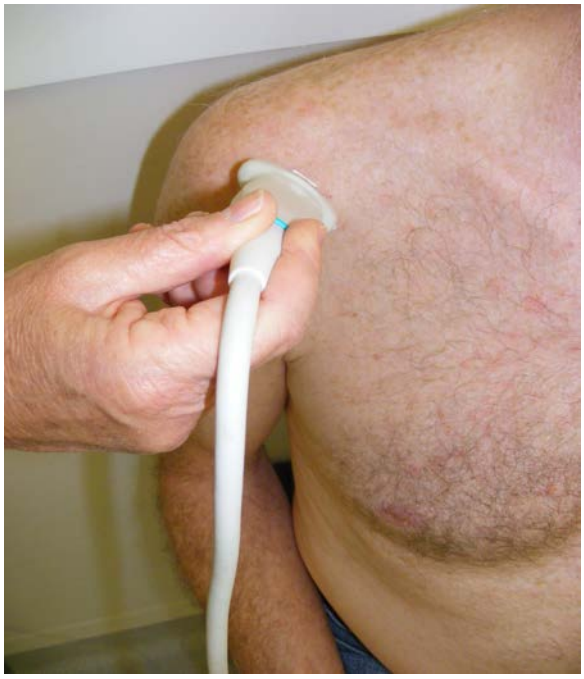


Figure 5.1 The position of the participant for the examination, with the hand of the affected shoulder held in supination beside the patient's thigh and transducer over the anterior shoulder

The transducer was positioned on the anterior shoulder with the biceps tendon visualised in its groove and the rotator interval identified. The rotator interval was visualised in the oblique plane as in previously published work (Lee, Sykes et al. 2005). This triangular area is located in the anterior portion of the glenohumeral joint capsule and is defined by the bordering structures (Kim, Rhee et al. 2009). Superiorly, the rotator interval area is bordered by the leading edge of the supraspinatus tendon, the superior edge of the subscapularis tendon inferiorly, the base of the coracoid medially and laterally by the long head of biceps tendon (Kim, Rhee et al. 2009) (Figure 5.2).

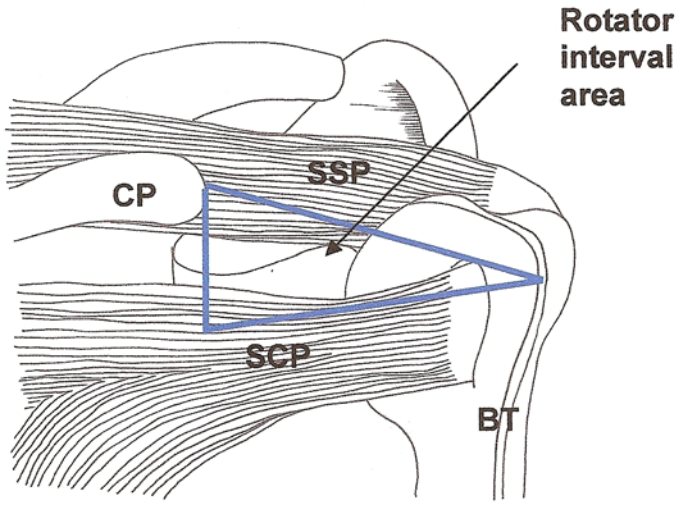


Figure 5.2 The rotator interval area of the glenohumeral joint capsule

Legend: BT = biceps tendon, CP = coracoid process, SCP = subscapularis muscle, SSP = supraspinatus muscle

The PDUS assessment was performed with settings standardised to a Doppler frequency of 6.6 MHz, and pulse repetition frequency and wall filters were set at a value determined by the system to be optimum according to the characteristics of the tissue being scanned. Still images were recorded and stored for later review. The operator's pressure on the probe was minimized to avoid compression of the small vessels. A pilot study of 10 patients was completed prior to the investigation to ensure technical aspects of the examination were optimised.

Following the PDUS examination, participants underwent clinical examination including measurement of passive, total shoulder flexion and abduction, glenohumeral joint flexion and abduction, external rotation in neutral and 90° abduction, and internal rotation in 90° abduction using a Baseline digital inclinometer (Fabrication Enterprises Incorporated. Irvington, NY, USA). Hand behind back range of movement was evaluated by measuring the distance between the radial styloid process and the spinous process of T1. Pain at the end of each passive movement was also recorded on a visual analogue scale. Both the examiner and the participant were blinded to the results of the US examination during the actual clinical examination, as this was performed prior to the radiologists' review of the recorded US scans.

Three blinded radiologists, each with a minimum of 17 years experience in musculoskeletal radiology, independently reviewed the recorded still images for the presence of a signal within the rotator interval area indicative of increased vascularity. The presence of increased signal in the rotator interval area was scored dichotomously as either absent or present. Although electronic quantification of power Doppler signal

has recently become available, to date it has been reported less frequently than scoring as present or absent (Joshua, Edmonds et al. 2006). Consensus was determined when two or more of the radiologists agreed on the presence of an increased signal in the rotator interval area. Consensus interpretation of US images has been used in previously published studies (Lee, Sykes et al. 2005).

5.3.4 Data Analysis

Data were analysed using Stata 11.0 statistical software (Stata Corporation, Texas, USA). Values for each clinical examination variable were analysed by the reported presence (positive group) or absence (negative group) of increased PDUS signal in the rotator interval area. The differences between group mean values or medians were evaluated with the independent t-test or Mann-Whitney tests for continuous variables, and $\chi 2$ or Fisher's exact tests were used for categorical variables. A difference with a *P* value of less than or equal to 0.05 was considered statistically significant.

5.4 Results

5.4.1 Characteristics of participants

Demographic and clinical characteristics of the participants are shown in Table 5.1. The age of participants in the positive PDUS group was higher than that of the negative PDUS group, although this did not quite achieve statistical significance ($P = 0.08$). There were a slightly higher proportion of female participants, a shorter mean duration of symptoms, and a slightly higher incidence of Dupytren's disease and thyroid disorders in the participants with a positive scan. There was also a lower SPADI score

and complete absence of diabetic participants in the positive PDUS group, as well as a trend for the non-dominant shoulder to be more frequently affected. The positive PDUS group also had a greater proportion of participants who reported preceding minor trauma to the affected shoulder. Despite these differences, there was no statistically significant disparity between the groups of participants with a positive PDUS signal and a negative PDUS signal with respect to any of these variables.

Table 5.1 Demographic and clinical characteristics of participants

Characteristic	Total sample (n = 41)	Positive PDUS (n = 12)	Negative PDUS (n = 29)	*P* value for difference between groups
Age (mean ± SD years)	56.0 ± 7.2	59.2 ± 6.5	54.8 ± 7.2	0.08
No. (%) female	19 (46.3)	6 (50.0)	13 (44.8)	0.76
Duration of symptoms (mean ± SD months)	5.4 ± 1.8	4.8 ± 1.7	5.7 ± 1.8	0.15
Preceding minor trauma No. (%)	14 (34.2)	5 (41.7)	9 (31.0)	0.51
Affected shoulder dominant No. (%)	19 (46.3)	4 (33.3)	15 (51.7)	0.28
Dupytren's disease No. (%)	7 (17.1)	3 (25.0)	4 (13.8)	0.39
Diabetes No. (%)	3 (7.3)	0 (0)	3 (10.3)	n/a
Thyroid disorders No. (%)	3 (7.3)	1 (8.3)	2 (6.9)	0.66
SPADI score (mean ± SD)	48.9 ± 18.1	43.3 ± 19.3	51.3 ± 17.3	0.11

Legend: PDUS, power Doppler ultrasound, SPADI, Shoulder Pain and Disability Index

5.4.2 Patient reported findings

The comparison of the various pain descriptors in the positive and negative groups is shown in Table 5.2.

Table 5.2 Comparison of reported descriptors of pain in the positive PDUS and negative PDUS groups

Descriptor	Total sample (n = 41)	Positive PDUS (n = 12)	Negative PDUS (n = 29)	*P* value for difference between groups
Current pain (VAS mean ± SD)	24 ± 26	16 ± 28	27 ± 26	0.08
Pain during preceding night (VAS mean ± SD)	54 ± 24	51 ± 25	55 ± 24	0.71
Waking at night > 2x No. (%)	32 (78.0)	10 (83.3)	22 (75.9)	0.70
Pain aggravated by movement No. (%)	35 (85.4)	10 (83.3)	25 (86.2)	0.58
Pain settles quickly after movement No (%)	32 (78.0)	10 (83.3)	22 (75.9)	0.60
Pain with rapid movement No. (%)	37 (90.2)	11 (91.7)	26 (89.7)	0.67
Nausea with movement No. (%)	20 (48.8)	3 (25)	17 (58.6)	0.05 a
Pain worse towards the end of range No. (%)	38 (92.7)	11 (91.7)	27 (93.1)	0.66

Legend: PDUS, power Doppler ultrasound; VAS, visual analogue scale (0.100mm); [a] $P \leq 0.05$

Reported descriptors of pain, including severity of night pain and waking due to pain were not significantly different between the groups of participants with and without a positive PDUS scan. The only exception to this was the descriptor of the feeling of nausea with movement which was reported less frequently in the positive group ($P = 0.05$). Levels of pain at rest before the examination (current pain) were less in the positive group, approaching statistical significance ($P = 0.08$).

5.4.3 Physical examination findings

Measurements of passive range of movement and pain at the end of range of passive movement are shown in Table 5.3.

Table 5.3 Comparison of passive range of movement (degrees) and pain (visual analogue scale) at the end of ranges of passive movement (mean ± SD) in the positive and negative PDUS groups

	Total sample (n = 41)	Positive PDUS (n = 12)	Negative PDUS (n = 29)	*P* value for difference between groups
Range total shoulder flexion, (mean ± SD, deg)	126.4 ± 20.3	124 ± 21.7	131.3 ± 16.1	0.33
Pain total shoulder flexion (mean ± SD, VAS)	67 ±23	65 ± 26	67 ± 22	0.98
Range glenohumeral joint flexion (mean ± SD, deg)	103.9 ± 18.6	101.2 ± 18.0	110.4 ± 16.8	0.15
Pain glenohumeral joint flexion (mean ± SD, VAS)	49 ± 33	33 ± 32	56 ± 27	0.03[a]
Range total shoulder abduction (mean ± SD, deg)	92.1 ± 21.2	88.7 ± 23.9	100.6 ± 8.7	0.080
Pain total shoulder abduction (mean ± SD, VAS)	68 ± 27	67 ± 26	68 ± 28	0.67
Range glenohumeral joint abduction (mean ± SD, deg)	69.8 ± 18.2	67.4 ± 18.3	75.7 ± 17.1	0.187
Pain glenohumeral joint abduction (mean ± SD, VAS)	66 ± 22	64 ± 22	67 ± 20	0.69
Range external rotation in adduction (mean ± SD, deg)	43.3 ± 16.4	41.1 ± 16.6	48.6 ± 15.0	0.186
External rotation in adduction (mean ± SD, VAS)	67 ± 25	60 ± 32	70 ± 21	0.46
Range external rotation in abduction (mean ± SD, deg)	38.5 ± 17.5	36.3 ± 15.0	43.8 ± 22.3	0.430
External rotation in 90° abduction (mean ± SD, VAS)	77 ± 18	74 ± 22	70 ± 21	0.56
Range internal rotation in abduction (mean ± SD, deg)	53.0 ± 14.1	53.0 ± 14.6	52.8 ± 13.2	0.785
Internal rotation in 90° abduction (mean ± SD, VAS)	49 ± 29	49 ± 35	49 ± 27	0.93
Range hand behind back (mean ± SD, cm) [b]	43.5 ± 8.3	45.0 ± 9.1	39.9 ± 4.4	0.055
Hand behind back (mean ± SD, VAS)	74 ± 22	69 ± 28	76 ± 19	0.57

Legend: VAS = visual analogue scale (0-100 mm), [a] $P \leq 0.05$, [b] note larger distance indicates more restricted range

There was an overall tendency to report less pain at the end of range of passive movement in the positive PDUS participants, but these generally failed to reach

statistical significance. The exception was pain at the end of glenohumeral joint flexion which was significantly less in the positive PDUS group ($P = 0.03$). None of the measured ranges of passive movement showed significant differences between the two groups of participants, although 'hand behind back' demonstrated a strong trend to be less restricted in the positive PDUS group ($P = 0.055$). Following review of the recorded images by the radiologists, 12 (29%) of the 41 patients were considered to demonstrate the presence of an increased signal in the rotator interval area, as shown in Figure 5.3.

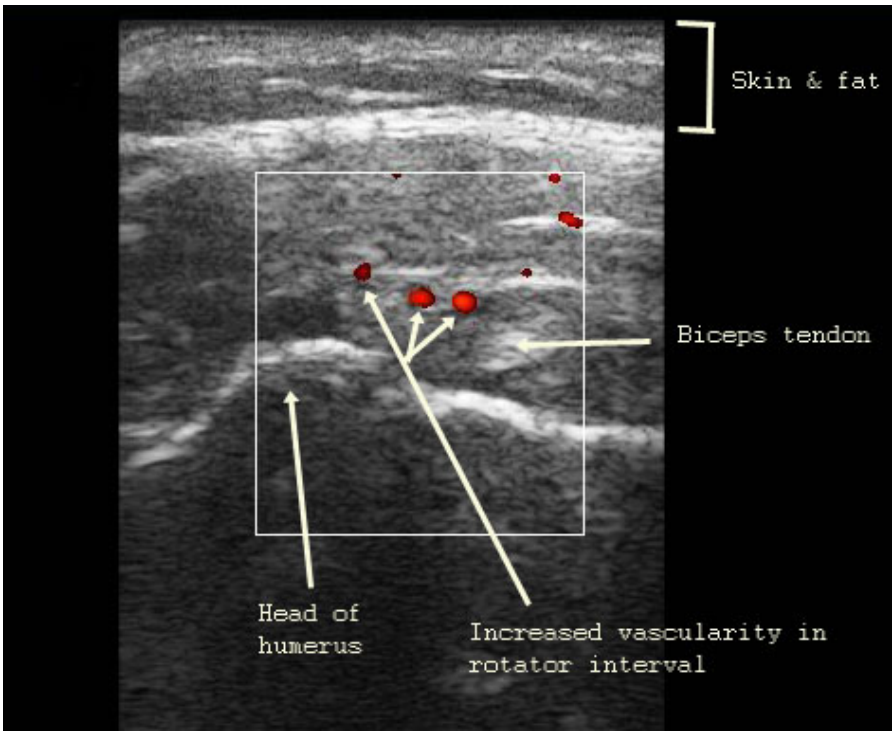


Figure 5.3 Power Doppler ultrasound image of the right shoulder of a 60 year old female demonstrating the presence of increased signal in the rotator interval area

5.5 Discussion

This is the first study to examine the rotator interval area of the shoulder using PDUS in a group of patients diagnosed clinically with early stage primary adhesive capsulitis. The findings of this study can be considered hypothesis generating with regard to the potential value of PDUS in demonstrating increased vascularity in the rotator interval area of the shoulder in patients diagnosed with early stage adhesive capsulitis. An increase in vascularity was demonstrated in 12 (29%) of 41 participants, indicating that it may be clinically possible to visualise an increased signal in the rotator interval area of the shoulder using PDUS examination. However, participants with an increased signal did not demonstrate a characteristic set of identifying features that differentiated them from those with a negative PDUS examination, suggesting that they do not constitute a distinct sub-group in this population.

Most of the reported descriptions of changes seen on US and MRI examination (Ryu, Lee et al. 1993; Emig, Schweitzer et al. 1995; Torstensen and Hollinshead 1999; Manton, Schweitzer et al. 2001; Connell, Padmanabhan et al. 2002; Mengiardi, Pfirrmann et al. 2004; Lee, Sykes et al. 2005; Lefevre-Colau, Drape et al. 2005; Homsi, Bordalo-Rodrigues et al. 2006; Ahn, Kang et al. 2012) have been concerned with the latter stages of adhesive capsulitis when clinically recognisable signs and symptoms are quite obvious, essentially rendering imaging of little value. Nonetheless, rotator interval radiological abnormalities have been reported to correlate well with surgical and pathological findings (Connell, Padmanabhan et al. 2002). Notably, in the early stage of adhesive capsulitis, hypertrophic vascular synovitis has been identified at arthroscopic

examination (Hannafin and Chiaia 2000). It has therefore been suggested that Doppler US has the potential to identify this area of increased vascularity in the rotator interval area of the shoulder in patients with adhesive capsulitis (Lee, Sykes et al. 2005). Lee et al examined subjects with adhesive capsulitis with CDUS before arthroscopy who had symptoms for less than 12 months and demonstrated enhanced vascularity and hypoechoic change in the rotator interval that correlated well with the surgical findings (Lee, Sykes et al. 2005). In particular, PDUS enables the assessment of vascular tissues along with the detection of low velocity blood flow at the microvascular level (Wamser, Bohndorf et al. 2003) and so is well suited to identify the inflammation reported to be present in the early stage of adhesive capsulitis.

The present study was able to demonstrate the presence of increased vascularity with PDUS in 29% of the participants examined, suggesting that this diagnostic imaging tool may be useful in identifying some patients with early stage adhesive capsulitis. Some of the measured variables in this exploratory study have demonstrated trends that, in future experimental studies, have the potential to be further investigated using a larger sample and suitable study design. Interestingly, although failing to reach statistical significance, the 12 participants who demonstrated the presence of increased vascularity in the rotator interval area reported a shorter mean duration of symptoms, consistent with observed inflammatory changes in the early stage of the disorder (Hannafin and Chiaia 2000). Adhesive capsulitis has been described in three stages with the early stage lasting up to nine months (Pearsall and Speer 1998). Participants in this study were required to have had symptoms for less than nine months; however, it

may be that this increase in vascularity is more pronounced or more easily observed with PDUS at an earlier stage of the disorder. The mean duration of symptoms for all participants was 5.4 (± 1.8) months, which may be beyond the period when changes are most apparent using PDUS. Only one patient reported symptoms for less than three months when arguably it may be the best time to visualise an increase of vascularity in this area using PDUS due to the inflammatory nature of the disorder at that time (Hannafin and Chiaia 2000). Notably this participant, with a history of symptoms of two and a half months, had a positive PDUS finding.

It is widely reported that the age at which adhesive capsulitis most frequently occurs is between 40 and 60 years (Hand, Clipsham et al. 2008). The age of participants in the current study was consistent with this characteristic, although there was a trend for participants with a positive finding to demonstrate a greater mean age than those with a negative finding. Other findings include a greater percentage of females, and a higher incidence of Dupytren's disease and thyroid disorders in the positive PDUS group which is consistent with the frequently cited characteristics of this disorder (Brue, Valentin et al. 2007; Manske and Prohaska 2008; Neviaser and Hannafin 2010). In contrast, the lack of diabetic participants in the positive PDUS group is an unexpected finding considering the strong association that this disease has with adhesive capsulitis (Scarlat, Goldberg et al. 2000); however the group size was relatively modest. Although the clinic manages patients from a variety of demographic groups and socio-economic backgrounds within its geographic region, it is possible that other populations may display different characteristics, such as a higher prevalence of diabetes. It has recently

been argued that adhesive capsulitis may be clinically over-diagnosed (Bunker 2009) which raises the possibility that some of the participants in this study may have had disorders other than adhesive capsulitis, potentially explaining some of the negative PDUS findings. Bunker (Bunker 2009) has also challenged several traditional associations including with female sex and thyroid disorders, whilst noting that associations with diabetes and Dupytren's disease have a more robust scientific basis.

It is now considered that capsular inflammation is a predominant pathological feature of the early stage of adhesive capsulitis (Hand, Athanasou et al. 2007), and therefore arguably may be considered responsible for the pain behaviour seen at this stage. It was therefore surprising that analysis of various pain descriptors revealed lower scores in the positive PDUS group, although not statistically significant. Similarly, the severity of pain at the end of passive range of movement was less in the positive PDUS group, significantly so with glenohumeral shoulder flexion, which is somewhat difficult to explain.

Musculoskeletal medicine uses a combination of assessment tools, including patient reported symptoms and physical examination findings, together with results of various diagnostic imaging and pathological investigations to achieve a diagnosis. It has been suggested that the diagnosis of adhesive capsulitis is essentially clinical (Ahn, Kang et al. 2012); however the addition of a pathognomic diagnostic imaging finding may provide valuable information to support a diagnosis in some cases. The main finding of the current study is that we have confirmed that it may be possible to visualise the presence of vascularity using PDUS in the rotator interval area of the glenohumeral

joint capsule in some patients diagnosed with early stage adhesive capsulitis in the clinical setting. Ultrasonographic examination in the clinical setting is becoming increasingly more common, and the findings from this study provide preliminary evidence to suggest that it may be useful in cases of suspected early stage adhesive capsulitis.

5.5.1 Limitations

Firstly, because of the requirement that patients have symptoms for less than nine months a comparison against a criterion standard was not possible. As acknowledged in other studies (Ahn, Kang et al. 2012), the lack of a criterion standard, such as surgical findings with which to make comparison, may limit the conclusions that can be drawn. The diagnosis of adhesive capsulitis was based on patient history and physical examination findings together with diagnostic imaging to exclude other pathologies. Thus, it is possible that some of the patients in this study did not have early stage adhesive capsulitis. Secondly, the sample size was modest, as appropriate for an exploratory case series. A larger sample may have increased the overall power of the study to find statistically significant differences between patients with a positive PDUS finding and a negative PDUS finding with some of the variables measured. This may have helped identify the characteristics of a sub-group of patients for which this tool is able to assist the diagnosis of early stage adhesive capsulitis. Slow recruitment of participants with adhesive capsulitis has been previously reported (Buchbinder, Green et al. 2004), however the strict but necessary criteria that were set for inclusion were required to ensure an appropriate sample. As this was an exploratory study, a control

group was not included. An experimental study with matched control participants would be required to confirm the results of this preliminary study. It would be useful in future studies to compare these findings in patients with clinical signs of other pathologies.

Finally there are potential technical limitations. Ultrasonography is known to be operator dependent (Wakefield, Brown et al. 2003; Boesen, Boesen et al. 2010), however, specific, individualised training was given to the researcher who performed the scans in examining the rotator interval area. Nonetheless, if this tool continues to be increasingly used in the primary care clinical setting, many clinicians will likely received similar training to that of the researcher who performed the US examinations in the present study. Although this study has demonstrated the presence of an increased PDUS signal in 29% of patients with the clinical diagnosis of early stage adhesive capsulitis, the lack of a signal in the others may be due to the blood flow in the synovium being under the detection threshold of the machine that was used (Koski, Saarakkala et al. 2006). With rapid advances in technology, however, this may not remain an ongoing issue. Although limiting the external generalisability of PDUS in the primary care clinical setting, further studies in a specialised diagnostic imaging clinic using machines with greater sensitivity and more experienced operators may provide different findings.

5.6 Conclusion

The findings of this exploratory study suggest that PDUS may have the potential to assist in identification of increased vascularisation in early stages of adhesive capsulitis. Further research in the use of PDUS in diagnosing early stage adhesive capsulitis using a study design involving a control group and larger patient numbers and including various other shoulder disorders is warranted.

Chapter 6 Movement and pain patterns in early stage primary/idiopathic adhesive capsulitis: a factor analysis

This chapter has been published in a peer-reviewed scientific journal:

Walmsley S, Osmotherly PG, Rivett DA (2014). Movement and pain patterns in early stage primary/idiopathic adhesive capsulitis: a factor analysis. Physiotherapy. In press, doi: 10.1016/j.physio2014.02.001.

The work presented in this manuscript was completed in collaboration with the co-authors (Appendix 1).The ethics approval and supporting documents for the study reported in this chapter appear in Appendix 3.

Overview

Assessment of patients with shoulder pain involves combining information gained through the history as well as the physical examination, and may also include special clinical tests. Identification of characteristic patterns of movement and pain are integral to this assessment and traditionally have been used to facilitate diagnosis in many musculoskeletal disorders. Interestingly a particular pattern of movement restriction and pain was not identified by the expert panel in the Delphi study (Chapter 3). This chapter explores the possibility of a pattern of movement loss and associated pain that may exist in a group of patients clinically diagnosed with early stage adhesive capsulitis.

6.1 Abstract

Objectives: To evaluate patients clinically diagnosed with early stage primary/idiopathic adhesive capsulitis to determine the existence of any pattern of movement loss and associated pain that may facilitate early recognition.

Design: Cross-sectional study.

Setting: Private upper limb specialty clinic, Newcastle, Australia.

Participants: Fifty-two patients clinically diagnosed with early stage adhesive capsulitis by a medical practitioner or physiotherapist.

Main outcome measures: Percentage loss of active and passive ranges of eight shoulder movements and the pain level at the end of each movement. The reason for limitation of movement was also recorded.

Results: Factor analysis clearly identified two groups for percentage loss of active movement. Notably external rotation movements grouped separately from other movements. A single group emerged for percentage loss of passive range of movement suggesting a non-specific global loss. For both pain at the end of active and passive ranges of movement two groups emerged, however the delineation between the groups was less clear than for percentage loss of active range of movement suggesting pain at the end of range may be less useful in identifying patients in this stage.

Conclusions: External rotation movements in neutral and abduction generally group together and behave differently to other shoulder movements in patients clinically

diagnosed with early stage primary/idiopathic adhesive capsulitis. In particular external rotation in abduction has emerged as the most painfully limited movement in this sample. This study provides preliminary evidence of patterns of range of movement and end range pain that require testing in a population of mixed shoulder diagnoses to determine their diagnostic utility for early stage adhesive capsulitis.

6.2 Introduction

Adhesive capsulitis is a shoulder disorder that is recognised as consisting of three stages and reported to last from one to three years (Reeves 1975). The disorder is described as either primary or idiopathic when the onset is insidious, and secondary when a known event precedes the onset (Hannafin and Chiaia 2000). Adhesive capsulitis has a number of reported associations that include, but are not limited to, diabetes (Massoud, Pearce et al. 2002), Dupytren's disease (Smith, Devaraj et al. 2001) and thyroid dysfunction (Cakir, Samanci et al. 2003), as well as a reported higher incidence in females (Stam 1994). The first or early stage is generally agreed to last up to nine months and is characterised by pain rather than marked loss of movement (Pearsall and Speer 1998). Whilst adhesive capsulitis is usually recognisable in the later stages due to distinct restriction of both active and passive ranges of movement (Kelley, McClure et al. 2009), it is considered difficult to identify and differentiate from other shoulder disorders in its early stage (Lubiecki and Carr 2007).

Routine assessment of patients with musculoskeletal disorders generally includes measurement of both active and passive ranges of movement, as well as any pain

associated with each movement. Patterns of movement deficit and the behaviour of pain often assist in diagnosis (Carter, Hall et al. 2012). As a means of differentiating joint capsular pathology from other causes of symptoms, James Cyriax described what is called the 'capsular pattern' (Cyriax and Cyriax 1993). This capsular pattern suggests a fixed proportion of movement loss is present and that each joint has a characteristic pattern (Cyriax and Cyriax 1993). The pattern for the glenohumeral joint proposed by Cyriax is that the proportional passive loss of external rotation will be greater than the proportional loss of abduction, which will be greater than the proportional loss of internal rotation. Although the literature on adhesive capsulitis frequently acknowledges this 'capsular pattern' (Reeves 1975; Vermeulen, Stokdijk et al. 2002), recent studies have demonstrated that it may not be consistently present (Rundquist, Anderson et al. 2003; Mitsch, Casey et al. 2004; Rundquist and Ludewig 2004). Notably, however, these studies have involved populations in the latter stages of the disorder. No studies have examined the presence of the 'capsular pattern', nor any other recognisable pattern of movement loss in the early stage of adhesive capsulitis.

Recent research into the pathology of adhesive capsulitis has identified that initial inflammation of the glenohumeral joint capsule is followed by fibrosis and contracture (Hand, Athanasou et al. 2007). This understanding of the pathology provides an explanation for the temporal behaviour of the symptoms, which are reported to initially manifest with pain followed by subsequent progressive movement restriction (Hannafin and Chiaia 2000). Surgical and radiological investigations have identified that anterior structures of the glenohumeral joint are predominantly affected (Ozaki,

Nakagawa et al. 1989; Connell, Padmanabhan et al. 2002), which may help explain the observed pattern of movement loss or pain reported in adhesive capsulitis, notably in external rotation (Hanchard, Goodchild et al. 2011). However, the contribution of other active and passive shoulder movements to diagnosis have not been similarly considered.

As well as the lack of investigation of any pattern of either active or passive movement loss in early stage adhesive capsulitis, any associated pain pattern has also not been described to date. As pain is reported to be a key component of the early stage, it would therefore be potentially valuable to evaluate any contribution it may make to the clinical presentation of this disorder.

It has been suggested that treatment in the early stage of adhesive capsulitis may reduce the overall morbidity of the disorder (Hannafin and Chiaia 2000). The mixed results of treatment of adhesive capsulitis reported however, have been suggested to be at least partially as a result of the inability to define or classify sub-groups of patients likely to respond to physiotherapy and other interventions (Yang, Chang et al. 2008). Although a set of clinical identifiers that may assist diagnosis in the early stage have been proposed, including global loss of active and passive ranges of movement and pain at the end-range in all directions, they have yet to be validated (Walmsley, Rivett et al. 2009). The recognition of any pattern of movement restriction or pain that may assist early stage diagnosis or identify sub-groups of patients would therefore be valuable. The overall aim of this study was to evaluate patients with a clinical diagnosis of early stage adhesive capsulitis to determine if it was possible to identify a

pattern of movement loss and/or associated end range pain that may facilitate recognition of this diagnostically challenging stage of the disorder. The findings of this preliminary study will enable future studies of mixed diagnosis populations to determine whether any patterns that may emerge are unique to the early stage of primary/idiopathic adhesive capsulitis.

6.3 Materials and methods

The Human Research Ethics Committee of The University of Newcastle granted ethical approval for this study.

6.3.1 Participants

Fifty-two participants attending an upper limb speciality clinic diagnosed with early stage adhesive capsulitis on the basis of clinical presentation by various health care practitioners, including orthopaedic surgeons, a shoulder physician, general practitioners and physiotherapists were included in the study. In the absence of any validated criteria for the diagnosis of early stage primary/idiopathic adhesive capsulitis the clinical decision of the referring practitioner was considered pragmatically appropriate. Participants were required to have had symptoms for less than nine months, consistent with the reported duration of the early stage of the disorder (Pearsall and Speer 1998). As primary/idiopathic adhesive capsulitis was being investigated, patients with a history of major trauma or surgery of the shoulder were excluded. Potential participants were also required to have had recent shoulder X-rays and ultrasound examinations which did not demonstrate potential alternate diagnoses.

Further exclusion criteria included a diagnosis of any systemic inflammatory joint disease, as well as neurological or current cervical spine disorders. Glenohumeral joint injection in the preceding six weeks was also an exclusion criterion.

6.3.2 Procedure

Each participant underwent routine clinical examination including measurement of active and passive shoulder ranges of movement. These included total shoulder flexion (TSF) and abduction (TSA), glenohumeral joint flexion (GHF) and abduction (GHA), and external rotation in neutral (ERN), together with external and internal rotation in 90° abduction (ERA and IRA respectively). Hand behind back (HBB) range was also measured. Measurement was performed by one of the researchers, an experienced musculoskeletal physiotherapist, using a Baseline digital inclinometer (Fabrication Enterprises Incorporated, Irvington, NY, USA) for all movements with the exception of HBB which was measured with a tape measure. Digital inclinometery has been demonstrated to have a measurement error of ±1° (Downer and Sauers 2005). The range of movement was recorded in degrees for all movements other than HBB which was recorded in millimetres.

Measurement of shoulder ranges of movement was based on the method described by Green et al (1998). The following movements were performed in sitting: TSF, GHF, TSA, and GHA. The starting position for these movements was with the palm of the hand facing medially. The inclinometer was held on the mid shaft of the humerus by the researcher and the participant maintained an extended elbow (Green, Buchbinder et al. 1998). In order to stabilise the scapula and isolate the glenohumeral joint for GHF

and GHA, a device was developed that provided an arm that rested on the acromion, preventing upward rotation of the scapula Figure 6.1.

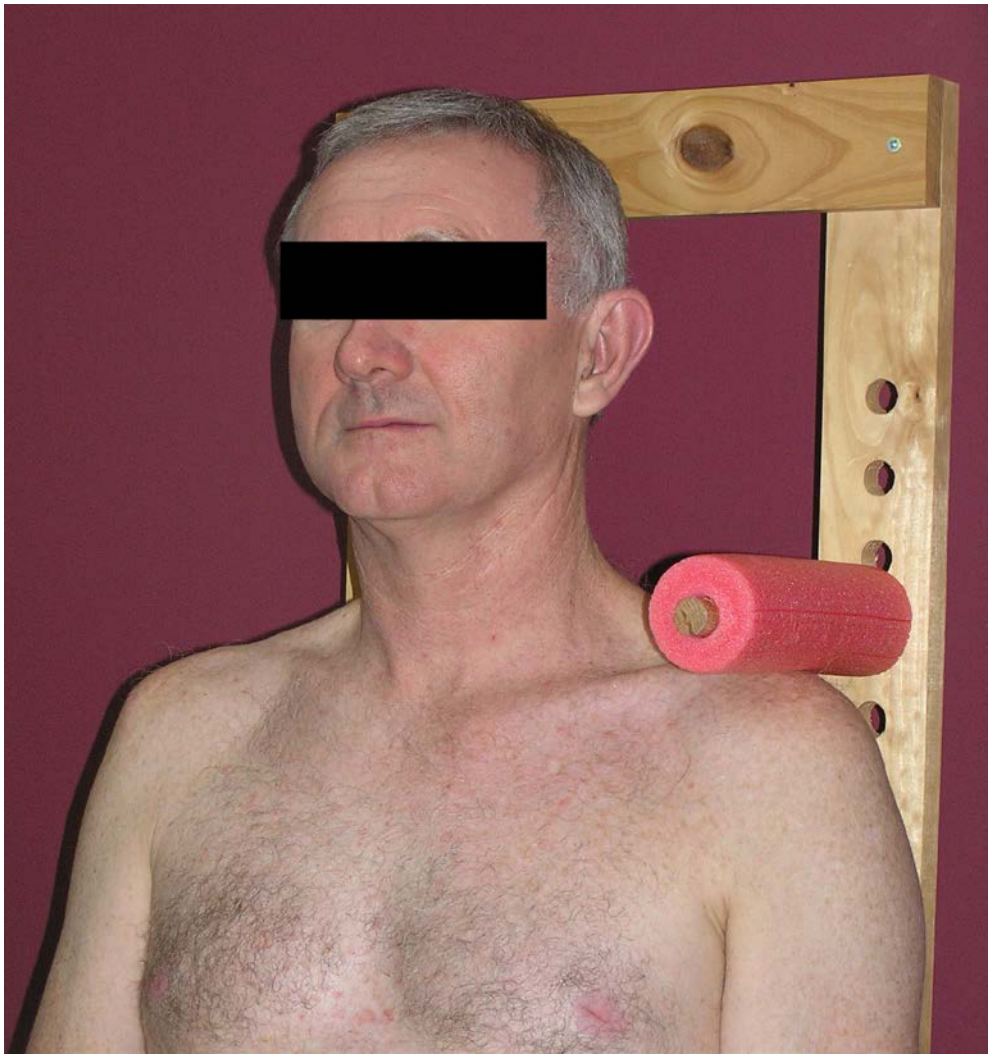


Figure 6.1. Device to isolate glenohumeral joint movement

The following movements were performed in the supine lying position:

- ERN: The shaft of the humerus was placed beside the participant's trunk in 0° of abduction and rotation. A towel was placed under the humerus to ensure it rested parallel to the plinth. The elbow was flexed to 90° and the forearm was in neutral

rotation. The inclinometer was placed on the dorsal surface of the participant's forearm.

- ERA: The arm was abducted to 90° where possible, or if not possible due to either movement restriction or pain, abduction was taken to the limit of movement. The position of the humerus and placement of the inclinometer was the same as measurement of ERN.
- IRA: The arm was placed as described for ERA and internally rotated until either the posterolateral acromion was visualised to rise off the plinth (Awan, Smith et al. 2002), or the movement was limited by pain.

HBB was measured in standing as the distance between the spinous process of T1 and the radial styloid process. This has been demonstrated to have excellent intrarater reliability (Ginn, Cohen et al. 2006).

In order not to aggravate the participant's pain, each movement was performed only once. All active movements were performed prior to passive movements and in the same sequence for each participant. The order of measurement was: TSF, GHF, TSA, GHA, ERN, ERA, IRA, HBB. Active range of movement was performed by asking the participant to move their arm in the required direction until it was not possible to move any further or the pain became intolerable. Similarly, passive range of movement was performed by the researcher to the point of resistance limitation or when the participant reported the pain was intolerable. The limiting factor to movement was recorded simply as pain or inability to move for active movements and resistance or pain for passive movements. Regardless of the cause of limitation, each participant

scored their level of pain at the end of each movement on a 100mm visual analogue scale.

6.4 Statistical analysis

The data were analysed initially using descriptive statistics. The affected shoulder's percentage of movement of the unaffected shoulder was calculated for each of the eight active and eight passive movements.

For all movements with the exception of HBB:

$$\frac{unaffected\ shoulder\ range\ of\ movement\ -\ affected\ shoulder\ range\ of\ movement}{unaffected\ shoulder\ range\ of\ movement}$$

For HBB:

$$\frac{d1\,affected\ shoulder - d1\,unaffected\ shoulder}{d1\,unaffected\ shoulder}$$

($d1$ = distance between T1 spinous process and radial styloid process)

Factor analysis was then used to determine if it was possible to identify any relationships between the ranges of movement loss and similarly the pain behaviour at the end of each of the ranges of movement. Any such relationships, or movements grouping together, may denote the formation of patterns. Exploratory factor analysis was performed using the principal components method for extraction of factors followed by Varimax rotation. A combination of an Eigenvalue of >1.00 and inspection of the scree plot was used to determine the optimum number of factors within each

range of movement or pain score. Item loadings of ≥0.60 were considered to contribute strongly to that factor. Factors with four or more variables ≥0.60 were considered strong factors. All statistical analyses were performed using JMP 9.0, (SAS Institute Inc, Cary, NC, USA).

6.5 Results

Demographic characteristics of the participants are presented in Table 6.1. The mean (SD) shoulder ranges of active and passive movement (affected and unaffected), percentage loss of range of movement and pain scores at the end of range of movement are reported in Table 6.2.

Table 6.1 Demographic characteristics of the participants (n = 52)

Characteristic	
Age (yrs), mean (SD)	55.2 (6.9)
Duration of symptoms (months), mean (SD)	5.5 (1.9)
Gender (% female)	51.9
Dominance (% right)	84.6
History of diabetes (%)	9.6
History of Dupytren's disease (%)	13.5

Table 6.2 Mean (SD) shoulder ranges of active and passive movement (unaffected and affected), percentage loss of active ranges of movement and pain scores at the end of range of each movement

Movement	Unaffected shoulder ROM (degrees) Mean (SD)	Affected shoulder ROM (degrees) Mean (SD)	% loss ROM Mean (SD)	Pain score end of range (mm) Mean (SD)
A: ACTIVE MOVEMENT				
Total shoulder flexion	161.9 (12.8)	116.4 (22.8)	28 (13)	62 (25)
Glenohumeral joint flexion	126.8 (12.8)	93.6 (18.2)	26 (14)	50 (28)
Total shoulder abduction	146.0 (16.4)	81.4 (28.3)	46 (18)	69 (25)
Glenohumeral joint abduction	114.9 (21.0)	55.6 (23.2)	52 (18)	59 (28)
External rotation in neutral	67.3 (9.9)	38.5 (14.6)	42 (21)	57 (30)
External rotation in abduction	83.2 (12.9)	36.0 (17.6)	57 (20)	71 (22)
Internal rotation in abduction	77.1 (9.1)	51.7 (14.6)	33 (19)	45 (29)
Hand behind back (mm)	28.3 (5.3)	46.4 (9.4)	68 (43)	6 (28)

Movement	Unaffected shoulder ROM (degrees) Mean (SD)	Affected shoulder ROM (degrees) Mean (SD)	% loss ROM Mean (SD)	Pain score end of range (mm) Mean (SD)
B: PASSIVE MOVEMENT				
Total shoulder flexion	170.4 (9.4)	129.7 (21.1)	24 (11)	63 (25)
Glenohumeral joint flexion	132.3 (11.1)	105.7 (18.4)	20 (12)	48 (31)
Total shoulder abduction	153.9 (14.4)	97.0 (25.0)	37 (16)	63 (29)
Glenohumeral joint abduction	118.8 (14.0)	72.8 (19.8)	39 (16)	64 (23)
External rotation in neutral	73.2 (9.6)	42.3 (16.8)	42 (21)	68 (24)
External rotation in abduction	92.4 (12.8)	38.9 (16.0)	58(17)	77 (18)
Internal rotation in abduction	84.1 (8.8)	55.8 (15.7)	34 (18)	45 (29)
Hand behind back (mm)	24.7 (4.3)	42.2 (9.0)	72 (36)	71 (22)

6.5.1 Percentage loss of movement

Active range of movement

The mean percentage loss of active range of movement ranged between 68% (HBB) and 26% (GHF).

Two factors were extracted which accounted for 68% of the variance of the eight measured ranges of active movement (Table 6.3). These two factors represented a pattern comprising two groups of movements. The first group of movements (movement group 1), accounting for 52% of the variance included TSF, GHF, TSA and GHA. The second group of movements (movement group 2), accounting for 16% of the variance included ERN and ERA. The loadings of the eight movements on the two factors are shown in Table 6.3.

Table 6.3 Factor loadings for the factor models for percentage loss of active and passive ranges of movement

	Active		Passive
Movement	Factor 1: Movement group 1 (Eigenvalue = 4.13)	Factor 2: Movement group 2 (Eigenvalue = 1.31)	Factor 1: Global loss of movement (Eigenvalue = 4.76)
Total shoulder flexion	0.90*	0.08	0.85*
Glenohumeral joint flexion	0.83*	0.15	0.83*
Total shoulder abduction	0.73*	0.17	0.87*
Glenohumeral shoulder abduction	0.75*	0.35	0.84*
External rotation in neutral	0.15	0.66*	0.51
External rotation in abduction	0.25	0.97*	0.58
Internal rotation in abduction	0.48	0.18	0.62*
Hand behind back	0.55	0.22	0.68*

Legend: * loadings $\geq$ 0.60

Passive range of movement

The mean percentage loss of passive range of movement ranged between 72% (HBB) and 20% (GHF).

A single factor with an Eigenvalue of 4.76 was extracted for the measured ranges of passive movement which accounted for 60% of the variance suggesting a global loss of passive range of movement rather than an identifiable pattern. Six of the eight loadings (TSF, GHF, TSA, GHA IRA, HBB) were > 0.60 (range 0.62 – 0.87). The loadings of the eight movements are shown in Table 6.3.

6.5.2 Pain at the end of range of movement

Active range of movement

The active range of movement scoring the highest mean (SD) score for all participants was ERA, (71 mm (22)).

A two factor structure accounted for 66% of the variance of the pain scores at the end of active range of movement. These two factors represented a pattern of two groups of movements. The relative weights of the eight movements are shown in Table 6.4, which provides factor loadings for each of the ranges of active movement in the two-factor solution. The first group of movements (movement group 1), accounting for 53% of the variance included TSF, TSA and GHA. The second group (movement group 2), accounting for 13% of the variance included ERA and IRA.

Table 6.4 Factor loadings for two factor models for pain at the end of active and passive ranges of movement

	Active		Passive	
Movement	Factor 1: Movement group 1 (Eigenvalue = 4.20)	Factor 2: Movement group 2 (Eigenvalue = 1.06)	Factor 1: Movement group 1 (Eigenvalue = 4.60)	Factor 2: Movement group 2 (Eigenvalue = 1.01)
Total shoulder flexion	0.71*	0.23	0.76*	0.21
Glenohumeral joint flexion	0.50	0.33	0.51	0.24
Total shoulder abduction	0.86*	0.22	0.78*	0.26
Glenohumeral joint abduction	0.70*	0.39	0.72*	0.46
External rotation in neutral	0.47	0.54	0.22	0.98*
External rotation in abduction	0.22	0.73*	0.41	0.72*
Internal rotation in abduction	0.21	0.67*	0.32	0.53
Hand behind back	0.36	0.58	0.60*	0.44

Legend: * loadings $\geq$ 0.60

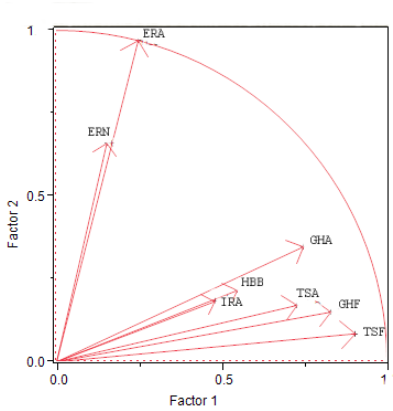
Passive range of movement

The passive range of movement scoring the highest mean (SD) score for all participants was ERA, (77 mm (18)).

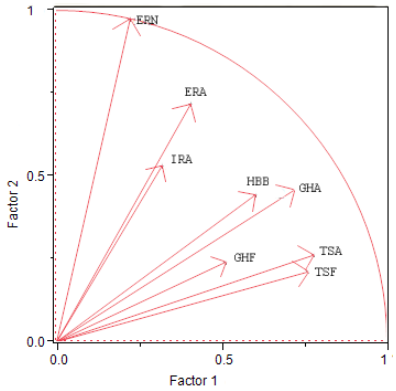
A two factor structure accounted for 70% of the variance for pain scores at the end of passive range of movement. These two factors suggested a pattern of two groups of

movements. The relative weights of the eight movements are shown in Table 6.4, which provides factor loadings for each of the ranges of passive movement in the two-factor solution. The first group of movements (movement group 1), accounting for 58% of the variance included TSF, TSA, GHA and HBB. The second group of movements (movement group 2), accounting for 13% of the variance included ERN and ERA.

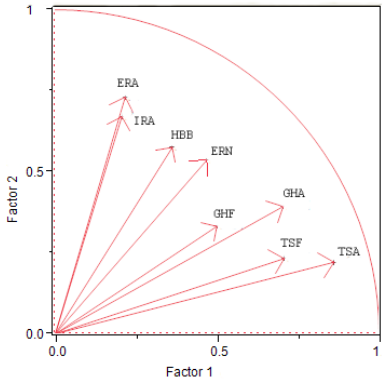
The factor loading plots for percentage loss of active range of movement, and for the pain level scores at the end of each of the active and passive ranges of movement are presented in Figure 6.2. These plots demonstrate that only percentage loss of active range of movement resulted in a clear separation of the two groups of movements (ERN and ERA with the other group of movements comprising TSF, GHF, TSA and GHA) (Figure 6.2A). Similar separation is not observed for pain at the end of both active and passive movements (Figures 6.2B and 6.2C) suggesting a recognisable pattern for pain at the end of range did not emerge.



A. Percentage loss of active range of movement (ROM) demonstrating clear separation of ERN and ERA



B. Pain at the end of active ranges of movement demonstrating no clear separation of movements



C. Pain at the end of passive ranges of movement demonstrating no clear separation of movements

Figure 6.2 Factor loading plots following Varimax rotation

A. Percentage loss of active range of movement (ROM) demonstrating clear separation of ERN and ERA

B. Pain at the end of active ranges of movement demonstrating no clear separation of movements

C. Pain at the end of passive ranges of movement demonstrating no clear separation of movements

6.5.3 Limitation to movement

Descriptive statistics describing the reason for limitation to movement are presented in Table 6.5. The movement most frequently limited by pain, rather than active inability to move or passive resistance was ERA for both active (71%) and passive (94%) ranges

of shoulder movement. The movement least frequently limited by pain was GHF (35%) for active movement and IRA (46%) for passive movements.

Table 6.5 Reason for limitation of movement

	Active		Passive	
Movement	Pain limited N (mean % loss ROM)	Movement limited N (mean % loss ROM)	Pain limited N (mean % loss ROM)	Resistance limited N (mean % loss ROM)
Total shoulder flexion	26 (28)	26 (28)	45 (23)	7 (28)
Glenohumeral joint flexion	18 (25)	34 (26)	29 (22)	23 (18)
Total shoulder abduction	30 (49)	22 (38)	37 (40)	15 (29)
Glenohumeral joint abduction	26 (55)	26 (48)	42 (39)	10 (37)
External rotation in neutral	30 (42)	22 (42)	44 (45)	8 (30)
External rotation in abduction	37 (55)	15 (62)	49 (58)	3 (50)
Internal rotation in abduction	19 (33)	33 (32)	24 (31)	28 (36)
Hand behind back	34 (60)	18 (84)	48 (74)	4 (53)

6.6 Discussion

This is the first study to investigate the presence of any recognisable pattern of movement loss that may exist in a group of participants clinically diagnosed with early stage primary/idiopathic adhesive capsulitis. Unlike earlier studies, this study has utilised factor analysis to determine relationships or patterns that may exist within the percentage loss of both active and passive ranges of movement and pain experienced at the end of each range of movement. It is also unique as it has considered the reason for limitation to movement in a larger sample than previously reported. The results of this study have demonstrated that in this group of patients diagnosed clinically with early stage primary/idiopathic adhesive capsulitis, the percentage loss of both active and passive ranges of movement does not fit the 'capsular pattern' previously reported by

Cyriax to be characteristic of this disorder (Reeves 1975; Vermeulen, Stokdijk et al. 2002). The selection of factor analysis has enabled the detection of groups, rather than isolated shoulder movements that may involve common anatomical, pathological or biomechanical characteristics. In this study the movements that have grouped together as a result of the factor analysis may be reflecting the underlying pathological process in the glenohumeral joint capsule. In particular, the grouping together of the two external rotation movements may indicate an area of capsular involvement leading to restriction or pain different from the other measured shoulder movements.

The clearest pattern to emerge from this study was from the analysis of the percentage loss of active range of movement which identified a pattern with two distinct groups (Table 6.3 and Figure 6.2A). One group included the shoulder movements TSF, GHF, TSA and GHA, whilst the other comprised the two measured external rotation movements (ERN and ERA). The two groups of movements show a degree of correlation with each other and this is demonstrated by the acute angle between each of the groups of variables in Figure 6.2A. The two external rotation movements are not completely independent from the other group of movements suggesting there is a small amount of similarity between the two. Although perhaps not surprising, external rotation in both neutral and abduction appeared to behave differently from the other measured shoulder movements. However the classic 'capsular pattern' of proportional loss of external rotation being greater than the proportional loss of abduction, which is in turn greater than the proportional loss of internal rotation, did not emerge. Although not entirely consistent with the 'capsular pattern' previously described for

loss of passive range of movement (Cyriax and Cyriax 1993), this is in accordance with the reported pathological involvement of the anterior glenohumeral structures in adhesive capsulitis and the previously recognised involvement of external rotation (Hanchard, Goodchild et al. 2011).

Percentage loss of passive range of movement grouped differently to active movement and demonstrated only one pattern of approximately equivalent loss across all movements (Table 6.3). Again the 'capsular pattern' did not emerge and in contrast to active movement, this would suggest a non-specific global loss of passive shoulder movement. Whilst not clearly emerging as a second group, ERN appeared least related to the other movements. Similarly an earlier study of passive range of movement loss in adhesive capsulitis, reported loss in all measured ranges, with no 'capsular pattern' evident in their sample of 30 participants (Mitsch, Casey et al. 2004). That study measured abduction as well as internal and external rotation in 45° of abduction. They demonstrated that external rotation was significantly limited in comparison to abduction and internal rotation, with the latter two movements not differing from each other. Whilst direct comparison with the current study is problematic due to methodological differences the trend for global passive movement loss appears to be consistent with a greater loss in external rotation.

The early stage of adhesive capsulitis has been reported to be characterised by pain rather than movement restriction (Pearsall and Speer 1998), and to our knowledge there are no other reported studies that have quantified and analysed pain at the end of range of movement in this stage of the disorder. Pain at the end of active movement

suggested two groups of movements (Table 6.4 and Figure 6.2B). The first group contained only three movements with loadings ≥ 0.60, suggesting only a weak association. This group comprised the movements of TSF, TSA and GHA, while the second suggested a relationship between two of the rotational movements (ERA and IRA). Consideration of the descriptive data would suggest that when ERA recorded a high level of pain at the end of range, IRA conversely recorded a low level of pain. Interestingly, of the two groups that emerged in analysing pain at the end of passive range of movement (Table 6.4 and Figure 6.2C), the first contained HBB as well as TSF, TSA and GHA. While active HBB has been used clinically to assess shoulder internal rotation, it has been reported that it is not solely related to internal rotation at the glenohumeral joint (Mallon, Herring et al. 1996). This might help explain HBB clustering with the other movements. Notably the second group again consisted of the two external rotation movements (ERN and ERA). Despite the presence of this grouping, inspection of the factor loading plots (Figures 6.2B and 6.2C) would suggest that a clear pattern did not emerge. This indicates that whilst pain is reportedly a feature of early adhesive capsulitis, the absence of a pattern may make this symptom less useful than percentage loss of active range of movement in identifying patients at this stage.

It would be reasonable to expect that the limitation to movement in early stage adhesive capsulitis may be more likely due to pain rather than resistance or weakness. Interestingly, for both active and passive movements, ERA and HBB were those movements most frequently limited by pain. ERA is reportedly limited by anterior

capsular structures (Gagey and Boisrenoult 2004), which suggests those structures may be responsible for pain experienced with that movement. As pain not only from the capsule, but also from muscle spasm has been previously suggested as a limiting factor to movement (Rundquist and Ludewig 2004), it could potentially be that spasm from the scapulothoracic musculature is responsible for at least some of the pain limiting the HBB movement in these participants.

There are some limitations to this study. Firstly, the sample size was modest although it compares favourably with earlier studies (Rundquist, Anderson et al. 2003; Mitsch, Casey et al. 2004; Rundquist and Ludewig 2004). Interpretation of factor analysis with this sample has suggested findings that require confirmation with a larger sample. The participants in this sample were recruited from a limited number of practice environments and it is possible this may have led to biased estimates due to participants not being representative of other patient sources. The absence of a gold standard for diagnosis of adhesive capsulitis in its early stage remains a limitation in all related research. Heterogeneity of participants has previously been reported as a limitation of similar studies (Rundquist and Ludewig 2004), however strict inclusion and exclusion criteria in the current study were used to minimise participants with potentially alternate diagnoses. Although based on previously reported reliable measurement methods, intrarater reliability was not specifically determined in this study due to the clinical nature of the research and the ethical requirement to minimise any worsening of each participant's pain. The order of testing was not randomised

which may have resulted in greater pain scores for the later measured movements due to aggravation by earlier movements.

6.7 Conclusion

This study has specifically investigated patients clinically diagnosed with early stage primary/idiopathic adhesive capsulitis to determine whether any recognisable movement patterns may be present which could assist diagnosis. The main finding of the study was that active external rotation movements in both neutral and in abduction grouped together and behaved differently to the other measured active shoulder movements. Percentage loss of passive ranges of movement identified a non-specific global loss. Unlike the percentage loss of active range of movement, a clear pattern for pain at the end of range of movement did not emerge. Interestingly, ERA has emerged as both the most painful active and passive movement and the movement most frequently limited by pain, rather than weakness or resistance. Clinically this indicates the involvement of this movement in the early stage as has been previously recognised in the later stages, and suggests that careful assessment of movement range and pain at the end of range of external rotation in both neutral and 90 degrees abduction should be undertaken in patients with suspected early stage adhesive capsulitis. Whilst percentage loss of active and passive ranges of movement, pain at the end of range of movement and limitation to movement have highlighted the involvement of external rotation, further studies are required to investigate the inter-relationships among these parameters. The findings of this preliminary study therefore, will direct future studies of mixed populations comprising patients with varying shoulder diagnoses, to test the

patterns that have emerged, and determine if they are unique to the early stage of adhesive capsulitis.

Chapter 7 Clinical identifiers for early stage primary/idiopathic adhesive capsulitis: are we seeing the real picture?

This chapter has been published in a peer-reviewed scientific journal:

Walmsley S, Osmotherly PG, Rivett DA (2014). Clinical identifiers for early stage primary/idiopathic adhesive capsulitis: are we seeing the real picture? Physical Therapy 94 (7):968-976.

The work presented in this manuscript was completed in collaboration with the co-authors (Appendix 1). The ethics approval and supporting documents for the study reported in this chapter appear in Appendix 3.

Overview

The consensus of a group of experts for necessary and sufficient clinical identifiers for early stage adhesive capsulitis was presented in Chapter 3. Although the identifiers proposed in that study were determined by the Delphi technique, which is a recognised method of achieving consensus on a given topic, their validity requires formal investigation. The aim of the study described in this chapter was therefore to validate all or any of the clinical identifiers proposed in the earlier Delphi study.

7.1 Abstract

Background: Adhesive capsulitis is often difficult to diagnose in its early stage and differentiate from other common shoulder disorders.

Objective: The aim of this study was to validate any or all of the eight clinical identifiers of early stage primary/idiopathic adhesive capsulitis established in an earlier Delphi study.

Design*:* Cross-sectional study.

Methods: Sixty-four patients diagnosed with early stage adhesive capsulitis by a physical therapist or medical practitioner were included in the study. Eight active and eight passive shoulder movements and visual analogue scale pain scores for each movement were recorded, prior to and immediately following an intraarticular injection of corticosteroid and local anaesthetic. Using the local anaesthetic as the reference standard, pain relief of ≥70% for passive external rotation was deemed a positive anaesthetic response (PAR).

Results: Sixteen (25%) participants demonstrated a PAR. Univariate logistic regression identified that of the proposed identifiers, global loss of passive range of movement (OR 0.26; p = 0.03), pain at the end of range of all measured active movements (OR 0.06; p = 0.02) and global loss of passive glenohumeral movements (OR 0.23; p = 0.02) were associated with a PAR. Following stepwise removal of the variables, pain at the end of range of all measured active movements remained the only identifier but was associated with reduced odds of a PAR.

Limitations: The lack of a recognised reference standard for diagnosing early stage adhesive capsulitis remains problematic in all related research.

Conclusions: None of the clinical identifiers for early stage adhesive capsulitis previously proposed by expert consensus have been validated in this study. Clinicians should be aware that commonly used clinical identifiers may not be applicable to this stage.

7.2 Introduction

Adhesive capsulitis is a diagnostic label attributed to a disorder of the glenohumeral joint capsule that has been reported to affect up to five percent of the population (Hannafin and Chiaia 2000; Hand, Clipsham et al. 2008). Primary adhesive capsulitis is due to an unknown cause as opposed to secondary which results from a known cause or extrinsic event (Chambler and Carr 2003). The condition is generally described as consisting of three stages (Chambler and Carr 2003). These have been identified as the painful stage (first), adhesive stage (second) and resolution stage (third) (Pearsall and Speer 1998). The first or painful stage, which is being considered in this study, is generally considered to last 3-9 months (Pearsall and Speer 1998). Whilst the later stages are easily recognised often due to marked restriction of movement, the early stage of this disorder is commonly difficult to identify and correctly diagnose (Walmsley, Rivett et al. 2009). It has however been proposed that treatment in the early stage of adhesive capsulitis may decrease the overall morbidity (Hannafin and Chiaia 2000), arguably suggesting that early recognition of this disorder is desirable.

Musculoskeletal healthcare frequently relies on recognition of patient reported and physical examination findings, together with special tests and medical imaging to

inform diagnosis and direct management. Determining the clinical features considered necessary to establish a diagnosis is frequently achieved through research using various types of consensus methodology (Graham, Regeher et al. 2003; Cook, Brismee et al. 2005; Cook, Brismee et al. 2006). Several studies using this approach have attempted to identify clinical characteristics of adhesive capsulitis in general (Hanchard, Goodchild et al. 2011; Zuckerman and Rokito 2011), as well as specific to the early stage (Walmsley, Rivett et al. 2009), however validation of these characteristics is lacking. As well as routine clinical assessment, musculoskeletal assessment often relies on a 'gold standard' that may include a particular diagnostic test, imaging procedure or even surgical findings with which to determine a diagnosis. As surgery is not indicated and imaging procedures in the early stage of adhesive capsulitis have yet to be systematically explored (Walmsley, Osmotherly et al. 2013) a 'gold standard' for diagnosis remains problematic in this population. Clinical tests have recently been described that may assist the diagnosis of adhesive capsulitis (Carbone, Gumina et al. 2009; Wolf and Cox 2010), however the duration of symptoms of participants in these studies was not reported resulting in difficulty determining the stage of the disorder and whether the findings are valid for patients in the early stage.

A set of clinical identifiers considered necessary and sufficient by a group of experts to diagnose early stage adhesive capsulitis (Walmsley, Rivett et al. 2009) (Table 7.1) has been proposed as a framework with which to begin the process of addressing this diagnostic dilemma. The identifiers established in that study by our research group

included both patient reported and physical examination findings, and interestingly clustered into two discrete dimensions of pain and movement.

Table 7.1 Clinical identifiers achieving consensus (Walmsley, Rivett et al. 2009)

Criterion
There is a strong component of night pain
There is a marked increase in pain with rapid or unguarded movements
It is uncomfortable to lie on the affected shoulder
The patient reports the pain is easily aggravated by movement
The onset is generally in people greater than 35 years of age
On examination there is pain at the end of range in all directions
On examination there is global loss of active and passive range of movement
There is global loss of passive glenohumeral joint movement

As pain is reportedly a significant feature of the early stage (Hannafin and Chiaia 2000), it was therefore not surprising that several dimensions in pain were reported to achieve consensus. Night pain, a marked increase of pain with rapid or unguarded movements, discomfort lying on the affected shoulder and pain easily aggravated by movement, were all identified as required to achieve diagnosis. These descriptors were suggested to reflect the inflammatory nature of the disorder in the early stage (Hand, Athanasou et al. 2007). Although often unquantified, recognition of the later stages of adhesive capsulitis through marked movement restriction, in particular external rotation, has been previously reported (Bulgen, Binder et al. 1984). Conversely there is a lack of description of movement dysfunction in the early stage of the disorder. Physical examination findings achieving consensus in our Delphi study (Walmsley, Rivett et al. 2009) similarly lacked quantification, but it was suggested global loss of both active and passive ranges of movement, together with pain at the end of range in all directions were necessary characteristics. Although the clinical identifiers proposed for early stage adhesive capsulitis by expert consensus (Walmsley, Rivett et al. 2009)

were suggested as a starting point for future validation studies, it was recognised that they could not at this time be regarded as a gold standard or provide a certain differential diagnosis, but could rather potentially be used to assist in clinical decision-making.

The aim of this study was therefore to validate any or all of the eight clinical identifiers previously proposed for the early stage of adhesive capsulitis (Walmsley, Rivett et al. 2009).

7.3 Materials and methods

The Human Research Ethics Committee of The University of Newcastle granted ethical approval for this study. All participants signed an informed consent form prior to entering the study.

7.3.1 Participants

Participants were recruited from a private upper limb physical therapy clinic in Newcastle, Australia over a three year period between May 2010 and April 2013. Patients clinically diagnosed with adhesive capsulitis by various health care practitioners including orthopaedic surgeons, shoulder physicians, general practitioners and physiotherapists were invited to participate in the study. To be considered for inclusion, potential participants were required to have been referred for an intraarticular glenohumeral joint corticosteroid and local anaesthetic injection using radiological guidance to confirm correct placement of the needle, as part of routine clinical care. Consistent with the reported duration of the early stage of adhesive

capsulitis (Pearsall and Speer 1998), potential participants were excluded from the study if they had a symptom duration of greater than nine months. As primary/idiopathic adhesive capsulitis was being investigated, individuals with a history of previous major trauma or surgery on the affected shoulder were also excluded. Reported minor trauma was not an exclusion criterion. Potential participants were required to have had a recent unremarkable X-ray examination in order to eliminate glenohumeral osteoarthritis, calcific deposits or other potentially confounding diagnoses. They were also required to have had a recent ultrasound examination that excluded a full-thickness rotator cuff tear. Potential participants who had undergone an intraarticular corticosteroid injection into the glenohumeral joint in the preceding six weeks, had a history of inflammatory arthropathies or of cervical spine pathology that may refer into the shoulder joint, were also excluded from the study. As the contralateral shoulder was being used to determine percentage loss of range of movement, the presence of pain or restriction of movement in that shoulder was a further exclusion criterion.

7.3.2 Procedure

Immediately prior to the injection each participant attended the clinic to complete routine assessment including measurement of active and passive ranges of movement and pain at the end of ranges of movement. Additional questions were asked to determine the presence of the eight clinical identifiers being validated. To provide baseline measurements of shoulder pain and disability, the Shoulder Pain and Disability Index (SPADI) (Roach, Budiman-Mak et al. 1991; Staples, Forbes et al. 2010)

was administered. This instrument is a validated questionnaire measuring shoulder pain and impairment and has a high level of internal consistency and good test-retest reliability (Heald, Riddle et al. 1997). General health status was measured using the Short Form 36 (SF-36) (Brazier, Harper et al. 1992). This instrument is easy to administer, has been demonstrated to be reliable and valid (Brazier, Harper et al. 1992) and has been previously used to describe study samples with adhesive capsulitis (Carette, Moffet et al. 2003; Jacobs, Smith et al. 2009). On completion of the assessment, participants attended a radiology practice to undergo the intraarticular glenohumeral corticosteroid and local anaesthetic injection under radiological guidance. Within one hour of administration of the injection the participant returned for re-assessment including measurement of active and passive ranges of movement and pain at the end of ranges of movement. Following the measurement of range of movement and recording of post-injection pain levels the participant continued with routine clinical management.

7.3.3 Shoulder movement measurement

A comprehensive series of active and passive shoulder ranges of movement were evaluated. Seated upright in a chair to limit trunk extension, measurement of the following ranges of movement were performed based on the method described by Green et al (1998): total shoulder flexion (TSF), glenohumeral flexion (GHF), total shoulder abduction (TSA), glenohumeral abduction (GHA). The starting position for each of these movements was with the palm facing medially to ensure consistent rotation. The elbow was extended and the inclinometer placed along the shaft of the

humerus (Green, Buchbinder et al. 1998). As GHF and GHA were being measured, a device was constructed to limit movement of the acromion so as to provide consistent scapular stabilization (Figure 7.1).

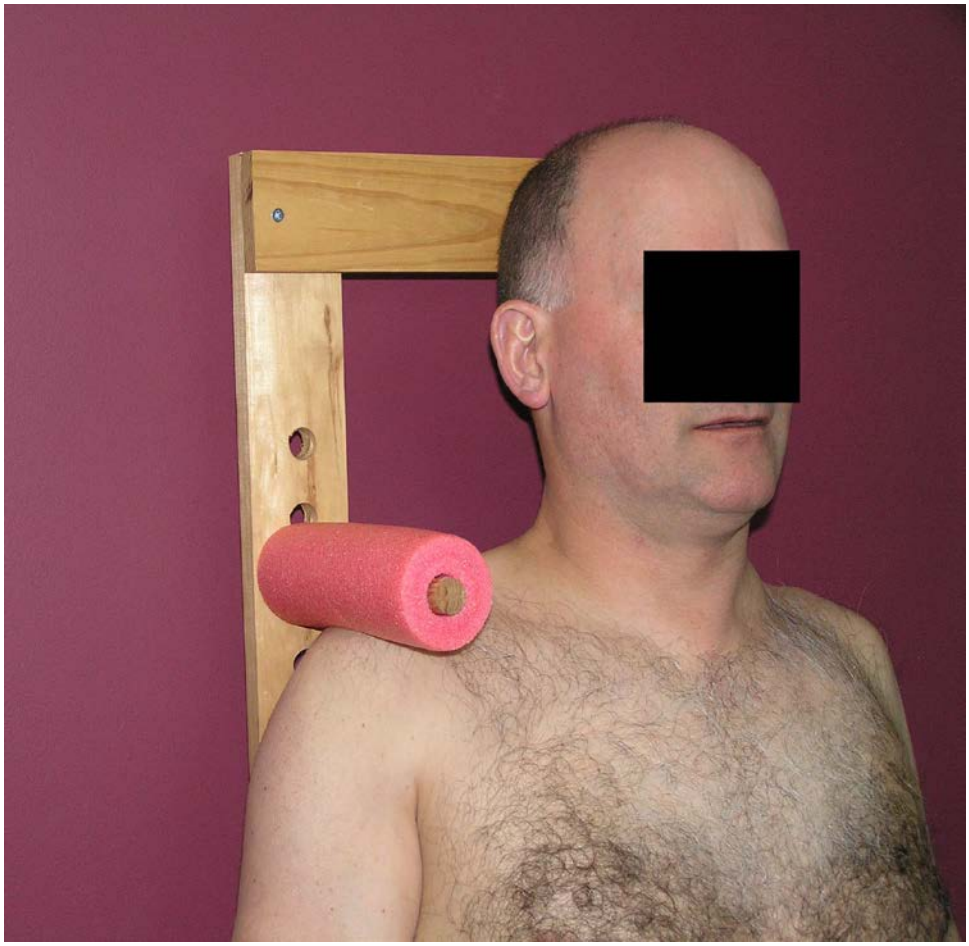


Figure 7.1 Device to stabilise the scapula for measurement of glenohumeral joint movement.

Each of the following movements was performed in the supine lying position based on previously described methods (Clarke, Willis et al. 1974; Bower 1982; Green, Buchbinder et al. 1998): external rotation in neutral abduction (ERN), external rotation in 90 degrees abduction (ERA), internal rotation in 90 degrees abduction (IRA) . A

towel was placed under the shaft of the humerus to ensure it was parallel to the plinth, the elbow flexed to 90 degrees and the inclinometer was placed on the dorsal surface of the participant's forearm. For ERA and IRA the arm was abducted to 90 degrees or if this was not possible it was taken to the limit of movement. Internal rotation in abduction was measured based on a method previously described whereby the end range was determined as the point at which the posterolateral acromion was visualised to rise off the plinth (Awan, Smith et al. 2002). In addition, hand behind back (HBB) was measured in standing using the distance between the spinous process of T1 and the spinal level reached by the radial styloid process with the arm taken behind the back (Ginn, Cohen et al. 2006).

All movements, with the exception of HBB were measured in degrees using a Baseline digital inclinometer (Fabrication Enterprises Incorporated, Irvington, NY, USA). Prior to each measurement the digital inclinometer was reset to zero after placement on the participant to ensure consistency. Digital inclinometery has been demonstrated to have a measurement error of ±1° (Downer and Sauers 2005). HBB was measured with a tape measure and recorded in millimetres. The order of measurement was standardised (TSF, GHF, TSA, GHA, ERN, ERA, IRA, HBB) and all active movements were performed prior to any passive movements.

The instruction to participants for all active movements was to move the arm as far as possible until they were no longer able to tolerate the movement due to pain or they were unable to move the arm any further. For passive movements, the researcher performed each of the movements to the point of resistance or when the participant

reported the pain was intolerable. To determine percentage loss of active and passive ranges of movement, contralateral shoulder range of movement was also measured prior to the injection of corticosteroid and local anaesthetic in an identical manner to the affected shoulder. In the absence of any documented deficit, a loss of range of movement of 10% or greater with respect to the contralateral shoulder was determined to constitute loss of movement. Such a loss exceeds the measurement error of shoulder range of movement of less than 7% previously reported (Clarke, Willis et al. 1974) as well as that reported for the commonly used universal goniometer (5-7 degrees) (MacDermid, Chesworth et al. 1999) thus affording some translation of the findings to the clinical setting.

7.3.4 Calculation of post injection pain intensity

In the absence of a 'gold standard' for the diagnosis of early stage adhesive capsulitis, the response to the local anaesthetic (administered concurrently with the corticosteroid injection) was used as the reference test standard. Local anaesthetic injection has been previously proposed as a method of determining diagnosis (Sheridan and Hannafin 2006; Neviaser and Hannafin 2010). To determine the anaesthetic response, each participant was required to record their level of pain at the end of active and passive ranges of movement on a 100 mm visual analogue scale (VAS) with 0 mm = 'no pain' and 100 mm = 'worst pain imaginable'. The percentage change in pain intensity from before to after the injection was calculated for each active and passive movement. Pain relief of ≥ 70% for ERN was considered a positive anaesthetic response (PAR). External rotation in neutral abduction was chosen as it is generally recognised as the most

frequently affected movement in adhesive capsulitis (Hanchard, Goodchild et al. 2011). The required ≥ 70% of pain relief obtained was chosen as it is considered clinically relevant and has been used in previous research (Strobel, Pfirrmann et al. 2003).

7.3.5 Statistical analysis

Descriptive statistics were used to summarise the characteristics of the participants and presence of the eight clinical identifiers. The participant characteristics together with the eight identifiers were analysed against anaesthetic response using univariate logistic regression. As the clinical identifier describing pain at the end of range in all directions was non specific about whether this was active or passive range of movement, both dimensions were included in the analysis. Further, although only global loss of passive glenohumeral joint movement was proposed as a clinical identifier, for completeness active range of movement was also included in the model. The criterion that described glenohumeral joint movements comprised the movements of GHF, GHA, ERN, ERA and IRA. All factors with a p-value of 0.20 or less were included in a multiple logistic regression model. Outcomes were expressed as odds ratios with 95% confidence intervals. A p-value of < 0.05 was considered to be statistically significant. Data were analysed using Stata 12.0 statistical software (Stata Corporation, Texas, USA).

7.4 Results

The flow of participants through the study is shown in Figure 7.2.

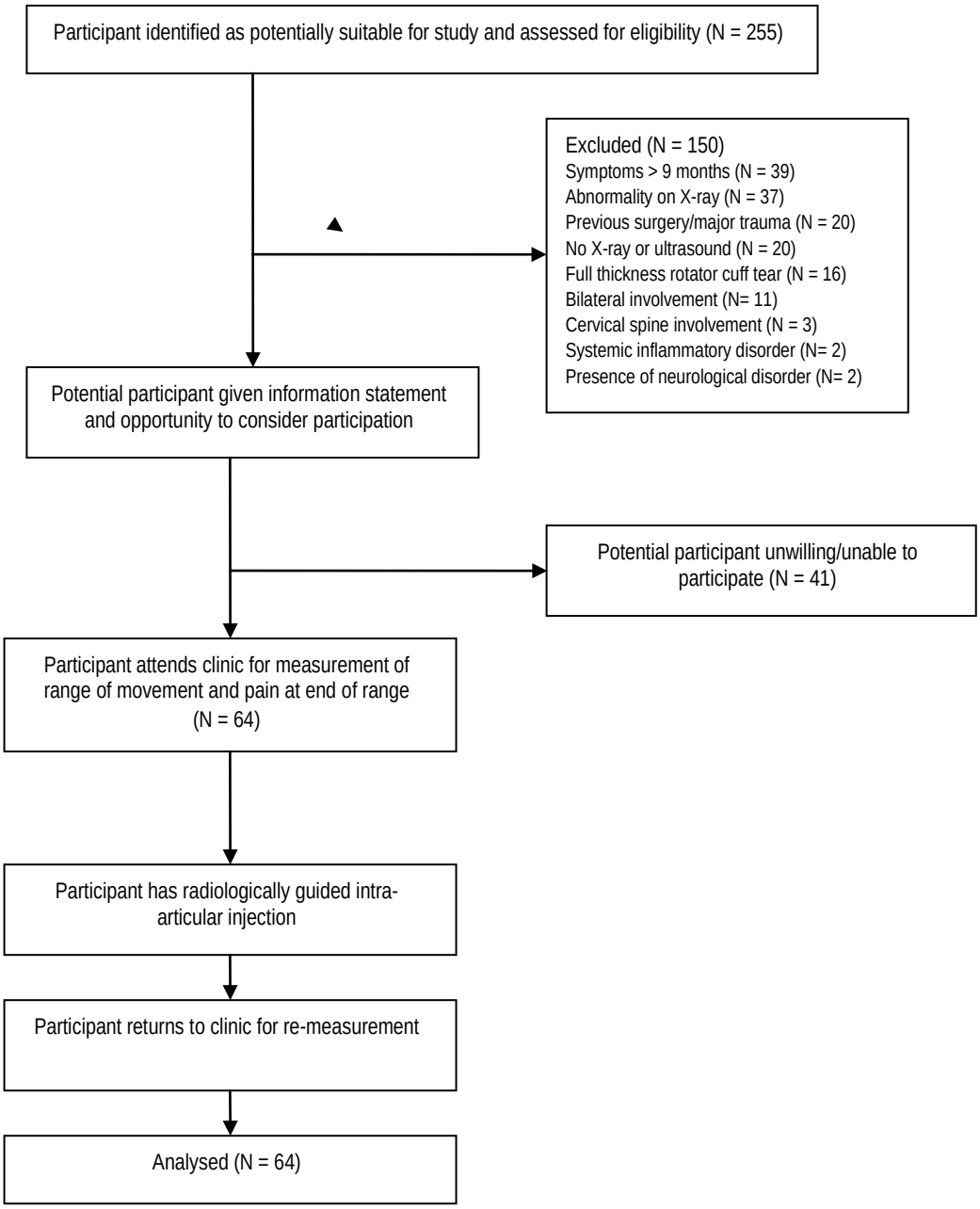


Figure 7.2 Design and flow of participants through the study

In total, 255 patients were assessed for inclusion in the study and 191 were excluded for either not meeting the inclusion or exclusion criteria (N = 150), or being unwilling

or unable to participate (N = 41). Sixty-four participants were included in the study and participant demographic characteristics are reported in Table 7.2.

Table 7.2 Characteristics of the study participants (N=64)

Variable	
Age (yrs), mean (SD)	55.1 (6.5)
Female (%)	33 (51.6)
Duration of symptoms (months), mean (SD)	5.4 (1.9)
Affected shoulder dominant	28 (43.8)
History of minor trauma (%)	23 (35.9)
History of diabetes (%)	6 (9.4)
History of Dupytren's disease (%)	8 (12.5)
SPADI (mean, SD)	49.2 (1.9)
SF-36 (PCS) (mean, SD)	41.2 (6.8)
SF-36 (MCS) (mean, SD)	50.9 (10.6)

Legend: SPADI = Shoulder Pain and Disability Index, SF-36 = Short Form 36, PCS = physical component summary, MCS = mental component summary

The prevalence of the eight clinical identifiers is presented in Table 7.3. All of the participants were aged over 35 years. Global loss of active and passive ranges of movement were the least prevalent of the eight criteria (65% and 67% respectively).

Table 7.3 Prevalence of the eight clinical identifiers (N = 64)

Criterion	Number of participants (%)
There is a strong component of night pain	62 (96.9)
There is a marked increase in pain with rapid or unguarded movements	57 (89.1)
It is uncomfortable to lie on the affected shoulder	61 (95.3)
The patient reports the pain is easily aggravated by movement	55 (85.9)
The onset is generally in people greater than 35 years of age	64 (100)
On examination there is pain at the end of range in all directions	Active 59 (92.2) Passive 60 (93.8)
On examination there is global loss of active and passive range of movement	Active 42 (65.6) Passive 43 (67.2)
There is global loss of passive glenohumeral joint movement	47 (73.4)

Sixteen (25%) participants demonstrated a PAR. The relationship between the demographic characteristics and the proposed eight clinical identifiers of the participants with a positive PAR is reported in Table 7.4.

Table 7.4 Relationship between participant characteristics and the eight clinical identifiers and PAR (N = 64).

Variable	Univariate association		Multivariate association	
	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value
Age	1.08 (0.98, 1. 18)	0.12		
Gender	0.92 (0.16, 0.78)	0.89		
History of minor trauma	1.09 (0.34, 3.53)	0.88		
History of diabetes[1]				
History of Dupytren's disease	1.98 (0.42, 9.44)	0.39		
SPADI	0.38 (0.02,8.09)	0.54		
SF-36 (PCS)	1.02 (0.93, 1.11)	0.69		
Sf-36 (MCS)	1.02 (0.96, 1.08)	0.46		
Presence of night pain	0.32 (0.02, 5.42)	0.43		
Pain with rapid movement	2.14 (0.24, 19.30)	0.50		
Uncomfortable lying on affected shoulder[1]				
Pain easily aggravated by movement	0.62 (0.14, 2.83)	0.54		
Global loss of active movement	0.41 (0.13, 1.31)	0.13		
Global loss of passive movement	0.26 (0.08,0.85)	0.03*		
Pain at the end of range of active movements	0.06 (0.01, 0.62)	0.02*	0.06 (0.01, 0.62)	0.02*
Pain at the end of range of passive movements[1]				
Global loss of active glenohumeral movements	0.43 (0.13, 1.40)	0.16		
Global loss of passive glenohumeral movements	0.23 (0.07, 0.78)	0.02*		

Legend: SPADI = Shoulder Pain and Disability Index, SF-36 = Short Form 36, PCS = physical component summary, MCS = mental component summary; * $p < 0.05$; [1] omitted due to collineraity

Univariate logistic regression identified that none of the patient demographic characteristics were associated with a PAR. Of the eight proposed clinical identifiers, pain at the end of range of all measured active movements (OR 0.06; p = 0.02), global loss of passive range of all measured movements (OR 0.26; p = 0.03), and global loss of passive glenohumeral movements (OR 0.23; p = 0.02) were associated with a PAR. Following stepwise removal of the variables, pain at the end of range of all measured active movements remained the only identifier but was associated with a reduced odds of a positive response (OR 0.06; p = 0.018).

7.5 Discussion

This is the first study that has attempted to validate a set of clinical identifiers for the early stage of primary/idiopathic adhesive capsulitis. It is unique in that it has used clinical identifiers previously established by expert consensus (Walmsley, Rivett et al. 2009) and only investigated patients with symptoms for less than nine months. Whilst the identifiers established by this consensus method have also been frequently recognised in the literature (Nash and Hazleman 1989; Lin, Jarmain et al. 2004; Mitchell, Adebajo et al. 2005), none were validated in this study. Interestingly of the eight clinical identifiers, pain at the end of all active ranges of movement has emerged as the least likely to indicate a diagnosis of early stage adhesive capsulitis. These results may suggest expert opinion and possibly clinical practice may not be recognising the appropriate clinical identifiers of patients in the early stage of this disorder. This study highlights the difficulty in quantitatively determining an exclusive set of criteria for the early stage of adhesive capsulitis.

Using the effect of intraarticular local anaesthetic injection as the diagnostic reference standard and associated pain relief of ≥ 70% in external rotation, 25% of participants in this study were determined to have early stage adhesive capsulitis. This was less than may have been anticipated but possibly in keeping with the proposal that this disorder is over diagnosed and the true incidence is much lower than generally reported (Bunker 2009). A further consideration is that every patient with a painful shoulder and apparent limitation of motion may not necessarily indicate a diagnosis of early stage adhesive capsulitis (Neviaser and Neviaser 1987). It is likely that the clinicians assessing the patients in the current study used similar clinical identifiers as the experts in the Delphi study (Walmsley, Rivett et al. 2009) given the specialist nature of the practice from which the participants were recruited. It is therefore not surprising that the prevalence of the identifiers in the participants was generally high, as demonstrated in Table 7.2. Our results suggest that using these criteria may not actually be appropriate to identify the early stage of this disorder. The differences of opinion and lack of understanding of adhesive capsulitis in its early stage, as well as the general appreciation of the specific diagnostic criteria which distinguish it at this stage from other shoulder disorders have been previously reported (Bell, Coghlan et al. 2003). Further, there is no consensus as to the exact range of motion restriction required for a patient to qualify for a diagnosis of early stage adhesive capsulitis (Brue, Valentin et al. 2007). Although consensus exists regarding the presence of three phases of the disorder, controversy still arises regarding the diagnostic criteria that distinguishes

these stages (Dudkiewicz, Oran et al. 2004). The findings of this study are consistent with this confused picture.

Recent understanding of the pathology of adhesive capsulitis has suggested that the behaviour of the symptoms throughout the stages of the disorder may be explained by the underlying pathological process of initial inflammation followed by subsequent contracture (Hand, Athanasou et al. 2007). In particular, inflammation of the anterior glenohumeral joint capsule (Ozaki, Nakagawa et al. 1989; Wiley 1991) has been implicated in early adhesive capsulitis. It may therefore be reasonable to expect pain or restriction of movement to not be global in the early stage of adhesive capsulitis, given this reported pathology (Hand, Athanasou et al. 2007). Despite this, consensus studies on diagnostic criteria or clinical identifiers previously reported (with the exception of the Delphi study (Walmsley, Rivett et al. 2009), notably omit consideration of the stages described when proposing diagnostic criteria (Hanchard, Goodchild et al. 2011; Zuckerman and Rokito 2011). Further, the degree and directions of restriction required to constitute adhesive capsulitis have not been previously identified as necessary to determine appropriate diagnosis (Shaffer, Tibone et al. 1992). As each of the eight measured active and passive movements stresses various aspects of the glenohumeral joint capsule, this may provide an explanation for none of the clinical identifiers involving physical assessment being validated. This may suggest that a 'one size fits all' approach has been taken to diagnosis and, as the later stages reportedly present with global restriction of movement and end-range pain (Siegel, Cohen et al. 1999; Mitchell, Adebajo et al. 2005), this is likely to be similarly assumed in the early stage of

the disorder. Potentially, it is the global rather than specific nature of these clinical identifiers that resulted in reduced odds of a PAR. The suggestion that limitation of external rotation may be the most recognisable feature (Hanchard, Goodchild et al. 2011) may warrant specific further exploration in a similar population.

The early stage of adhesive capsulitis has been reported to be frequently confused with impingement syndrome, with differentiation between the two disorders often difficult (Lubiecki and Carr 2007; Manske and Prohaska 2008). Compounding the confusion between these two disorders, impingement tests used clinically have been reported to lack specificity (Hanchard, Goodchild et al. 2012). As well as recognition of groups of physical examination findings, the use of local anaesthetic as a diagnostic tool in shoulder disorders has been previously reported (Cadogan, Laslett et al. 2011). The confusion between early stage adhesive capsulitis and impingement syndrome may be better addressed with use of local anaesthetic into the subacromial space (Neer 1983) to facilitate the diagnosis of adhesive capsulitis by exclusion.

The aim of musculoskeletal healthcare is to provide effective management of patients presenting with various disorders. However, the lack of strong evidence for treatment success of shoulder disorders reported in systematic reviews (Buchbinder, Green et al. 2006) has been suggested to be a result of the lack of uniformity of the use of diagnostic labels or that the criteria used in determining diagnostic sub-groups are not related to treatment success (Schellingerhout, Verhagen et al. 2008). Establishing diagnostic criteria or clinical identifiers for various shoulder disorders allows identification of a homogeneous subgroup of patients with which to evaluate treatment outcomes and

make comparisons across trials more meaningful (Walmsley, Rivett et al. 2009). However, in the shoulder the validity of various shoulder examination procedures has recently been challenged (Hegedus, Goode et al. 2007) with the lack of diagnostic accuracy possibly explained by the lack of anatomical validity of most shoulder tests (Green, Shanley et al. 2008). Various authors (Schellingerhout, Verhagen et al. 2008) have proposed that alternate methods should be used to classify patients with shoulder disorders. The shoulder symptom modification procedure (SSMP) approach proposed recently to address rotator cuff tendinopathy/subacromial impingement syndrome (Lewis 2009) may be worthy of further exploration in the group of patients with presumed early adhesive capsulitis.

There are a number of limitations that require consideration in this study. Firstly the lack of an agreed reference standard for early stage adhesive capsulitis makes any validation investigation problematic. The selection of intraarticular local anaesthetic was however based on its previously reported diagnostic utility as a method of determining the source of patient symptoms (Sheridan and Hannafin 2006; Neviaser and Hannafin 2010). Whilst an alternative reference standard may be to follow-up patients in the long term to confirm the diagnosis of adhesive capsulitis, (as the characteristic loss of motion becomes evident), this was not feasible in the present study because participants were being concurrently clinically treated with a corticosteroid injection and stretching exercises. Secondly, as this study used patients undergoing normal clinical management, it was not ethically possible to administer a local anaesthetic injection without the simultaneous corticosteroid component. In some

patients this may have resulted in a corticosteroid reaction that was not sufficiently negated by the local anaesthetic (Cardone 2002), although all participants were re-measured within one hour. A further limitation of this study was the large number (N = 191) of potential participants who were excluded. The requirement to use strict inclusion/exclusion criteria to obtain a homogeneous sample resulted in recruitment being slower than projected and the sample size accordingly modest. Interestingly, earlier authors have reported similar recruitment difficulties (Carette, Moffet et al. 2003; Buchbinder, Green et al. 2004), perhaps supporting recent opinions that the incidence of the disorder is overestimated (Bunker 2009). Although intrarater reliability was not specifically determined for the measurements due to the ethical consideration of patient pain provocation, previous published reports support the reliability of the method on which it was based (Clarke, Willis et al. 1974; Strout and Fleiss 1979; Bower 1982; Green, Buchbinder et al. 1998). Finally, the study may have been strengthened if participants had been randomly sampled over a wider area and as such the generalisability may be limited if these patients are not representative of other areas.

In conclusion, the early diagnosis of adhesive capsulitis remains problematic. Clinicians should be aware that commonly used clinical identifiers may not be applicable to this stage, which may also explain some of the poor reported outcomes of treatment to date. Recognition that the features of adhesive capsulitis in its early stage are likely to differ from the later stages is also required to correctly diagnose this disorder. This study raises a number of issues that may warrant exploration in future research. Firstly, given the reported confusion with impingement syndrome (Lubiecki

and Carr 2007; Manske and Prohaska 2008), it may be worthwhile to include patients with 'general' shoulder pain and assess the presence of any of the agreed identifiers in a heterogeneous group. Secondly, analysis of sub-groups of movement deficit and pain at the end of range of groups of movements, rather than global movement, may also be worthy of further exploration.

Chapter 8 Discussion and conclusions

This final chapter draws together and summarises the findings of the studies contained in this thesis. It discusses the clinical and research implications of the results, their generalisability to the wider population, as well as the broad limitations of the studies. The chapter concludes with an overall summary of the thesis.

8.1 Summary of study findings

The overall aim of this thesis was to identify diagnostic criteria or clinical identifiers for the early stage of adhesive capsulitis in order to facilitate more timely recognition of this diagnostically challenging stage of the disorder. This may then inform appropriate and timely management which has been suggested to minimise the often protracted course of the disorder (Hannafin and Chiaia 2000; Marx, Malizia et al. 2007). In addition, the identification of more homogeneous groups to guide future research would be facilitated.

The thesis comprises four studies, together with a published review of the diagnostic imaging literature pertaining to adhesive capsulitis. As an initial step (Chapter 3), a Delphi study design was used to gather expert opinion on the clinical identifiers/diagnostic criteria considered necessary and sufficient to determine an early diagnosis of adhesive capsulitis. As medical imaging is frequently an integral component of the diagnosis of musculoskeletal disorders, this chapter was followed by a review of current diagnostic medical imaging investigations that could be used to facilitate an early diagnosis of adhesive capsulitis (Chapter 4). Two studies (Chapters 5

and 6) subsequently explored the potential utility of two clinical methods to recognise the characteristics of early stage adhesive capsulitis: diagnostic imaging and the recognition of typical movement and pain patterns. The final study (Chapter 7) aimed to validate the clinical identifiers proposed by the initial Delphi study. Unlike most previous research in adhesive capsulitis, each of the studies undertaken specifically investigated the early stage of the disorder rather than the disease process as a whole. This thesis adds to the body of knowledge on the diagnosis of adhesive capsulitis and, importantly highlights the ongoing difficulties in recognition of the early stage of this disorder.

It has been previously acknowledged that definitions and diagnostic criteria for shoulder disorders, including adhesive capsulitis, are not consistently or reliably applied (Shaffer, Tibone et al. 1992; Stam 1994; Buchbinder, Goel et al. 1996; Green, Buchbinder et al. 1998; Cleland and Durall 2002). This lack of clear definitions makes comparison of the results of different studies describing both diagnosis and management difficult. As adhesive capsulitis is recognised to consist of a series of stages due to the progressive nature of its pathological process, arguably identifying diagnostic criteria or clinical identifiers specific to each stage is appropriate. In order to begin the process of establishing a set of diagnostic criteria or clinical identifiers for the early stage of adhesive capsulitis, it was determined that the opinion of experts would be the most appropriate initial step. For the first study, a three round Delphi technique was therefore selected to gather expert opinion and resulted in eight clinical identifiers being proposed as necessary and sufficient to recognise the early stage of adhesive

capsulitis. Unlike earlier studies using the Delphi technique, this study applied rigorous statistical analysis rather than simple descriptive statistics to determine consensus (Cook, Brismee et al. 2005; Cook, Brismee et al. 2006; Wilde, Ford et al. 2007). The eight identifiers elicited clustered into two discrete domains: that of i) pain and ii) movement, and included both patient reported and physical examination findings which concurred with identifiers previously described (Cleland and Durall 2002). Notably, the clinical identifiers were suggested as being possibly limited in their ability to differentially diagnose early stage adhesive capsulitis and they required formal validation (Walmsley, Rivett et al. 2009).

Musculoskeletal medicine frequently relies on diagnostic imaging, as well as clinical findings to confirm or reject a diagnosis. Interestingly, of the eight clinical identifiers established by the Delphi study described in Chapter 3, none included any positive or negative diagnostic imaging findings despite these being previously raised in the literature (Farrell, Sperling et al. 2005). The contribution of diagnostic imaging to the diagnosis of adhesive capsulitis was therefore explored in Chapter 4. This review highlighted that most of the available literature was concerned with the later stages of the disorder when clinical diagnosis was more straightforward. The review particularly identified the emerging role that power Doppler ultrasound may have in the diagnosis and management of inflammatory arthropathies. The potential of this modality to assist in early diagnosis of adhesive capsulitis was proposed in light of the current pathological understanding of the disorder of inflammation followed by capsular fibrosis (Hand, Athanasou et al. 2007). As a result of this review, an

exploratory study (Chapter 5) was undertaken to determine the potential of power Doppler ultrasound to identify an area of increased vascularity in the rotator interval area of the shoulder in a group of patients clinically diagnosed with early stage adhesive capsulitis. This study supported previous research (Lee, Sykes et al. 2005) and suggested that this diagnostic imaging modality may have potential to be an additional clinically accessible tool to facilitate diagnosis of early stage adhesive capsulitis.

It has been previously highlighted that randomised controlled trials of patients with adhesive capsulitis notably lack consistency, in particular regarding the direction, degree and quality of restriction of shoulder movement used for inclusion in studies (Schellingerhout, Verhagen et al. 2008). Importantly, quantification of movement restriction in the early stage has not been described. The Delphi study (Chapter 3) identified several descriptions of movement loss, including global loss of range of movement which concurred with previous reports (Pearsall and Speer 1998; Siegel, Cohen et al. 1999). Traditionally adhesive capsulitis has been suggested to demonstrate a 'capsular' pattern of movement loss (Cyriax 1982), however verification of this, in particular in the early stage of the disorder is lacking in the literature. The notion of a specific and identifiable pattern of movement restriction or pain in patients clinically diagnosed with early stage adhesive capsulitis was therefore explored in Chapter 6. Unlike previous research investigating the presence of movement patterns in patients diagnosed with adhesive capsulitis (Rundquist, Anderson et al. 2003; Mitsch, Casey et al. 2004; Rundquist and Ludewig 2004), this study was the first to analyse not only movement restriction but also quantify the amount of pain at the end of range of

movement. It highlighted that limitation and pain on external rotation in both neutral and 90 degrees abduction may be a potentially useful clinical sign and although more specific, concurs with published evidence-based clinical guidelines (Hanchard, Goodchild et al. 2011).

The final study (Chapter 7) investigated the validity of the clinical identifiers established as a result of expert opinion in the earlier Delphi study. In the absence of a recognised gold standard, this study used the intraarticular local anaesthetic administered concurrently with corticosteroid as a reference standard in a group of patients with a clinical diagnosis of early stage adhesive capsulitis. Interestingly, this study failed to validate any of the clinical identifiers proposed by the expert panel, which may suggest that currently used diagnostic criteria/clinical identifiers may not actually be correctly identifying individuals at the early stage of the disorder. Although one of the proposed clinical identifiers was that the onset of adhesive capsulitis was generally in people over 35 years of age, as all of the participants met this identifier age was considered a continuous variable in the analysis. The contribution of age therefore to the recognition of this disorder remains uncertain. The results of this final study (Chapter 7) challenge the traditionally accepted clinical presentation and suggest it may not specifically reflect adhesive capsulitis, particularly in its early stage.

8.2 Limitations of the studies

The use of the Delphi technique in the first study to determine consensus amongst a group of experts regarding the clinical identifiers for early stage diagnosis of adhesive

capsulitis (Chapter 3) is associated with a number of potential limitations. Consistent with research involving the use of questionnaires, it has been suggested that the Delphi technique may have low response rates that could influence the results (McKenna 1994; Sumsion 1998). Although the overall response rate in this study was moderate (37.8%), it compared favourably with similar previously published studies (Graham, Regeher et al. 2003; Cook, Brismee et al. 2005; Cook, Brismee et al. 2006). The lack of representation from some musculoskeletal professionals in the expert panel could further be seen as a limitation of this study. In particular, the omission of rheumatologists may have influenced the outcome. Despite these broad limitations, the study provided an appropriate first step in determining a set of diagnostic criteria/clinical identifiers for the early stage of adhesive capsulitis.

The exploratory power Doppler ultrasound study (Chapter 5) was limited by the lack of a reference standard to confirm the diagnosis of early stage adhesive capsulitis and would have been strengthened by inclusion of a control group. The rate of increased vascularisation in asymptomatic shoulders as well as those with alternate diagnoses is required to be determined to support the result of this study. As there is as yet no clear reference standard for this disorder in the early stage and given the exploratory nature of this study, with the aim to investigate a clinically viable assessment tool, this pragmatic approach was considered to be justified. Furthermore, although the power Doppler ultrasound images were obtained by a trained investigator, replicating the study using an ultrasonographer or radiologist as the operator, and in a diagnostic imaging centre setting (rather than in a physiotherapy clinic), may provide added

insight. Nonetheless, this approach was consistent with the clinical nature of the research comprising this thesis.

Chapter 6 describes movement and pain patterns that may exist in a group of patients with a clinical diagnosis of early stage adhesive capsulitis. This study used factor analysis to determine the presence of clusters of symptoms as it was considered the most appropriate statistical procedure for this purpose. The sample size for this study was however modest as a result of slow recruitment and the trends that emerged require confirmation with larger samples. In light of the results of the final study it could be argued that patients with restriction and pain in external rotation movements were diagnosed with early stage adhesive capsulitis on that basis, which may partly explain why those characteristics emerged. Future research may consider using additional inclusion criteria such as MRI findings, that are unrelated to the study question to minimise such effects.

Finally, the validation study (Chapter 7) was informed by the results of the Delphi study described in Chapter 3. The most remarkable limitation of this study was the lack of a recognised reference standard to use as the reference test. The use of local anaesthetic administered concurrently with the corticosteroid injection as a reference standard for comparison with the clinical criteria, which was both ethically and clinically necessary may have been limited in its ability to accurately and consistently identify the disorder.

The modest percentage (29%) of participants demonstrating an increase in vascularity in the rotator interval of the shoulder in the power Doppler ultrasound study (Chapter 5), and the lack of consistently clear movement and pain patterns emerging (Chapter 6) may be partly explained by the fact that inclusion of participants in these studies was on the basis of clinical presentation in the absence of a recognised reference standard. Given the results of the final study (Chapter 7), it is possible that a number of the participants involved in these earlier studies had pathologies other than adhesive capsulitis, as previously proposed (Bunker 2009) thus confounding the results.

The studies described in Chapters 5, 6 and 7 recruited participants on the basis of having symptoms for less than or equal to nine months. It is unknown however, whether some of the participants in these studies had progressed beyond the early stage of the disorder. As the stages of adhesive capsulitis are described as a continuum, with the early stage most commonly reported to last up to nine months, and because agreed criteria for each stage are yet to be defined, this duration of symptoms was considered appropriate for the studies. A final consideration is that the studies that comprise this thesis relied on participants from a clinical setting and as such numbers in each of the research studies were modest despite data collection occurring over a period of up to three years. Other authors (Carette, Moffet et al. 2003; Buchbinder, Green et al. 2004) have experienced similar recruitment difficulties, perhaps further reflecting the ongoing difficulty of research in this area.

8.3 Generalisability of the findings

The findings of these studies can be generalised to the wider population when considering the diagnosis of early stage adhesive capsulitis. Firstly, the mean age of participants in all three studies is similar to those in whom adhesive capsulitis has been previously described (Lubiecki and Carr 2007; Smith, White et al. 2012). Secondly, the gender distribution was approximately even in the reported studies, possibly in keeping with the more contemporary suggestion that adhesive capsulitis is similarly prevalent in males and females (Bunker 2009). This is in contrast to earlier reports of a higher incidence of the disorder in women. The prevalence of diabetes and Dupytren's disease, which have been traditionally associated with adhesive capsulitis, in the studies contained in this thesis was lower than previously identified for this disorder. This may also reflect more contemporary research questioning these associations (Smith, White et al. 2012). However, as patients were recruited from a private clinic specialising in disorders of the upper limb in a metropolitan area they may not be representative of the wider population in alternate geographic locations, socioeconomic or alternate clinical settings.

The Delphi study (Chapter 3), participants were a group of experts involved in the diagnosis and treatment of adhesive capsulitis from several different disciplines, so a wide range of opinion was obtained. Experts were only recruited from Australia and New Zealand and therefore may reflect the views held in these countries.

8.4 Conclusions

The early diagnosis of adhesive capsulitis remains problematic and the identification of a set of clinical identifiers or diagnostic criteria is confounded by the lack of an agreed reference standard. The clinical identifiers determined by expert consensus and arguably utilised by many clinicians may not accurately reflect the presentation of the disorder in its early stage, which may help explain the variable results of treatment reported to date. Diagnostic medical imaging currently does not provide advantage over clinical examination in early diagnosis, and indeed most previous studies have investigated the later stages of the disorder. However the emerging use of ultrasound in the clinical setting may enable the trained clinician to identify increased vascularisation in the early stages of adhesive capsulitis if it can be demonstrated this is unique to this disorder. Recognition of movement and pain patterns, in particular careful assessment of external rotation in both neutral and 90 degrees abduction may also facilitate early diagnosis. The final study indicated that the identifiers proposed by expert consensus may not be true predictors of early stage adhesive capsulitis. Overall this challenges the traditional presentation and supports lower prevalence estimates of adhesive capsulitis. Interestingly the results of the studies collectively suggest a new picture of presentation and diagnosis of early stage adhesive capsulitis may be emerging.

8.5 Implications of the body of research

8.5.1 Clinical

The findings of these studies suggest that recognition of adhesive capsulitis in its early stage is not straightforward. It is not possible to accurately diagnose the disorder with a single diagnostic test, consistent with many other musculoskeletal disorders, and careful consideration of a range of patient reported symptoms and physical examination findings is required. Importantly, it should be recognised that the characteristics of early stage adhesive capsulitis may not be consistent with those commonly accepted for the later stages of the disorder. Careful examination of range of movement and pain associated with external rotation in both neutral and 90 degrees abduction may facilitate recognition, and if readily accessible, ultrasound examination of the rotator interval may also support a diagnosis.

8.5.2 Future research

A recurrent theme throughout the studies was that there is currently no reference standard by which to diagnose early stage adhesive capsulitis. Participants were included on the basis of clinical presentation, rather than determined by a validated reference standard. This has limited the interpretation of the results of the studies. In the absence of such a reference standard for early stage adhesive capsulitis, and indeed the lack of anatomical validity of most shoulder tests (Hegedus, Goode et al. 2007; Green, Shanley et al. 2008) the approach recently suggested by Schellingerhout, et al (2008) to abolish the use of labels and direct future research to populations with 'general' shoulder pain may be reasonable. As more invasive diagnostic strategies

including surgery are not always ethical or generally common clinical practice for patients with shoulder pain, this may be an alternate method to facilitate identification of diagnostic sub-groups. Such identification of subgroups with common clinical characteristics may subsequently then be linked to treatment outcomes. To pursue this contemporary suggestion however would require recruitment of large numbers of participants which is beyond the scope of this thesis. The results of the studies that comprise this thesis provide valuable insight and direction to determining the appropriate clinical characteristics for the early stage of adhesive capsulitis that may be considered in future trials. In particular, examination of the rotator interval with power Doppler ultrasound (Chapter 5) and assessment of both range of movement and pain at the end of range (Chapter 6) in a heterogeneous population may facilitate the identification of sub-groups. The role of abnormal muscle function in the presentation of shoulder stiffness has also been proposed (Ginn 2005), and whilst it was not explored in this thesis it may be an area of future research worthy of consideration.

Future research that examines the relationships between each of the studies that comprise this thesis would be a valuable and logical progression to provide added insight to the diagnosis of early stage adhesive capsulitis. For example the relationship between the reference standard of a PAR on intraarticular injection, and a positive power Doppler signal (Chapter 5) warrants further exploration. Likewise any relationship between external rotation (Chapter 6) and a PAR may also assist in providing useful information to facilitate diagnosis of early stage adhesive capsulitis.

8.6 Summary of the thesis

Shoulder pain is a commonly presenting musculoskeletal disorder that is responsible for significant pain, disability and reduction in quality of life, as well as placing a financial burden on society. Adhesive capsulitis is a shoulder disorder that is frequently encountered in the musculoskeletal clinical setting. It is recognised as difficult to diagnose in its early stage and in particular to differentiate from other shoulder disorders, and it has the potential to cause considerable pain and restriction of movement. Treatment in the early stage has been proposed to reduce the overall morbidity of the disorder suggesting that recognition of the disorder in this stage may be clinically beneficial and cost effective.

The studies presented in this thesis have investigated several strategies that may assist the clinician in diagnosis and also the researcher to identify a homogeneous group of patients. It has proposed a set of clinical identifiers for the early stage of adhesive capsulitis determined by expert consensus and pursued their validation. It has also suggested a diagnostic imaging procedure which may assist in the early identification of adhesive capsulitis as well as movement and pain patterns that could facilitate diagnosis. Importantly, the findings of this thesis have indicated that early diagnosis of adhesive capsulitis is not clear-cut and will continue to pose a clinical and research challenge. The studies that comprise this thesis have however identified some valuable clinical characteristics that are an important step in meeting this challenge and which could inform clinical practice as well as direct future research.

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Appendices

Appendix 1

Statements of collaboration from authors

Appendix 2

Ethics approval and supporting documents for Study 1 (Chapter 3)

Appendix 3

Ethics approval and supporting documents for Studies 2, 3 and 4 (Chapters 5, 6 and 7)

Appendix 4

Journal publications

Appendix 1

Statements of collaboration from authors

The University of Newcastle guidelines for PhD thesis by publication with multiple authors require that a signed written statement from all authors of a work attesting to the nature and extent of the intellectual input for which the candidate is responsible is included in the thesis. As required, this Appendix contains copies of signed letters with statements on the contribution to each of the five published papers.

Statement from Darren A. Rivett relating to papers published with Sarah Walmsley

I, Darren A. Rivett, attest that Research Higher Degree candidate, Sarah Walmsley contributed to the listed publications by contributing to the conception and design of the studies, conducting and writing up the literature review, the collection of data, undertaking the statistical analysis, description and interpretation of the results, and writing the discussion and conclusions.

Walmsley S, Rivett DA, Osmotherly PG (2009). Adhesive capsulitis: establishing consensus on clinical identifiers for stage 1 using the Delphi technique. *Physical Therapy.* 89 (9): 906-917.

Walmsley S, Osmotherly PG, Rivett DA, McKiernan TS (2012). Early diagnosis of primary/idiopathic adhesive capsulitis: can imaging contribute? *International Musculoskeletal Medicine.* 34 (4): 166-174.

Walmsley S, Osmotherly PG., Walker CJ. Rivett DA (2013). Power Doppler ultrasound in the early diagnosis of primary/idiopathic adhesive capsulitis: an exploratory study. *Journal of Manipulative and Physiological Therapeutics.* 36 (7): 428-435.

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Walmsley S, Osmotherly PG, Rivett DA (2014). Clinical identifiers/diagnostic criteria for primary/idiopathic adhesive capsulitis: are we seeing the real picture? *Physical Therapy* 94 (7): 968-976.

……

Professor Darren A. Rivett **Date:**

……

Sarah Walmsley **Date:**

……

Professor Robert Callister **Date:**

Assistant Dean Research Training, Faculty of Health and Medicine

Statement from Peter G. Osmotherly relating to papers published with Sarah Walmsley

I, Peter G. Osmotherly, attest that Research Higher Degree candidate, Sarah Walmsley contributed to the listed publication by contributing to the conception and design of the studies, conducting and writing up the literature review, the collection of data, undertaking the statistical analysis, description and interpretation of the results, and writing the discussion and conclusions.

Walmsley S, Rivett DA, Osmotherly PG (2009). Adhesive capsulitis: establishing consensus on clinical identifiers for stage 1 using the Delphi technique. *Physical Therapy.* 89 (9): 906-917.

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……

Peter G. Osmotherly **Date:**

……

Sarah Walmsley **Date:**

……

Professor Robert Callister **Date:**

Assistant Dean Research Training, Faculty of Health and Medicine

Statement from Sharmaine T. McKiernan relating to a paper published with Sarah Walmsley

I, Sharmaine T. McKiernan, attest that Research Higher Degree candidate, Sarah Walmsley contributed to the listed publication by developing the review protocol, conducting and writing up the literature review including interpreting the literature and writing the discussion and conclusions.

Walmsley S, Osmotherly PG, Rivett DA, McKiernan TS (2012). Early diagnosis of primary/idiopathic adhesive capsulitis: can imaging contribute? *International Musculoskeletal Medicine*. 34 (4): 166-174.

……

Sharmaine T. McKiernan **Date:**

……

Sarah Walmsley **Date:**

……

Professor Robert Callister **Date:**

Assistant Dean Research Training, Faculty of Health and Medicine

Statement from Colin J. Walker relating to a paper published with Sarah Walmsley

I, Colin J. Walker, attest that Research Higher Degree candidate, Sarah Walmsley contributed to the listed publication by contributing to the conception and design of the study, conducting and writing up the literature review, the collection of data, undertaking the statistical analysis, description and interpretation of the results, and writing the discussion and conclusions.

Walmsley S, Osmotherly PG., Walker CJ. Rivett DA (2013). Power Doppler ultrasound in the early diagnosis of primary/idiopathic adhesive capsulitis: an exploratory study. *Journal of Manipulative and Physiological Therapeutics*. 36 (7): 428-435.

……

Colin J. Walker **Date:**

……

Sarah Walmsley **Date:**

……

Professor Robert Callister **Date:**

Assistant Dean Research Training, Faculty of Health and Medicine

Appendix 2

Ethics approval and supporting documents for Study 1 (Chapter 3)

The UNIVERSITY of NEWCASTLE

Form HE2 1.05

HUMAN RESEARCH ETHICS COMMITTEE

Certificate of Approval for a research project involving humans

Applicant

Chief Investigator/Project Supervisor: (First named in application)	*Associate Professor Darren Rivett*
Co-Investigators/Research Students:	*Mr Peter Osmotherly* *Ms Sarah Walmsley*
Project Title:	*Adhesive capsulitis: establishing consensus on diagnostic criteria of stage one using the Delphi technique*

In approving this project, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the *National Statement on Ethical Conduct in Research Involving Humans, 1999*, and the requirements within this University relating to human research.

Details of Approval

HREC Approval No: *H-243-0606*	**Date of Approval:** *21 June 2006*
Approval valid for: *3 years, or until project ceases, whichever occurs first.*	**Progress reports due:** *Annually*

NOTE: Approval is granted subject to the requirements set out in the attached document *Approval to Conduct Human Research*, and any additional comments or conditions noted below:

21 June 2006
The Committee commended the researchers on a well written application and agreed that approval would be granted subject to a satisfactory response to issues identified by the Committee.

14 July 2006
Response received and accepted.
Approval confirmed.

Variations to Approved Protocol:

13 December 2006
Variation as a result of piloting to:

1. Amend the study documents as follows:
   a. Highlight in the questionnaires, accompanying letters and reminder letters that it was stage one of the adhesive capsulitis that is being investigated.
   b. Indicate in initial letter that each questionnaire will take approximately 20 minutes to complete (rather than 10 minutes).
   c. Amend the Information Statement to more accurately describe the method of round two of the study.
2. Amend the reminder notifications as follows:
   a. Send two reminders (instead of one). Reminders would be sent two weeks after the questionnaire has been posted and against after a further two weeks if no response has been received.
   b. Utilise telephone reminders for questionnaires two and three where a telephone number was available. Participants would be able to indicate on the first questionnaire if they prefer not to receive telephone reminders.

Approved.
The Committee ratified the approval granted by the Deputy Chair on 7 December 2006

Variations to Approved Protocol Continued Over

The UNIVERSITY of NEWCASTLE
AUSTRALIA

Form HE2 1/05

Variations to Approved Protocol *Continued*:

21 February 2007
Variation to:

1. Extend source of recruitment to include members of the Australasian Faculty of Musculoskeletal Medicine.
2. Amend the Information Statement and Questionnaire accordingly (now Version 4, 17/1/07).

Approved.
The Committee ratified the approval granted by the Chair on 19 January 2007.

Signed for the Committee: _____

Ms Ruth Gibbins
Human Research Ethics Officer (Acting)

Researchers

Sarah Walmsley
PhD Candidate, Discipline of Physiotherapy,
The University of Newcastle

A/ Prof Darren Rivett
Discipline of Physiotherapy, The University of Newcastle

Peter Osmotherly
Discipline of Physiotherapy, The University of Newcastle

Discipline of Physiotherapy

School of Health Sciences
Faculty of Health
The University of Newcastle
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ADHESIVE CAPSULITIS: ESTABLISHING CONSENSUS ON DIAGNOSTIC CRITERIA OF STAGE ONE USING THE DELPHI TECHNIQUE

(date)

Dear

As an expert in a relevant area you are invited to take part in the research project identified above being conducted by Sarah Walmsley, as part of her PhD candidature under the supervision of Associate Professor Darren Rivett, Head of the Discipline of Physiotherapy at The University of Newcastle and Peter Osmotherly, Lecturer in Physiotherapy at The University of Newcastle.

The purpose of this study is to establish consensus on the set of necessary and sufficient diagnostic criteria experts use to achieve a diagnosis of **stage one** or the painful stage of primary or idiopathic adhesive capsulitis when differential diagnosis may be difficult. There is currently no agreement as to the early clinical characteristics and features which differentiate adhesive capsulitis at that stage from other disorders which present in a similar manner. The study uses the Delphi technique which is an iterative questionnaire of three sequential rounds, each building on the results of the previous round. Each questionnaire will take approximately 20 minutes to complete.

An information statement describing the study in more detail and what is involved in participation is attached. If you are willing to participate it would be much appreciated if you would complete Questionnaire 1, which is included with this letter, at your earliest convenience and at the latest by (**date**). Please mail it back to The University of Newcastle, Discipline of Physiotherapy in the supplied envelope.

If you would prefer this and subsequent questionnaires to be forwarded via email or fax please contact Sarah Walmsley or indicate your email address on Questionnaire 1. A facsimile transmission cover sheet is also attached if that is your preferred method of reply.

Please do not hesitate to contact the researchers if you have any queries:

Sarah Walmsley:	(02) 49624477	email	Sarah.Walmsley@newcastle.edu.au
A/Prof Darren Rivett:	(02) 49217821	email	Darren.Rivett@newcastle.edu.au
Peter Osmotherly:	(02) 49217718	email	Peter.Osmotherly@newcastle.edu.au

Thank you for considering this invitation to participate in this research.
With kind regards,

Sarah Walmsley	A/Prof Darren Rivett	Peter Osmotherly
BSc, GradDipPhty, MAppSc(Ortho Phty)	BAppSc(Phty), MAppSc(Manip Phty), PhD	BSc, GradDipPhty, MMed.Sc(Clin Epi)
PhD Candidate	Project Supervisor	Co-Supervisor

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-243-0606. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au

Researchers

Sarah Walmsley
PhD Candidate, Discipline of Physiotherapy,
The University of Newcastle

A/ Prof Darren Rivett
Discipline of Physiotherapy, The University of Newcastle

Peter Osmotherly
Discipline of Physiotherapy, The University of Newcastle

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ADHESIVE CAPSULITIS: ESTABLISHING CONSENSUS ON DIAGNOSTIC CRITERIA OF STAGE ONE USING THE DELPHI TECHNIQUE

INFORMATION STATEMENT

As an expert in musculoskeletal practice you are invited to participate in the research project identified above. The following information statement provides some background information on the project, and what is required if you decide to participate.

What is the purpose of the study?

The study recognizes that clinicians and researchers working with patients with adhesive capsulitis require improved methods to diagnose primary or idiopathic, adhesive capsulitis in its early stage. There is currently no clear description or agreement as to the **stage one** clinical characteristics and features which diagnose or differentiate adhesive capsulitis at that stage from other similar disorders. The second or later stage of the disorder is not being considered in this study as the clinical presentation after the stage one is more distinct and easier to recognize.

This study aims to establish consensus on the set of diagnostic criteria necessary and sufficient to achieve diagnosis of **stage one** or the **painful stage** of primary adhesive capsulitis using an expert panel of relevant Australian and New Zealand medical specialists, physiotherapists, chiropractors and osteopaths for the purpose of facilitating early intervention. Early recognition of adhesive capsulitis may also facilitate early, potentially more effective intervention.

Who can participate?

The panel comprises experts from the following:

1. Co-ordinators of Postgraduate Musculoskeletal Physiotherapy programs in Australia and New Zealand
2. Physiotherapists with Musculoskeletal Specialist status (Level 3 membership of Musculoskeletal Physiotherapy Australia)
3. Members of the Shoulder and Elbow Physiotherapists Australia special interest group
4. Co-ordinators of Postgraduate Chiropractic programs in Australia and New Zealand
5. Co-ordinators of Postgraduate Osteopathy programs in Australia and New Zealand
6. Orthopaedic Surgeons members of the Shoulder and Elbow Society of Australia
7. Rehabilitation Medicine Physicians members of the Musculoskeletal Medicine and Pain Special Interest Group
8. Members of the Australian College of Physical Medicine
9. Members of the Australasian Faculty of Musculoskeletal Medicine
10. Australian or New Zealand authors who have published in the area of adhesive capsulitis in the past 10 years

Participation is voluntary.

Participation in this research is entirely at your discretion and you are under no obligation to do so. If you decide to participate, you may withdraw from the project at any time without giving any reason. If you withdraw from the study you may withdraw data provided by you from the study results. Your relationship with the researchers will in no way be affected by your decision to participate or not.

What will you be asked to do?

You will have been selected as a possible participant for this study by virtue of your extensive experience and knowledge regarding musculoskeletal disorders.

This study will use the Delphi technique to collect information. This technique has been chosen as it is an established and recognized method of deriving the opinion of experts to determine consensus. The Delphi technique is a multi-stage process that uses a series of evolving, sequential questionnaires or rounds linked by feedback. Each round builds on the results of the previous one and results in consensus by the final round. This method allows a large group of participants without geographical constraints, permits open discussion of opinion without group dynamics and is anonymous.

The study will have a series of three rounds:

- **Round One** - Questionnaire 1 is included with this information statement. Your completion of this questionnaire will indicate your informed consent to participate in the study. You are requested to identify to which group of participants you belong then list the necessary and sufficient set of diagnostic criteria you believe appropriate for **stage one** of primary adhesive capsulitis (including your rationale if possible). Upon completion you are asked to return Questionnaire 1 (via mail/ email/ fax).

- **Round Two -** Upon receipt of all responses, the researchers will develop Questionnaire 2. This will list all criteria suggested by experts from Questionnaire 1 and you will be asked to score how important each criterion identified is in diagnosing **stage one** of primary adhesive capsulitis using a Likert (5 point) scale. Upon completion, you are asked to return Questionnaire 2 (via mail/ email/ fax).

- **Round Three** – Upon receipt of all responses to Questionnaire 2, Questionnaire 3 will be developed. This will be similar to Questionnaire 2, but will allow you to re-score your response on the Likert scale in the light of the responses of the other participants. Percentage response rates for each criterion from Questionnaire 2 will be supplied with this final round. Upon completion you are asked to return Questionnaire 3 (via mail/email/fax).

Final Result - The researchers will develop the diagnostic criteria for **stage one** primary adhesive capsulitis, based on the opinions of all the expert participants. You may request a copy of the study results from the researchers.

What are the risks and benefits of participating?

There are no risks to participants. There is no direct benefit to you as a participant other than learning from the opinions of the other experts. Your participation will allow us to establish current knowledge and practice in the diagnosis of **stage one** of primary adhesive capsulitis and will further research, clinical practice and education in this area.

How will your privacy be protected?

Your privacy will be protected. After collection of data through the process described above, all information will be numerically coded and no individuals will be identified. There will be a separation of identifying information and no findings which could identify you will be published or otherwise presented. Access to

individual findings will be restricted to the researchers. Numerically coded data as well as identifying information will be stored for 10 years in separate locked cabinets in an office of the School of Health Sciences at The University of Newcastle, after which time it will be destroyed. If questionnaires are returned via email the email address will be separated from the questionnaire as soon as it is received. Questionnaires returned by fax will be to a dedicated fax machine in the office of A/Prof Darren Rivett to which only he has access.

How will the information collected be used?

The results and conclusions drawn from this study will form part of the PhD thesis of the student researcher, Sarah Walmsley, and will be submitted for publication in scientific journals. The results of the study will also be presented at future University Seminars and at appropriate national or international conferences. No identification of participating individuals will be possible from the presentation of results in any form.

What do you need to do to participate?

If you are willing to participate please complete the enclosed Questionnaire 1 and return it in the enclosed reply paid envelope. If you would prefer this and subsequent questionnaires to be sent via email or fax please contact Sarah Walmsley Sarah.Walmsley@newcastle.edu.au or include that address where indicated on Questionnaire 1.

Further information

After reading this information statement if you have any questions or would like more information about the study, please do not hesitate to contact one of the researchers listed below. If you would like to know the outcomes of this research at its completion any of the researchers would be pleased to provide details.

Sarah Walmsley:	(02) 49624477	email Sarah.Walmsley@newcastle.edu.au
A/Prof Darren Rivett:	(02) 49217821	email Darren.Rivett@newcastle.edu.au
Peter Osmotherly:	(02) 49217718	email Peter.Osmotherly@newcastle.edu.au

Thank you for considering this invitation to participate.

With kind regards,

Sarah Walmsley	A/Prof Darren Rivett	Peter Osmotherly
BSc, GradDipPhty, MAppSc(Ortho Phty)	BAppSc(Phty), MAppSc(Manip Phty), PhD	BSc, GradDipPhty, MMed.Sc(Clin Epi)
PhD Candidate	Project Supervisor	Co-Supervisor

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H- 243-0606. *Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.*

Researchers

Sarah Walmsley
PhD Candidate, Discipline of Physiotherapy,
The University of Newcastle

A/ Prof Darren Rivett
Discipline of Physiotherapy, The University of Newcastle

Peter Osmotherly
Discipline of Physiotherapy, The University of Newcastle

Discipline of Physiotherapy

School of Health Sciences
Faculty of Health
The University of Newcastle
University Drive, Callaghan
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Fax: +61 2 4921 7902

ADHESIVE CAPSULITIS: ESTABLISHING CONSENSUS ON DIAGNOSTIC CRITERIA OF STAGE ONE USING THE DELPHI TECHNIQUE

QUESTIONNAIRE 1

This first questionnaire requests you to list the set of criteria, which you believe to be necessary and sufficient to achieve the diagnosis of **stage one** primary adhesive capsulitis. You may include as many or as few criteria you feel necessary. These may include patient characteristics, signs and symptoms, physical examination findings, coexisting diagnoses, negative findings and any other features you may think appropriate. List as many or as few as you consider relevant. You may also provide a rationale for your criterion if you feel it appropriate.
Note: The later stages of the disorder, when clinical presentation is more distinct, are not being considered in this study.

If you would prefer this and/or subsequent questionnaires to be sent via email or fax please contact Sarah Walmsley at Sarah.Walmsley@newcastle.edu.au or indicate your email or fax address in the space provided.

Email/fax address: ……

Please do not contact me by telephone if I do not submit subsequent questionnaires ☐

Please indicate the group to which you belong:

1. Co-ordinator of a postgraduate musculoskeletal physiotherapy program in Australia or New Zealand ☐
2. Specialist musculoskeletal physiotherapist (level 3 MPA member) in Australia ☐
3. Member of Shoulder and Elbow Physiotherapists Australia ☐
4. Co-ordinator of a postgraduate chiropractic program in Australia or New Zealand ☐
5. Co-ordinator of a postgraduate osteopathy program in Australia or New Zealand ☐
6. Member of the Australian Orthopaedic Association and Member of the Shoulder and Elbow Society of Australia ☐
7. Rehabilitation medicine physician and member of the Musculoskeletal and Pain Special Interest Group of The Australasian Faculty of Rehabilitation Medicine ☐
8. Member of the Australian College of Physical Medicine ☐
9. Member of the Australasian Faculty of Musculoskeletal Medicine ☐
10. Author of publication on adhesive capsulitis in the past 10 years ☐

Please list the criteria and rationale (optional)

1. Criterion 1: _____
_____

Rationale: _____
_____
_____

2. Criterion 2: _____
_____

Rationale: _____
_____
_____

3. Criterion 3: _____
_____

Rationale: _____
_____
_____

4. Criterion 4: _____
_____

Rationale: _____
_____
_____

5. Criterion 5: _____
_____

Rationale: _____
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_____

6. Criterion 6: _____

_____

Rationale: _____

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7. Criterion 7: _____

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Rationale: _____

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8. Criterion 8: _____

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Rationale: _____

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9. Criterion 9: _____

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Rationale: _____

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10. Criterion 10: _____

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Rationale: _____

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_____

11. Criterion 11: _____

_____

Rationale: _____

_____

_____

12. Criterion 12: _____

_____

Rationale: _____

_____

_____

13. Criterion 13: _____

_____

Rationale: _____

_____

_____

14. Criterion 14: _____

_____

Rationale: _____

_____

_____

Thank you for your time and participation.

Sarah Walmsley
BSc, GradDipPhty, MAppSc(Ortho Phty)
PhD Candidate

A/Prof Darren Rivett
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ADHESIVE CAPSULITIS: ESTABLISHING CONSENSUS ON DIAGNOSTIC CRITERIA OF STAGE ONE USING THE DELPHI TECHNIQUE

14 May 2007

Dear

Re : QUESTIONNAIRE 2

Thank you for responding to Questionnaire 1. A large number of responses were received which required lengthy analysis and reduction to a manageable number by the researchers. This was achieved by grouping similar answers together, eliminating single responses and those not supported by the literature. Items that represented later, more recognizable stages of the disorder and pertaining to secondary adhesive capsulitis or shoulder stiffness from a known cause were also omitted. As a result 60 possible criteria for **stage one or the early stage** of primary adhesive capsulitis have been identified.

Please find enclosed Questionnaire 2 which lists the criteria from all participants and asks you to rate the degree of importance each criterion has in diagnosing **stage one or the early stage** of primary/idiopathic adhesive capsulitis. The questionnaire will take approximately 10 – 15 minutes to complete.

Instructions:

1. For each criterion listed from Questionnaire 1 please circle or indicate the number on the Likert scale representing its importance in diagnosing **stage one** primary adhesive capsulitis.
2. Please return your response via mail/email/fax by 31 May 2007.

For any questions relating to this study, please contact any of the researchers:

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A/Prof Darren Rivett:	(02) 49217821	email	Darren.Rivett@newcastle.edu.au
Peter Osmotherly:	(02) 49217718	email	Peter.Osmotherly@newcastle.edu.au

Thank you again for your time and participation in this study.
With kind regards,

Sarah Walmsley	A/Prof Darren Rivett	Peter Osmotherly
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PhD Candidate	Project Supervisor	Co-Supervisor

Complaints about this research

*This project has been approved by the University's Human Research Ethics Committee, Approval No. H-*243 - 0606.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

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ADHESIVE CAPSULITIS: ESTABLISHING CONSENSUS ON DIAGNOSTIC CRITERIA OF STAGE ONE USING THE DELPHI TECHNIQUE

QUESTIONNAIRE 2

For each criterion listed please score the importance of the criterion in the diagnosis of **stage one or the early stage** of primary/idiopathic adhesive capsulitis using the following scale

1. ***Strongly Agree;*** the selected criterion is extremely important in the diagnosis of stage one of primary adhesive capsulitis
2. ***Agree;*** the selected criterion is important in the diagnosis of stage one of adhesive capsulitis
3. ***Undecided;*** uncertainty of the importance of the selected criterion in the diagnosis of stage one of adhesive capsulitis
4. ***Disagree;*** the selected criterion is not important in the diagnosis of stage one of adhesive capsulitis
5. ***Strongly Disagree;*** there is absolutely no importance whatsoever of the selected criterion in the diagnosis of stage one of adhesive capsulitis

Please circle or mark the number that best represents your opinion

Patient reported symptoms:

Criterion 1: **Pain is generally located over the upper arm**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 2: **Pain is predominately over the lateral shoulder/deltoid region**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 3: **Pain is predominately over the anterior shoulder**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 4: **Pain may be referred distally into the forearm**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 5: **Pain is diffuse or poorly localized**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 6: **The pain is described as deep**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 7: **The intensity of the pain is described as severe**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 8: **The pain is constant or unrelenting in nature**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 9: **The pain is described as an ache**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 10: **The level of pain is progressively increasing**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 11: **There is an intermittent catching or pinching pain**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 12: **There is a strong component of night pain**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 13: **There is a marked increase in pain with rapid or unguarded movements**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 14: **It is uncomfortable to lie on the affected shoulder**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 15: **The patient reports the pain is easily aggravated by movement**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 16: **Once aggravated the patient reports the pain is slow to settle**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 17: **Function is limited by increasing stiffness in this stage**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 18: **The history of onset of pain is spontaneous**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 19: **Symptoms have been present for greater than 4 weeks**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 20: **There is often a history of a minor trauma/precipitating event**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 21: **The onset of the condition is sudden**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Demographics:

Criterion 22: **The onset is generally in people greater than 35 years of age**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 23: **The onset is generally in people less than 60 years of age**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 24: **The condition more commonly presents in females**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Physical examination findings:

Criterion 25: **On examination there is a global loss of active and passive range of movement**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 26: **On examination there is pain at the end of range in all directions**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 27: **On examination there is no painful arc with shoulder elevation**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 28: **There is protective muscle guarding with movement**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 29: **The loss of movement in any direction is minor**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 30: **The greatest loss of movement is in external rotation**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 31: **There is painful limitation of active external rotation range performed in supine at 90° shoulder abduction**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 32: **There is marked pain during isometric external rotation strength testing performed in supine at 90° shoulder abduction**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 33: **The patient's range of movement is progressively decreasing due to pain**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 34: **There is a global loss of passive gleno-humeral joint movement**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 35: **The loss of movement is in a gleno-humeral joint capsular pattern ie: external rotation >abduction> internal rotation**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 36: **Resisted isometric muscle testing is painfree**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 37: **If pain is not inhibiting, muscle strength testing will be normal**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 38: **There is diffuse tenderness to palpation around the shoulder**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 39: **There is tenderness to palpation specifically over the anterior joint**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 40: **The scapula position is elevated at rest or with movement**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 41: **Provocative tests for tendonitis do not inform the diagnosis**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Associations:

Criterion 42: **There can be an association with diabetes**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 43: **There may be a co-existing history of a thyroid condition**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 44: **The onset is of the condition is more common in spring and autumn**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 45: **A minor viral illness may precede the onset**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 46: **There is often a past history of adhesive capsulitis of the opposite shoulder**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 47: **There is frequently a history of impingement syndrome in the same shoulder**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 48: **The thoracic spine is kyphotic or hypomobile**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Response to treatment:

Criterion 49: **There is a non-response or an exacerbation of pain with treatment involving physical therapies**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 50: **There is minimal or no response to usual analgesic medication**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 51: **There is minimal or no response to NSAIDs**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 52: **There is no response to sub-acromial steroid injection**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 53: **There is a favorable response to a steroid injection into the gleno-humeral joint**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Investigations:

Criterion 54: **A thickened joint capsule will be evident on magnetic resonance imaging (MRI)**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 55: **A decreased joint volume will be evident on MRI**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 56: **Ultrasound investigation does not inform the diagnosis**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 57: **X-Ray examination only excludes osteoarthritis and calcific tendonitis**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 58: **There is a mild elevation of erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP)**

1 _____ 2 _____ 3 _____ 4 _____ 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

Criterion 59: **Blood factors exclude an infective or systemic inflammatory state**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

Criterion 60: **Arthroscopy reveals synovitis and inflammation of the joint capsule**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

Thank you for your time and participation.

Sarah Walmsley
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PhD Candidate

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ADHESIVE CAPSULITIS: ESTABLISHING CONSENSUS ON DIAGNOSTIC CRITERIA OF STAGE ONE USING THE DELPHI TECHNIQUE.

18 July, 2007

Dear

Re: QUESTIONNAIRE 3

Thank you for responding to Questionnaire 2. This final round includes the same identified diagnostic criteria from Questionnaire 1 and the Likert scale used in Questionnaire 2. Additionally it provides you with a frequency count of the scoring for all participants as to the relative importance of each criterion identified. You are now asked to re-score each criterion in the light of the responses from the other expert participants.

Please return your response via mail/email/fax by 3 August 2007.

Upon receipt of all participants' responses, we hope to be able to develop a list of the criteria and their relative importance in the diagnosis of **stage one** of primary adhesive capsulitis based on the opinions of all the expert participants.

For any questions relating to this study, please contact any of the researchers:
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Peter Osmotherly: (02) 49217718 email Peter.Osmotherly@newcastle.edu.au

Thank you again for your time and participation in this study.
With kind regards,

Sarah Walmsley	A/Prof Darren Rivett	Peter Osmotherly
BSc, GradDipPhty, MAppSc(Ortho Phty)	BAppSc(Phty), MAppSc(Manip Phty), PhD	BSc, GradDipPhty, MMed.Sc(Clin Epi)
PhD Candidate	Project Supervisor	Co-Supervisor

Complaints about this research

*This project has been approved by the University's Human Research Ethics Committee, Approval No. H-*243-0606.
Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

(Version 3, 1/12/06)

Researchers

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ADHESIVE CAPSULITIS: ESTABLISHING CONSENSUS ON DIAGNOSTIC CRITERIA OF STAGE ONE USING THE DELPHI TECHNIQUE

QUESTIONNAIRE 3

For each criterion listed please score the importance of the criterion in the diagnosis of **stage one or the early stage** of primary/idiopathic adhesive capsulitis using the following scale

1. ***Strongly Agree;*** the selected criterion is extremely important in the diagnosis of **stage one** of primary adhesive capsulitis
2. ***Agree;*** the selected criterion is important in the diagnosis of **stage one** of primary adhesive capsulitis
3. ***Undecided;*** uncertainty of the importance of the selected criterion in the diagnosis of **stage one** of primary adhesive capsulitis
4. ***Disagree;*** the selected criterion is not important in the diagnosis of **stage one** of primary adhesive capsulitis
5. ***Strongly Disagree;*** there is absolutely no importance whatsoever of the selected criterion in the diagnosis of **stage one** of primary adhesive capsulitis

A percentage of all participants' responses from Questionnaire 2 is indicated below each level of importance. Please place an X in the box below the descriptor that best represents your opinion in the light of the responses from the other expert participants.

Patient reported symptoms:

Criterion 1: **Pain is generally located over the upper arm**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(22%)	**(53%)**	**(10%)**	**(15%)**	**(-)**

Criterion 2: **Pain is predominately over the lateral shoulder/deltoid region**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(26%)	**(48%)**	**(11%)**	**(15%)**	**(-)**

Criterion 3: **Pain is predominately over the anterior shoulder**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(8%)	**(43%)**	**(19%)**	**(27%)**	**(3%)**

Criterion 4: **Pain may be referred distally into the forearm**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(8%)	**(33%)**	**(21%)**	**(33%)**	**(5%)**

Criterion 5: **Pain is diffuse or poorly localized**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(15%)	**(50%)**	**(10%)**	**(22%)**	**(3%)**

Criterion 6: **The pain is described as deep**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(25%)	**(57%)**	**(14%)**	**(4%)**	**(-)**

Criterion 7: **The intensity of the pain is described as severe**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(26%)	**(47%)**	**(12%)**	**(14%)**	**(1%)**

Criterion 8: **The pain is constant or unrelenting in nature**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(14%)	**(54%)**	**(12%)**	**(16%)**	**(4%)**

Criterion 9: **The pain is described as an ache**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(28%)	**(53%)**	**(10%)**	**(8%)**	**(1%)**

Criterion 10: **The level of pain is progressively increasing**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(21%)	**(42%)**	**(15%)**	**(21%)**	**(1%)**

Criterion 11: **There is an intermittent catching or pinching pain**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(7%)	**(34%)**	**(25%)**	**(30%)**	**(4%)**

Criterion 12: **There is a strong component of night pain**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(44%)	**(44%)**	**(8%)**	**(4%)**	**(-)**

Criterion 13: **There is a marked increase in pain with rapid or unguarded movements**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(52%)	**(37%)**	**(10%)**	**(1%)**	**(-)**

Criterion 14: **It is uncomfortable to lie on the affected shoulder**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(48%)	**(48%)**	**(3%)**	**(1%)**	**(-)**

Criterion 15: **The patient reports the pain is easily aggravated by movement**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(38%)	**(47%)**	**(13%)**	**(1%)**	**(1%)**

Criterion 16: **Once aggravated the patient reports the pain is slow to settle**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(23%)	**(59%)**	**(10%)**	**(7%)**	**(1%)**

Criterion 17: **Function is limited by increasing stiffness in this stage**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(16%)	**(36%)**	**(14%)**	**(27%)**	**(7%)**

Criterion 18: **The history of onset of pain is spontaneous**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(18%)	**(45%)**	**(22%)**	**(12%)**	**(3%)**

Criterion 19: **Symptoms have been present for greater than 4 weeks**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(16%)	**(49%)**	**(26%)**	**(8%)**	**(1%)**

Criterion 20: **There is often a history of a minor trauma/precipitating event**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(8%)	**(54%)**	**(17%)**	**(17%)**	**(4%)**

Criterion 21: **The onset of the condition is sudden**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(3%)	**(14%)**	**(27%)**	**(49%)**	**(7%)**

Demographics:

Criterion 22: **The onset is generally in people greater than 35 years of age**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(42%)	**(55%)**	**(3%)**	**(-)**	**(-)**

Criterion 23: **The onset is generally in people less than 60 years of age**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(14%)	**(53%)**	**(22%)**	**(11%)**	**(-)**

Criterion 24: **The condition more commonly presents in females**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(23%)	**(59%)**	**(11%)**	**(4%)**	**(3%)**

Physical examination findings:

Criterion 25: **On examination there is a global loss of active and passive range of movement**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(45%)	**(33%)**	**(3%)**	**(11%)**	**(8%)**

Criterion 26: **On examination there is pain at the end of range in all directions**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(30%)	**(47%)**	**(7%)**	**(15%)**	**(1%)**

Criterion 27: **On examination there is no painful arc with shoulder elevation**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(18%)	**(41%)**	**(16%)**	**(21%)**	**(4%)**

Criterion 28: **There is protective muscle guarding with movement**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(18%)	**(43%)**	**(22%)**	**(16%)**	**(1%)**

Criterion 29: **The loss of movement in any direction is minor**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(3%)	**(25%)**	**(9%)**	**(34%)**	**(29%)**

Criterion 30: **The greatest loss of movement is in external rotation**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(16%)	**(43%)**	**(15%)**	**(22%)**	**(4%)**

Criterion 31: **There is painful limitation of active external rotation range performed in supine at 90° shoulder abduction**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(19%)	**(41%)**	**(22%)**	**(14%)**	**(4%)**

Criterion 32: **There is marked pain during isometric external rotation strength testing performed in supine at 90° shoulder abduction**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(4%)	**(22%)**	**(39%)**	**(27%)**	**(8%)**

Criterion 33: **The patient's range of movement is progressively decreasing due to pain**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(21%)	**(41%)**	**(15%)**	**(23%)**	**(-)**

Criterion 34: **There is a global loss of passive gleno-humeral joint movement**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(33%)	**(34%)**	**(14%)**	**(12%)**	**(7%)**

Criterion 35: **The loss of movement is in a gleno-humeral joint capsular pattern ie: external rotation >abduction> internal rotation**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(14%)	**(44%)**	**(22%)**	**(16%)**	**(4%)**

Criterion 36: **Resisted isometric muscle testing is painfree**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(3%)	**(27%)**	**(26%)**	**(37%)**	**(7%)**

Criterion 37: **If pain is not inhibiting, muscle strength testing will be normal**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(15%)	**(59%)**	**(14%)**	**(9%)**	**(3%)**

Criterion 38: **There is diffuse tenderness to palpation around the shoulder**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(8%)	**(41%)**	**(21%)**	**(29%)**	**(1%)**

Criterion 39: **There is tenderness to palpation specifically over the anterior joint**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(3%)	**(35%)**	**(24%)**	**(35%)**	**(3%)**

Criterion 40: **The scapula position is elevated at rest or with movement**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(3%)	**(36%)**	**(30%)**	**(24%)**	**(7%)**

Criterion 41: **Provocative tests for tendonitis do not inform the diagnosis**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(10%)	**(64%)**	**(19%)**	**(7%)**	**(-)**

Associations:

Criterion 42: **There can be an association with diabetes**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(52%)	**(29%)**	**(15%)**	**(3%)**	**(1%)**

Criterion 43: **There may be a co-existing history of a thyroid condition**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(8%)	**(29%)**	**(52%)**	**(10%)**	**(1%)**

Criterion 44: **The onset of the condition is more common in spring and autumn**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(1%)	**(-)**	**(75%)**	**(18%)**	**(6%)**

Criterion 45: **A minor viral illness may precede the onset**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(-)	**(18%)**	**(54%)**	**(21%)**	**(7%)**

Criterion 46: **There is often a past history of adhesive capsulitis of the opposite shoulder**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(10%)	**(58%)**	**(11%)**	**(20%)**	**(1%)**

Criterion 47: **There is frequently a history of impingement syndrome in the same shoulder**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(4%)	**(28%)**	**(23%)**	**(42%)**	**(3%)**

Criterion 48: **The thoracic spine is kyphotic or hypomobile**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(3%)	**(14%)**	**(40%)**	**(32%)**	**(11%)**

Response to treatment:

Criterion 49: **There is a non-response or an exacerbation of pain with treatment involving physical therapies**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(25%)	**(53%)**	**(11%)**	**(8%)**	**(3%)**

Criterion 50: **There is minimal or no response to usual analgesic medication**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(7%)	**(59%)**	**(14%)**	**(19%)**	**(1%)**

Criterion 51: **There is minimal or no response to NSAIDs**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(7%)	**(64%)**	**(14%)**	**(14%)**	**(1%)**

Criterion 52: **There is no response to sub-acromial steroid injection**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(10%)	**(49%)**	**(21%)**	**(19%)**	**(1%)**

Criterion 53: **There is a favorable response to a steroid injection into the gleno-humeral joint**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(19%)	**(53%)**	**(24%)**	**(3%)**	**(1%)**

Investigations:

Criterion 54: **A thickened joint capsule will be evident on magnetic resonance imaging (MRI)**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(4%)	**(39%)**	**(26%)**	**(25%)**	**(6%)**

Criterion 55: **A decreased joint volume will be evident on MRI**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(8%)	**(44%)**	**(24%)**	**(21%)**	**(3%)**

Criterion 56: **Ultrasound investigation does not inform the diagnosis**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(24%)	**(42%)**	**(12%)**	**(21%)**	**(1%)**

Criterion 57: **X-Ray examination only excludes osteoarthritis and calcific tendonitis**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(31%)	**(57%)**	**(3%)**	**(9%)**	**(-)**

Criterion 58: **There is a mild elevation of erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP)**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(-)	**(17%)**	**(61%)**	**(19%)**	**(3%)**

Criterion 59: **Blood factors exclude an infective or systemic inflammatory state**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(11%)	**(56%)**	**(20%)**	**(10%)**	**(3%)**

Criterion 60: **Arthroscopy reveals synovitis and inflammation of the joint capsule**

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
☐	☐	☐	☐	☐
(38%)	**(43%)**	**(12%)**	**(6%)**	**(1%)**

Thank you for your time and participation.

Sarah Walmsley
BSc, GradDipPhty, MAppSc(Ortho Phty)
PhD Candidate

A/Prof Darren Rivett
BAppSc(Phty), MAppSc(Manip Phty), PhD
Project Supervisor

Peter Osmotherly
BSc, GradDipPhty, MMed.Sc(Clin Epi)
Co-Supervisor

Appendix 3

Ethics approval and supporting documents for Studies 2, 3 and 4 (Chapters 5, 6 and 7)

HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Professor Darren Rivett**
Cc Co-investigators / Research Students:	**Miss Sarah Walmsley** **Mr Peter Osmotherly**
Re Protocol:	**Validation of a set of clinical identifiers for stage one primary adhesive capsulitis**
Date:	**11-Nov-2009**
Reference No:	**H-2009-0234**
Date of Initial Approval:	**10-Nov-2009**

Thank you for your **Response to Conditional Approval** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under **Expedited** review by the Chair/Deputy Chair.

I am pleased to advise that the decision on your submission is **Approved** effective **10-Nov-2009**.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. *If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.*

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2009-0234**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

Conditions of Approval

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as detailed below.

PLEASE NOTE:
In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's HREC.

- ***Monitoring of Progress***

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is

conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

- ***Reporting of Adverse Events***

1. It is the responsibility of the person **first named on this Approval Advice** to report adverse events.
2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
4. Serious adverse events are defined as:
    - Causing death, life threatening or serious disability.
    - Causing or prolonging hospitalisation.
    - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
    - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
    - Any other event which might affect the continued ethical acceptability of the project.

5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.

6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- ***Variations to approved protocol***

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research*. Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Associate Professor Alison Ferguson

Chair, Human Research Ethics Committee

For communications and enquiries:
Human Research Ethics Administration

Research Services
Research Office
The University of Newcastle
Callaghan NSW 2308
T +61 2 492 18999
F +61 2 492 17164
Human-Ethics@newcastle.edu.au

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref
		,	

FACULTY OF HEALTH

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

VALIDATION OF A SET OF CLINICAL IDENTIFIERS FOR STAGE ONE PRIMARY ADHESIVE CAPSULITIS.

Researchers:
Sarah Walmsley, PhD candidate
School of Health Sciences, The University of Newcastle
Prof Darren Rivett, Supervisor
School of Health Sciences, The University of Newcastle
Peter Osmotherly, Co-supervisor
School of Health Sciences, The University of Newcastle

Information Statement

Version 3, 1/12/09

You are invited to take part in the research project identified above which is being conducted by Sarah Walmsley, as part of her PhD under the supervision of Professor Darren Rivett and Peter Osmotherly at the School of Health Sciences at The University of Newcastle.

Background information

Adhesive capsulitis or frozen shoulder as it is commonly known is a disorder of the shoulder that affects about 2-3% of the general population. Adhesive capsulitis progresses through a series of three stages and resolves over a period of up to 2 years. In its early stage adhesive capsulitis can be difficult to diagnose and differentiate from other shoulder disorders that may cause pain and limitation of movement. We recently conducted a study that surveyed a number of Australian and New Zealand experts who diagnose and treat adhesive capsulitis. As a result of that study we established eight clinical features that were determined necessary to diagnose adhesive capsulitis in its early stage.

What is the purpose of the study?

The purpose of this research is to validate the set of clinical features for the early stage of adhesive capsulitis that were established in the earlier study.

Who can participate?

Patients who have been identified by the physiotherapists at Hunter Hand and Upper Limb Therapy following the normal initial assessment who, in the course of their normal treatment, would undergo a corticosteroid and local anaesthetic injection into their shoulder joint for management of the early stage of adhesive capsulitis may participate in the study.

Participation is voluntary

Participation in this research is entirely your choice. You may choose not to participate. If you choose to participate, you may change your mind and withdraw from the study before it begins or at any time during it, without having to give a reason. Whether or not you decide to participate, your decision will not disadvantage you. Should you decide not to participate in the

project your treatment will continue as normal and your relationship with the Clinic will not be affected in any way.

What will you be asked to do?

You will be required to complete a Consent Form to indicate your willingness to participate. At the time of your initial physiotherapy assessment the normal procedure will be followed that includes asking you a number of questions related to your shoulder pain, general health and the results of any radiological investigations you may have had. Your shoulder range of movement will also be measured and recorded. You will also be asked to complete 2 questionnaires that measure the pain and disability that you are experiencing as a result of your shoulder problem as well as general health and well being questions. These will be used to provide a baseline of information and form part the normal assessment process followed at Hunter Hand and Upper Limb Therapy.

Following the assessment you will be shown some exercises to perform and, if judged necessary by your doctor, and as part of normal care, you will be asked to make an appointment for an injection, under X-ray guidance at a local radiology practice and at a time suitable to you. Immediately prior to your injection you will be requested to attend Hunter Hand and Upper Limb Therapy Clinic for measurement of your shoulder range of movement and pain levels. At this time a Doppler ultrasound examination will also be performed on your shoulder to see if there are any blood flow changes consistent with inflammation in your shoulder. After the injection you will return to Hunter Hand and Upper Limb Therapy Clinic on a second occasion within one hour of the injection for the normal measurement of pain and shoulder range of movement as well as to receive treatment.

At 6 and 12 weeks after your injection you will be asked to complete the 2 questionnaires that were completed at the initial assessment. If you are no longer attending the practice at these times the questionnaires will be mailed to you to return in a postage paid envelope.

If you agree to participate, there will be no additional cost to yourself other than that normally incurred for physiotherapy assessment and treatment on the initial occasion as well as following the injection. There will be no cost for the visit immediately prior to the injection. If you are to undergo your injection at a radiology practice remote to Hunter Hand and Upper Limb Therapy Clinic you will be reimbursed $15 to cover travel expenses for the additional pre-injection visit.

How much time will it take?

A normal initial physiotherapy assessment takes approximately 40 minutes. It is anticipated that assessment of range of movement and pain levels, as well as performing the ultrasound examination immediately prior to your injection will take 30 minutes. The follow up appointment after the injection will be the normal time of 20 minutes. This appointment involves the measurement of shoulder range of motion and your level of pain, the application of heat, soft tissue massage and passive stretching of your shoulder.

Any further ongoing physiotherapy treatment will be at the discretion of your treating physiotherapist and will not form part of the study.

What are the risks and benefits of participating?

There is no direct benefit to you in taking part in this study. The injection into your shoulder will be undertaken as part of the normal medical treatment regime determined by your doctor. Your participation may allow us to better understand and diagnose adhesive capsulitis and assist in directing further research into this area. There is no anticipated risk in participating other than that normally associated with receiving an injection into your shoulder joint which will be explained fully to you at the time of injection. If it is considered inappropriate for you to undergo an injection you will not be referred for one by your treating doctor. Doppler ultrasound examination of your shoulder is a safe procedure and involves no risk to you.

How will your privacy be protected?

Information that is provided is confidential to the researchers and your privacy will be protected at all times. Data collected from you will be coded numerically and any de-coding will only be possible by the researchers. Any information obtained as a result of the study will not be identified to a specific individual.

How will the information collected be used?

The results of this research will form part of the thesis of the student researcher, Sarah Walmsley and will be submitted for publication in scientific journals. Results will also be presented at national and international scientific conferences. No identification of individuals will be possible from the presentation of the results in any form. You can be provided with a summary of the research findings at the conclusion of the study by marking the relevant section of the Consent Form and providing your contact details.

Individual participants will not be identified in any reports arising from this project. Data collection sheets, consent forms and electronic files stored on disc will be kept in a locked cabinet in the School of Health Sciences for a minimum of five years. After five years electronic files will be deleted and destroyed and all hard copy materials will be shredded.

What do you need to do to participate?

Please read this Information Statement and be sure of its contents before you consent to participate. If there is anything you do not understand, or you have questions, please do not hesitate to contact the researchers. The researchers will answer any questions you have about this study prior to your participation, and you may keep a copy of the Information Statement. You are also free to consult others before agreeing to participate in this research if you wish.

Further information

The researchers conducting this project support the principles governing both the ethical conduct of research, and the protection at all times of the interests, comfort and safety of participants. The protocol for this study has been approved by The University of Newcastle Human Research Ethics Committee.

If you would like further information please contact Sarah Walmsley on 49624477 or Sarah.Walmsley@newcastle.edu.au

Thank you for considering this invitation.

Sarah Walmsley (PhD candidate)	Prof Darren Rivett (Supervisor)	Peter Osmotherly (Co-supervisor)

Professor Darren A. Rivett
Head, School of Health Sciences
T +61 2 49217220
Darren.Rivett@newcastle.edu.au

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H- 2009-0234.
Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

FACULTY OF HEALTH

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

VALIDATION OF A SET OF CLINICAL IDENTIFIERS FOR STAGE ONE PRIMARY ADHESIVE CAPSULITIS.

Researchers:
Sarah Walmsley, PhD candidate
School of Health Sciences, The University of Newcastle
Prof Darren Rivett, Supervisor
School of Health Sciences, The University of Newcastle
Peter Osmotherly, Co-supervisor
School of Health Sciences, The University of Newcastle

CONSENT FORM

Version 3, 10/3/10

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand, that in addition to the normal treatment regime I will be required to attend Hunter Hand and Upper Limb Therapy Clinic on one extra occasion and immediately before the corticosteroid injection into my shoulder for measurement of range of movement and pain levels as well as a Doppler ultrasound examination of my shoulder.

I understand that I will be asked to complete the same two questionnaires that will be completed at the initial assessment on two further occasions at 6 and 12 weeks following the injection. If I am no longer a patient of Hunter Hand and Upper Limb Therapy at these times the questionnaires will be mailed to me for returning to the researchers in a provided postage paid envelope.

I understand I can withdraw from the project and remove any data at any time and do not have to give any reason for withdrawing.

I understand that while information gained during the study may be published, I will not be identified and my personal information will remain confidential to the researchers.

I understand that I can be provided with a summary of the research findings by providing my contact details in the appropriate section of this form below.

I have had the opportunity to have questions answered to my satisfaction.

Print name: _____

Signature: _____ Date: _____

Professor Darren A. Rivett
Head, School of Health Sciences
T +61 2 49217220 Darren.Rivett@newcastle.edu.au

☐ I wish to be provided with a summary of the research findings at the completion of the study. My preferred contact details are (e-mail, fax or mail):

_____

_____

DATA COLLECTION SHEET

Participant number: _____ Date of assessment:_____

DOB:_____ Age: _____ Male/Female

Affected shoulder:_____ Hand dominance:_____

Date of initial contact with physiotherapist: _____

Physiotherapy treatment commenced: Y/N Type of treatment: _____

Duration of symptoms:_____ Minor preceding trauma: Yes/No

Diabetes: Yes/No Thyroid disorder: Yes/No

Duyptrens: Yes/No

SPADI score: _____ SF-36 score: _____

Satisfies criteria Yes/No If no reason for exclusion:_____

Analgesia taken in last 24 hours: _____

PRE-INJECTION **DATE:**

Please mark on the line the current level of pain you have in your shoulder.

No Pain |_____| Worst pain imaginable

I am going to ask you a few questions that you need to respond to as a yes/no answer.

Criterion 1. There is a strong component of night pain:

Q. Do you get your shoulder pain at night?

Yes/No

Q. Does your shoulder pain wake you?

Yes/No

Q. How many times per night would you wake because of your shoulder pain?

_____

Can you please mark on this line the level of night pain you have experienced when your shoulder pain was at its worst

No Pain |_____| Worst pain imaginable

Can you please now mark this line for the amount of pain you experienced in your shoulder last night.

No Pain |_____| Worst pain imaginable

Criterion 2. There is a marked increase in pain with rapid or unguarded movements:

Q. Is the pain made much worse by rapid or unguarded movements?

Yes/No

Criterion 3. It is uncomfortable to lie on the affected shoulder:

Q. Is it uncomfortable to lie on your R/L shoulder?

Yes/No

Criterion 4. The patient reports the pain is easily aggravated by movement:

Q. Is the pain easily aggravated by movement?

Yes/No

Q. Does the pain make you feel sick when it is aggravated?

Yes/No

Q. Does the severe pain settle within 2 minutes once it is aggravated?

Yes/No

Q. Do you feel the pain worse towards the end of your range of movement?

Yes/No

Criterion 5. The onset is generally in people greater than 35 years of age:

Q. Are you older than 35?

Yes/No

Ultrasound performed: Yes/No Tenderness with transducer?: Yes/No

Machine settings: Gel pad?:

Comments:

Measure using Plurimeter	**Affected shoulder (active) ? limited by pain-p or resist - r**	Pain at end of range Y/N Rate on VAS	**Affected shoulder (passive) ? limited by pain - p or resist - r**	Pain at end of range Y/N Rate on VAS	**Unaffected shoulder (active)**	**Unaffected shoulder (passive)**
Total shoulder flexion						
Gleno-humeral shoulder flexion						
Total shoulder abduction						
Gleno-humeral abduction						
ER in neutral	s		s		s	s
ER 90° abduction	s		s		s	s
IR in abduction	s		s		s	s
HBB *						

s = measurement performed in supine

* the vertical distance between the spinous process of T1 and the wrist (anatomical snuff box) will be measured

Instruction for active movement: Take your arm as far as you can and stop when further movement makes your pain intolerable.

Instruction for passive movement: I am going to take your arm as far as I can but I will stop when you ask me to due to your pain becoming intolerable.

Pain pushing towards the end of range is greater than pain through mid range when loading into forward flexion.

Yes/No

No Pain |_____| Worst pain imaginable

Criterion 6. On examination there is global loss of active and passive range of movement:

Yes/No

Criterion 7. On examination there is pain at the end of range in all directions:

Yes/No

Criterion 8. There is global loss of gleno humeral joint movement:

Yes/No

POST INJECTION

Location of radiology practice: Radiologist:

Time of injection: Time of assessment:

Level of resting pain before examination:

No Pain |_____| Worst pain imaginable

Measure with Plurimeter	**Active ROM ? limited by p or r**	Pain at end of range Y/N Rate on VAS	**Passive ROM ?limited by p or r**	Pain at end of range Y/N Rate on VAS
Total shoulder flexion				
Gleno-humeral shoulder flexion				
Total shoulder abduction				
Gleno-humeral shoulder abduction				
External rotation in adduction	s		s	
External rotation 90° abduction	s		s	
Internal rotation in abduction	s		s	
HBB *				

s = measurement performed in supine

* the vertical distance between the spinous process of T1 and the wrist (anatomical snuff box) will be measured

Comments:

PAIN RATING SCALES
(Pre/post-injection)

Participant number:

Date:

Active TF

No Pain |_____| Worst pain imaginable

Active GH F

No Pain |_____| Worst pain imaginable

Active TA

No Pain |_____| Worst pain imaginable

Active GH GA

No Pain |_____| Worst pain imaginable

Active ER in adduction

No Pain |_____| Worst pain imaginable

Active ER in abduction

No Pain |_____| Worst pain imaginable

Active IR in abduction

No Pain |_____| Worst pain imaginable

Active HBB

No Pain |_____| Worst pain imaginable

Passive TF

No Pain |_____| Worst pain imaginable

Passive GH F

No Pain |_____| Worst pain imaginable

Passive T Abd

No Pain |_____| Worst pain imaginable

Passive GH Abd

No Pain |_____| Worst pain imaginable

Passive ER in adduction

No Pain |_____| Worst pain imaginable

Passive ER in abduction

No Pain |_____| Worst pain imaginable

Passive IR in abduction

No Pain |_____| Worst pain imaginable

Passive HBB

No Pain |_____| Worst pain imaginable

Appendix 4

Journal publications

Physical Therapy
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Adhesive Capsulitis: Establishing Consensus on Clinical Identifiers for Stage 1 Using the Delphi Technique

Sarah Walmsley, Darren A. Rivett and Peter G. Osmotherly

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Adhesive Capsulitis: Establishing Consensus on Clinical Identifiers for Stage 1 Using the Delphi Technique

Sarah Walmsley, Darren A. Rivett, Peter G. Osmotherly

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Background. Adhesive capsulitis often is difficult to diagnose in its early stage and to differentiate from other commonly seen shoulder disorders with the potential to cause pain and limited range of movement.

Objectives. The purpose of this study was to establish consensus among a group of experts regarding the clinical identifiers for the first or early stage of primary (idiopathic) adhesive capsulitis.

Design. A correspondence-based Delphi technique was used in this study.

Methods. Three sequential questionnaires, each building on the results of the previous round, were used to establish consensus.

Results. A total of 70 experts from Australia and New Zealand involved in the diagnosis and treatment of adhesive capsulitis completed the 3 rounds of questionnaires. Following round 3, descriptive statistics were used to screen the data into a meaningful subset. Cronbach alpha and factor analysis then were used to determine agreement among the experts. Consensus was achieved on 8 clinical identifiers. These identifiers clustered into 2 discrete domains of pain and movement. For pain, the clinical identifiers were a strong component of night pain, pain with rapid or unguarded movement, discomfort lying on the affected shoulder, and pain easily aggravated by movement. For movement, the clinical identifiers included a global loss of active and passive range of movement, with pain at the end-range in all directions. Onset of the disorder was at greater than 35 years of age.

Conclusions. This is the first study to use the Delphi technique to establish clinical identifiers indicative of the early stage of primary (idiopathic) adhesive capsulitis. Although limited in differential diagnostic ability, these identifiers may assist the clinician in recognizing early-stage adhesive capsulitis and may inform management, as well as facilitate future research.

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Adhesive capsulitis of the shoulder is a disorder frequently encountered by primary health care professionals. It often is difficult to identify and correctly diagnose in its early stage. Labeled "frozen shoulder" by Codman in 1934[1] but subsequently termed "adhesive capsulitis" by Neviaser[2] to better describe the pathology, this condition generally is characterized by pain and a gradual progressive loss of shoulder active and passive range of motion.[3] It has been reported that its prevalence is 2% to 3% in the general population.[3–5] This figure is higher in the diabetic population,[6] with a prevalence of 30% reported in patients with type 2 diabetes mellitus.[7] Adhesive capulitis also is reported to be more common in women, especially between the ages of 40 to 60 years.[3,5,8,9] The condition usually very slowly progresses toward spontaneous resolution; however, the findings of several long-term studies[10–14] suggest that ongoing impairment may persist in some patients.

Adhesive capsulitis is described as being either primary or secondary.[10,15,16] Primary adhesive capsulitis is due to an unknown cause (ie, it is idiopathic), whereas secondary adhesive capsulitis results from a known cause or surgical event.[4] Published descriptions of the condition commonly further subdivide it into 3 or 4 stages. Following arthroscopic evaluation, Neviaser and Neviaser[8] identified 4 stages of involvement. These 4 stages have been correlated with clinical examination findings and histological appearance of the tissues.[4] The more-recent literature, however, generally describes adhesive capsulitis as consisting of 3 stages.[3,5,15] These stages have been identified as the painful stage (first), the adhesive stage (second), and the resolution stage (third). The painful stage in this nomenclature includes both stage 1 (the pre-adhesive stage) and stage 2 as described by Neviaser and Neviaser.[8] The current study was concerned with identifying primary adhesive capsulitis in the painful or first stage of the condition.

Although "textbook" descriptions of diagnostic criteria for adhesive capsulitis, including variable pain and movement characteristics, are present in the literature, validation of these descriptions is lacking. Currently, the diagnosis of primary adhesive capsulitis is based on the findings of the patient history and physical examination. No specific clinical test or definitive investigation has been reported in the literature, and there remains no gold standard to diagnose this disorder. A varying range of "typical" signs and symptoms, such as pain aggravated by shoulder movement,[4,5] pain at night,[8] and multidirectional limitation of active and passive joint movement accompanied by pain at the extremes of range,[3] have been proposed instead. To date, however, there are no agreed-upon or validated diagnostic criteria for the disorder.

The lack of validity and reliability for the diagnostic classification of shoulder pain has been a topic of controversy for some time.[17–22] In a study of interobserver agreement between general practitioners and physical therapists, this deficit has been particularly highlighted.[23] However, the need for diagnostic labels for shoulder disorders has been questioned, as there is some evidence that the outcomes of treatment may be similar for heterogeneous groups of patients with shoulder pain lacking a specific diagnosis.[24–27] Conversely, other authors[28,29] have suggested that a uniform method of defining shoulder disorders is necessary. In a systematic review of randomized controlled trials of interventions for the painful shoulder,[28] the authors commented that, in the studies sampled, no standard diagnostic definitions were used, and indeed conflicting criteria were used to define the same condition in various trials. These limitations make drawing conclusions across studies difficult. Although a set of diagnostic criteria may not exclusively represent a single pathological entity, it may represent a subgroup of patients to whom randomized controlled trials may be directed.

Similarly, early and accurate identification of diagnostic criteria is recommended for determining prognosis as well as optimizing treatment outcomes in the clinic.[30] Early presentation of shoulder disorders has been associated with a favorable outcome.[31] Some authors[4,8] have recommended that treatment and prognosis for adhesive capsulitis should be tailored to the stage of the disorder. Consequently, it is arguably appropriate to establish diagnostic criteria for each stage rather than for the disease process as a whole.

The difficulty faced by clinicians in the diagnosis of shoulder disorders recently was addressed by Mitchell and colleagues.[32] They proposed a simple model to assist in the diagnosis of rotator cuff, glenohumeral, and acromioclavicular joint disorders, as well as referred cervical spine pain. Although potentially facilitating aspects of the clinical reasoning process, this model fails to recognize the various stages of adhesive capsulitis. Agreed-upon diagnostic criteria for

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early-stage adhesive capsulitis, therefore, remain to be established.

The aim of this study was to reveal such consensus that may currently exist among a group of experts regarding the clinical signs and symptoms indicative of the first stage of primary adhesive capsulitis. The establishment of such consensus is the first step in the process of identification and validation of agreed-upon diagnostic criteria for this disorder.

Method

The Delphi technique was chosen to explore this issue because it is an established and recognized method of deriving the opinion of experts to determine the degree of consensus where there is a lack of empirical evidence.[33,34] This technique has the advantages of maintaining anonymity among respondents, allowing time for participants to consider their response while not being influenced by dominant individuals and enabling recruitment from diverse geographical locations and clinical backgrounds.[35,36] Using a panel of experts, the Delphi technique is a multistage process using a series of sequential questionnaires or rounds linked by feedback. Each round of the process builds on the results of the previous one and results in consensus by the final round. This technique has been widely used in establishing consensus on various diagnostic descriptors and clinical identifiers.[37–42]

Participants

The participants were a group of experts involved in the diagnosis and treatment of adhesive capsulitis and recruited from several disciplines. These disciplines included rehabilitation medicine, physical medicine, orthopedic surgery, physical therapy, chiropractic, and osteopathy. Medical practitioners invited to participate in the study were required to hold postgraduate qualifications in a relevant specialty or be members of a special interest group in a discipline relevant to the study. Rehabilitation medicine physicians were recruited from the Musculoskeletal Medicine and Pain Special Interest Group, a subgroup of the Australasian Faculty of Rehabilitation Medicine. Members of the Australasian Faculty of Musculoskeletal Medicine also were included, as were members of the College of Physical Medicine. As a special interest group of the Australian Orthopaedic Association, members of the Shoulder and Elbow Society of Australia were approached. Physical therapist participants were members of Shoulder and Elbow Physiotherapists Australia (a physical therapy subgroup of the Shoulder and Elbow Society of Australia), as well as coordinators of postgraduate musculoskeletal physical therapy programs at Australian and New Zealand universities. In addition, specialist musculoskeletal physical therapists recognized by the Australian Physiotherapy Association and the Australian College of Physiotherapists were included. Australian and New Zealand authors who had published on the topic of adhesive capsulitis in peer-reviewed journals or texts in the past 10 years also were invited to participate. These potential participants were identified by searching MEDLINE and CINAHL databases using the search terms “adhesive capsulitis” and “frozen shoulder.” Only articles published in the English language between February 1996 and February 2006 were identified. The reference lists of identified articles also were scrutinized in an attempt to identify any texts or other references that may have been published during this period. Where contact details indicated the authors were located in Australia or New Zealand, these individuals were included in the expert group. Finally, chiropractors and osteopaths who were coordinators of postgraduate musculoskeletal programs offered at Australian and New Zealand universities were approached. A total of 185 potential participants were contacted in the first round.

Pilot Study

A pilot study, using a sample of convenience comprising 6 participants representative of the overall sample, was performed prior to the commencement of the main study to determine whether the instructions to participants were clear and to identify any improvements to the method. Following the pilot study, it was determined that 2 reminders should be issued to nonresponding participants to maximize the response rate. It also was determined that documents should be highlighted to more clearly indicate that stage 1 of adhesive capsulitis was being investigated, not the later, more easily recognizable stages.

Procedure

The study was correspondence based, and the questionnaires were distributed by the researchers to the participants’ work addresses. Addresses were obtained from the appropriate organizations, and all contact details were available in the public domain, with the exception of the rehabilitation medicine physicians, whose members were approached through the chairperson of the Musculoskeletal Medicine and Pain Special Interest Group. In this case, the letter of invitation was sent to the chairperson of the group, requesting it be forwarded to members. Those members who were potentially interested in participating were asked to contact the researchers directly. Members of the Faculty of Musculoskeletal Medicine also were approached through the chairperson of the faculty, who provided names and contact details of members. All of the participants who were clinicians were approached at their private clinics.

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Experts were asked to participate in 3 rounds of questionnaires. For the first round, potential participants were sent a letter of invitation along with the first questionnaire and were given 2 weeks to reply. Participants were given the opportunity to receive the subsequent questionnaires electronically and to supply a contact telephone number. A reminder was sent if a response was not received in the specified time, and, if necessary, a second reminder was issued after a further 2 weeks. The same approach and time frame for reminders were used for the 2 subsequent rounds. Telephone contact was used in the second and third rounds for the second reminder if a telephone number was made available by the participant.

Round 1. The first questionnaire requested participants to list as many or as few diagnostic criteria as they considered necessary and sufficient to diagnose stage 1 primary adhesive capsulitis. Respondents were given the opportunity to provide a rationale for their criteria if they felt this appropriate. The responses were independently reviewed and collated by each of the 3 researchers, using a series of operational rules. These rules involved listing all of the criteria (individual responses) proposed, grouping the criteria into relevant clinical categories, eliminating single responses, merging repeated responses, and discarding unclear responses. Responses clearly inconsistent with the literature or obviously relating to secondary adhesive capsulitis or the later stages of the target disorder also were discarded. Following initial independent review, the researchers met and reached a consensus on the criteria to constitute the second round.

Round 2. The second round used the criteria identified in round 1 by all participants. In this round, participants were asked to score the importance of each criterion in the diagnosis of stage 1 adhesive capsulitis using the following 5-point Likert scale adapted from Cook et al[39]:

1. *Strongly agree*: the selected criterion is extremely important in the diagnosis of stage 1 of primary adhesive capsulitis.
2. *Agree*: the selected criterion is important in the diagnosis of stage 1 of primary adhesive capsulitis.
3. *Undecided*: uncertainty about the importance of the selected criterion in the diagnosis of stage 1 of primary adhesive capsulitis.
4. *Disagree*: the selected criterion is not important in the diagnosis of stage 1 of primary adhesive capsulitis.
5. *Strongly disagree*: there is absolutely no importance whatsoever of the selected criterion in the diagnosis of stage 1 of primary adhesive capsulitis.

Round 3. The third round provided feedback to the participants in the form of the percentages for each of the 5 response options as to how all participants rated each criterion in round 2. In the light of this information, participants were requested to rescore each criterion on the same Likert scale used in round 2.

Data Analysis

The data were analyzed initially using simple descriptive statistics. The Cronbach coefficient alpha then was used as a measure of the level of consistency of opinion among the respondents regarding the agreed-upon criteria. Finally, to determine the underlying structure of the criteria, a factor analysis was performed.

Results

From the 185 potential participants approached in the first round, 89 responses (48.1%) were received. From the 89 respondents from round 1, 75 responses (84.3%) were received following round 2. Seventy (93.3%) of these respondents completed the final round. Overall, 37.8% of the original sample completed all 3 rounds. The response rate of participants in each discipline is indicated in Table 1, and the flow of participants through the study is depicted in Figure 1.

Following the first round, 367 criteria were generated. Collation of the data resulted in the establishment of 60 diagnostic criteria structured into 6 sections to form round 2. These criteria are outlined in Table 2. Following round 3, the data were analyzed initially using descriptive statistics. As the purpose of the study was to seek strongly held views of experts and the initial request had been for necessary and sufficient criteria, it was determined that only the "strongly agree" response would be analyzed. Therefore, the number of respondents scoring "strongly agree" was calculated and is graphically represented in Figure 2. In order to determine the criteria to be used in further analysis, several principles were applied. First, the Pareto principle,[43] which suggests that 20% of the items would determine 80% of the value or benefit in deciding what is important in diagnosis, was used to commence analysis. By applying this principle, 12 criteria were identified. Second, the pattern of drop-off of frequency for these items resulted in a delineation at 10 criteria. As this delineation was in reasonable agreement with the Pareto principle, it was considered that this was an appropriate cutoff to select. As a result, 10 criteria (in descending order, criteria 13, 14, 25, 42, 12, 15, 34, 22, 60, and 26) were selected for further analysis.

In order to measure the internal consistency of the criteria, Cronbach al-

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Table 1.
Composition and Response Rate of Participants in Delphi Study

Group	Participants Approached, n (%)	Respondents Round 1, n (%)	Respondents Round 2, n (%)	Respondents Round 3, n (%)
Member of the Musculoskeletal and Pain Special Interest Group of the Australasian Faculty of Rehabilitation Medicine	3 (1.6)	2 (2.2)	1 (1.3)	1 (1.4)
Member of the Australasian Faculty of Musculoskeletal Medicine	28 (15.1)	11 (12.4)	9 (12)	7 (10)
Member of the Australian College of Physical Medicine	28 (15.1)	10 (11.2)	7 (9.3)	6 (8.6)
Member of the Shoulder and Elbow Society of Australia	81 (43.8)	36 (40.4)	28 (37.3)	27 (38.6)
Member of Shoulder and Elbow Physiotherapists Australia	12 (6.5)	10 (11.2)	10 (13.3)	9 (12.9)
Coordinator of a postgraduate musculoskeletal physical therapy program	11 (5.9)	11 (12.4)	11 (14.7)	11 (15.7)
Specialist musculoskeletal physical therapist	4 (2.2)	3 (3.4)	3 (4)	3 (4.3)
Author of publication on adhesive capsulitis in the past 10 years	11 (5.9)	3 (3.4)	3 (4)	3 (4.3)
Coordinator of a postgraduate chiropractic program	5 (2.7)	3 (3.4)	3 (4)	3 (4.3)
Coordinator of a postgraduate osteopathic program	2 (1.1)	0 (0)	0 (0)	0 (0)
Total	185	89	75	70

pha was used. Using SPSS version 15,* an analysis of the 10 selected criteria resulted in a Cronbach alpha value of .63. Stepwise removal of items whose inclusion reduced the alpha value was performed (criteria 42 and 60). Removal of these 2 criteria maximized Cronbach alpha to .71. Eight criteria were established as a result of this analysis and are presented in Table 3. As the underlying structure of these criteria was of interest and factor analysis was proposed, a Kaiser-Meyer-Olkin measure of sampling adequacy was performed to determine whether factor analysis would be of benefit. The value of this test was .661. A value above .60 indicates that it is worthwhile proceeding with factor analyis.[44] A factor analysis using varimax rotation, therefore, was performed on the remaining 8 criteria to examine their underlying structure. Figure 3 demonstrates the scree plot for this calculation. The result of this factor analysis determined 2 discrete dimensions of pain and movement into which the criteria clustered. This is represented in Figure 4. These factors together accounted for 56.3% of the total variance of the expert responses, with the pain factor accounting for 36% and the movement factor accounting for 20.3%. The relative weights of the 8 criteria are shown in Table 4, which provides factor loadings for each criterion in the 2-factor solution.

Discussion

The Delphi technique was used successfully in this study to establish consensus among a group of musculoskeletal professionals on 8 clinical identifiers for the first stage of primary (idiopathic) adhesive capsulitis. Although the initial aim of the study had been to establish diagnostic criteria and instructions to participants had been to respond as such, following data analysis it was considered more appropriate to alter the nomenclature of the set of resultant criteria to clinical identifiers. In a recent Delphi study of lumbar zygapophyseal joint pain,[42] a similar dilemma was encountered, with experts in medical disciplines applying different definitions to the term "diagnostic criteria." Following the first round of that study, it was decided to replace the phrase "diagnostic criteria" with "criteria indicative" of lumbar zygapophyseal joint pain to more appropriately reflect the responses received. At the conclusion of the current study, the term "clinical identifiers" was similarly determined to be more appropriate for the set of criteria established, as they could not be regarded as a gold standard for diagnosis or provide a differential diagnosis, but rather are a set of clinical identifiers that may assist the cli-

* SPSS Inc, 233 S Wacker Dr, Chicago, Il 60606.

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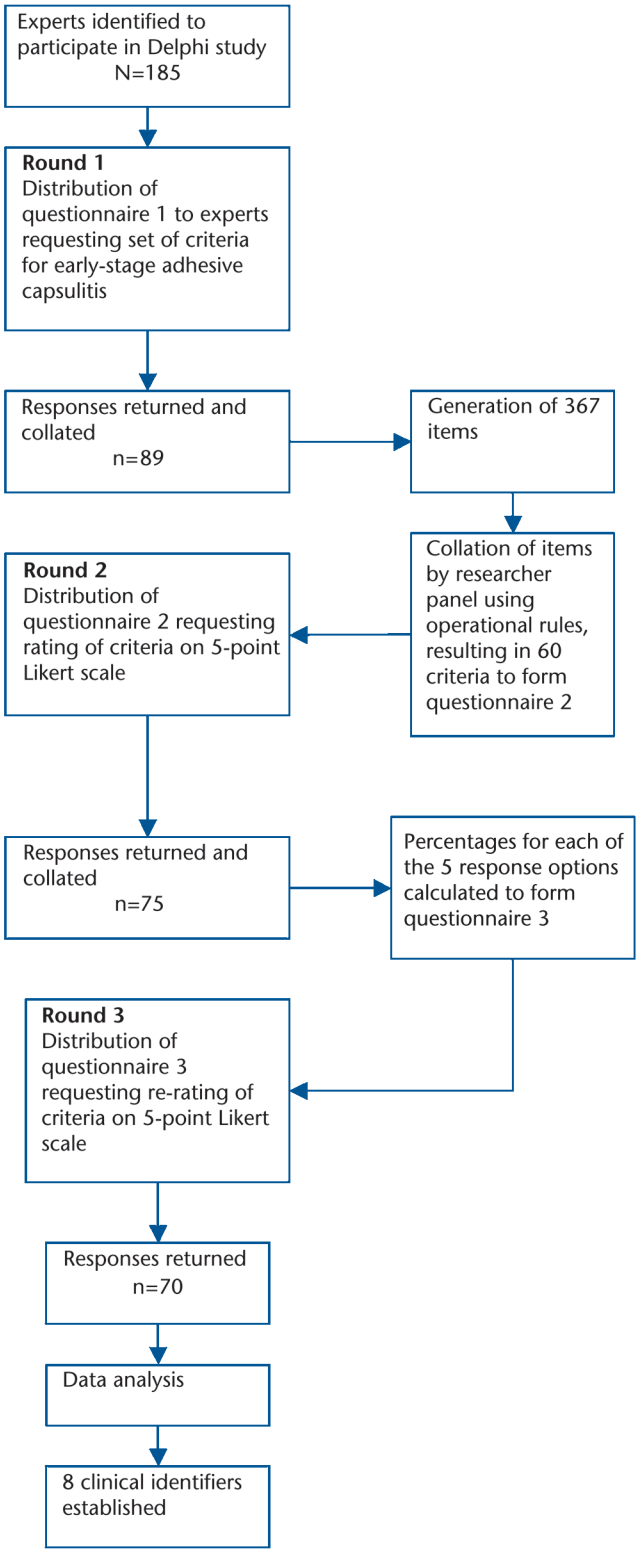

Figure 1.
Flow of participants through the study.

nician in diagnosis, as well as help form the basis for further research.

Unlike many earlier published studies using the Delphi technique, the application of rigorous statistical analysis, rather than only simple descriptive statistics, was used to determine consensus in this study. Notably, factor analysis in this study has resulted in identifiers clustering into 2 discrete domains of pain and movement.

Clinically, diagnosis of adhesive capsulitis is made through the history and physical examination. Textbook descriptions of the clinical characteristics of adhesive capsulitis identify a number of features present in each of the various stages of the disorder.[45] These features encompass onset and description of pain, as well as effect on movement. Similarly, in published studies such as a recent systematic review of physical therapy for adhesive capsulitis,[46] many of the clinical identifiers proposed by respondents in the present study are described, despite a lack of validation. Although these identifiers (including descriptions of pain and movement) are commonly proposed, they have not previously been subjected to formal evaluation. Using the Delphi technique, the present study is the first to subject these descriptors to scrutiny and begin the process of validation.

To date, there has been no agreement on the necessary criteria or clinical identifiers required for diagnosing adhesive capsulitis in its early stage.[20,45,47,48] However, it has been suggested that although the exact identifiers are poorly defined, pain is a significant feature in this stage.[4] Our study supports this premise, with several dimensions of pain being qualified and achieving consensus. A strong component of night pain, a marked increase of pain with rapid or unguarded movements, dis-

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Table 2.
Items Generated Following Round 1

Category	Criterion/Descriptor
Patient-reported findings	1. Pain is generally located over the upper arm
	2. Pain is predominantly over the lateral shoulder/deltoid region
	3. Pain is predominately over the anterior shoulder
	4. Pain may be referred distally into the forearm
	5. Pain is diffuse or poorly localized
	6. The pain is described as deep
	7. The intensity of the pain is described as severe
	8. The pain is constant or unrelenting in nature
	9. The pain is described as an ache
	10. The level of pain is progressively increasing
	11. There is an intermittent catching or pinching pain
	12. There is a strong component of night pain
	13. There is a marked increase in pain with rapid or unguarded movements
	14. It is uncomfortable to lie on the affected shoulder
	15. The patient reports the pain is easily aggravated by movement
	16. Once aggravated, the patient reports the pain is slow to settle
	17. Function is limited by increasing stiffness in this stage
	18. The history of onset of pain is spontaneous
	19. Symptoms have been present for greater than 4 weeks
	20. There is often a history of a minor trauma/precipitating event
	21. The onset of the condition is sudden
Demographic factors	22. The onset is generally in people greater than 35 years of age
	23. The onset is generally in people less than 60 years of age
	24. The condition more commonly presents in females
Physical examination findings	25. On examination, there is a global loss of active and passive range of movement
	26. On examination, there is pain at the end of range in all directions
	27. On examination, there is no painful arc with shoulder elevation
	28. There is protective muscle guarding with movement
	29. The loss of movement in any direction is minor
	30. The greatest loss of movement is in external rotation
	31. There is painful limitation of active external rotation range performed in supine at 90° shoulder abduction
	32. There is marked pain during isometric external rotation strength testing performed in supine at 90° shoulder abduction
	33. The patient's range of movement is progressively decreasing due to pain
	34. There is a global loss of passive glenohumeral joint movement
	35. The loss of movement is in a glenohumeral joint capsular pattern (ie, external rotation>abduction>internal rotation)
	36. Resisted isometric muscle testing is pain-free
	37. If pain is not inhibiting, muscle strength testing will be normal
	38. There is diffuse tenderness to palpation around the shoulder
	39. There is tenderness to palpation specifically over the anterior joint
	40. The scapula position is elevated at rest or with movement
	41. Provocative tests for tendinitis do not inform the diagnosis

(continued)

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Table 2.
Continued

Category	Criterion/Descriptor
Associated factors	42. There can be an association with diabetes
	43. There may be a coexisting history of a thyroid condition
	44. The onset of the condition is more common in spring and autumn
	45. A minor viral illness may precede the onset
	46. There is often a past history of adhesive capsulitis of the opposite shoulder
	47. There is frequently a history of impingement syndrome in the same shoulder
	48. The thoracic spine is kyphotic or hypomobile
Response to treatment	49. There is a nonresponse or an exacerbation of pain with treatment involving physical therapies
	50. There is minimal or no response to usual analgesic medication
	51. There is minimal or no response to nonsteroidal anti-inflammatory drugs (NSAIDs)
	52. There is no response to subacromial steroid injection
	53. There is a favorable response to a steroid injection into the glenohumeral joint
Investigations	54. A thickened joint capsule will be evident on magnetic resonance imaging (MRI)
	55. A decreased joint volume will be evident on MRI
	56. Ultrasound investigation does not inform the diagnosis
	57. X-ray examination only excludes osteoarthritis and calcific tendinitis
	58. There is a mild elevation of erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP)
	59. Blood factors exclude an infective or systemic inflammatory state
	60. Arthroscopy reveals synovitis and inflammation of the joint capsule

comfort lying on the affected shoulder, and pain easily aggravated by movement were the 4 descriptors of pain on which consensus was achieved. Although not validated, night pain or sleep disturbance has been described previously as a feature of this disorder in the early stage.[8,10,46,47] There also are descriptions in the literature of pain easily aggravated by movement.[4,5] Although probably not exclusive to adhesive capsulitis, these descriptors of pain may reflect the pathology of inflammatory synovitis that has been demonstrated at this stage.[8,49] The panel of experts in this study concur that these identifiers are necessary to diagnose early-stage primary adhesive capsulitis. Although the identifiers describing location and intensity of pain did not reach consensus, the pain identifiers described and for which consensus was reached may assist the clinician in the diagnosis of early-stage adhesive capsulitis.

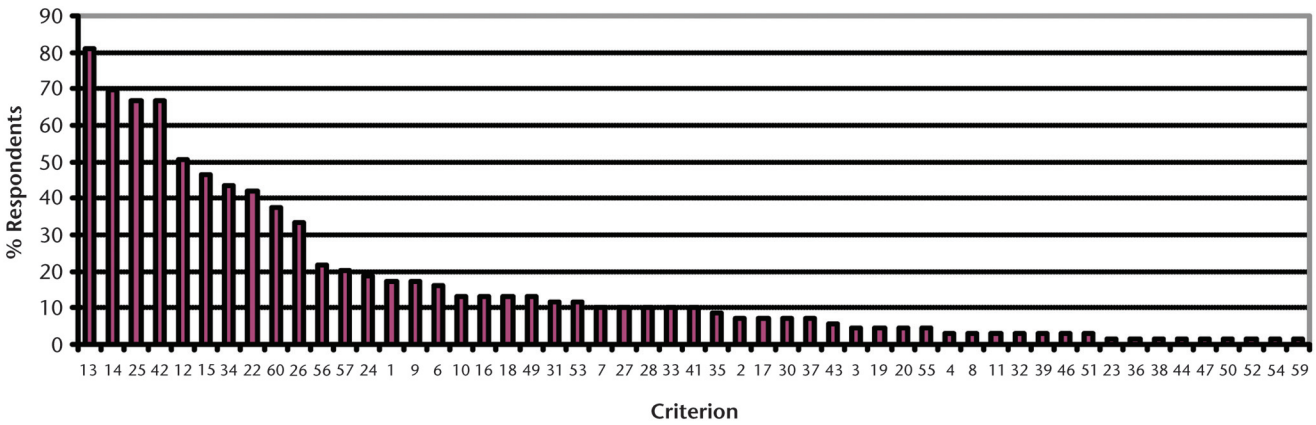

Figure 2.
Percentage of respondents scoring a criterion as "strongly agree" (n=70).

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Table 3.
Diagnostic Criteria Achieving Consensus

Criterion	Descriptor
12	There is a strong component of night pain
13	There is a marked increase in pain with rapid or unguarded movements
14	It is uncomfortable to lie on the affected shoulder
15	The patient reports the pain is easily aggravated by movement
22	The onset is generally in people greater than 35 years of age
25	On examination, there is global loss of active and passive range of movement
26	On examination, there is pain at the end of range in all directions
34	There is global loss of passive glenohumeral joint movement

The exact characteristics of movement dysfunction in the early stage of adhesive capsulitis are not clearly described in the literature. Although the effect on movement in the later stages of the disorder usually is described and even quantified, description of any movement deficit in the early stage generally is minimal. Nonetheless, general restriction of movement in all directions at this early stage has been described previously.[3,5,10] This study achieved consensus on the clinical identifiers of global loss of both active and passive ranges of movement, accompanied by pain at the end-range in all directions. Although no specific quantification of the loss at this stage has been determined, the fact that loss is global, rather than related to a specific direction, is the key feature in this clinical descriptor. Unlike many other shoulder pathologies, adhesive capsulitis is a disorder mainly affecting the glenohumeral joint capsule.[8] Global loss of active and passive range of motion is consistent with pathology of this structure. In addition, pain at the end-range in all directions is a feature that also may raise the level of clinical suspicion of adhesive capsulitis and also is consistent with capsular pathology.[3]

Demographic factors of adhesive capsulitis, including the age of onset, are considered relevant clinical features important in diagnosis. Generally, it is suggested in the literature that patients affected by this disorder are over 40 years of age.[3,4,8,9] Following round 1, a variety of responses quantifying age were received from the expert panel, such as "not seen less than 30 years of age," "middle aged 45–60," and "age 50s." The most-frequent response was captured in criterion 22 ("the onset is generally in people greater than 35 years of age"). Interestingly, criterion 23 ("The onset is generally in people less than 60 years of age"), which was descriptive of the upper age limit for this disorder, did not achieve consensus. Therefore, in this study, there was consensus that the age of onset of the disorder generally is greater than 35 years. This finding is consistent with previous published literature, although no explanation was offered.[3,4,8,9] The higher incidence of women in the 40- to 60-year age group, which failed to reach consensus, has been hypothesized to coincide with menopause and perimenopause,[50] but as yet this hypothesis remains unproven. The factor analysis determined that those respondents who regarded clinical identifiers in the pain dimension as diagnostically important consistently reported age (criterion 22) alongside the pain identifiers. As pain behavior and age generally are considered patient-reported data and not physical examination findings, it is appropriate that the clinical identifier describing age clustered with identifiers describing pain rather than with movement findings.

Interestingly, the 8 clinical identifiers established in this study did not include any negative findings. Instructions to participants were not

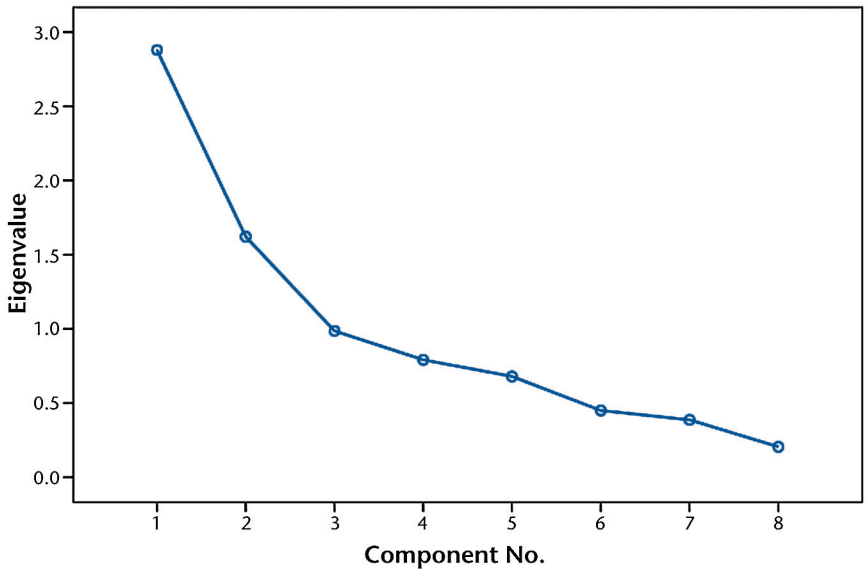

Figure 3.
Scree plot of final components selected.

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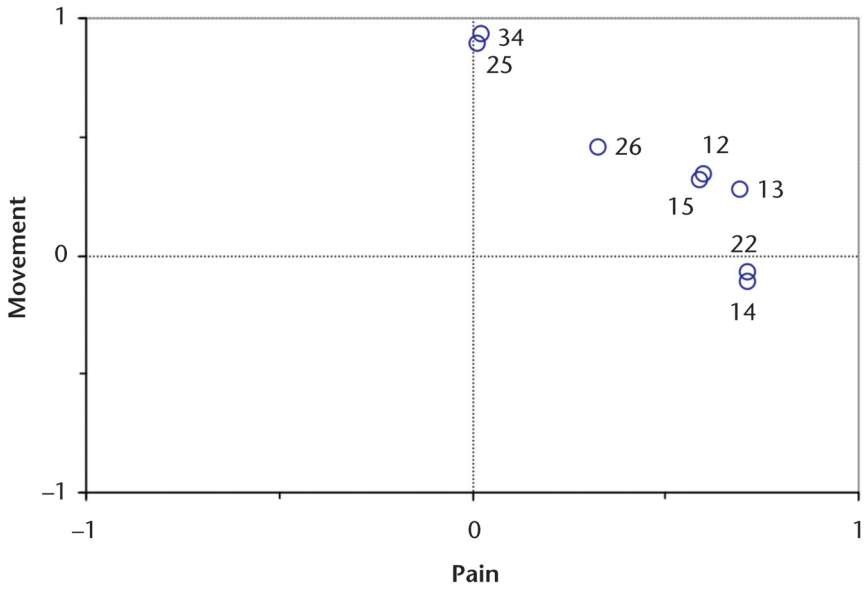

Figure 4.
Component plot of diagnostic criteria following factor analysis.

Table 4.
Factor Loadings Following Principal Components Factor Analysis of Clinical Criteria

Criterion	Factor	
	Pain (Eigenvalue=2.88)	Movement (Eigenvalue=1.62)
14	.719	
22	.717	
13	.695	
12	.604	
15	.595	
34		.928
25		.888
26		.447

to limit responses to positive findings, and indeed negative findings were solicited; however, they failed to reach consensus. This finding is relevant, as the presence of pathology in structures other than the glenohumeral joint capsule may elicit differing clinical characteristics that would raise doubts about a diagnosis of adhesive capsulitis. Acute cervical radiculopathy or rotator cuff tendinitis, for example, may be recognized by other clinical features that would contribute to a differential diagnosis. As such features did not reach consensus in the current study, the limitation of the results in assisting differential diagnosis is acknowledged. A further consideration is whether the resultant group of identifiers should be regarded as a set or as individual items. Instructions to participants had been to give a "set of necessary and sufficient diagnostic criteria"; however, it remains to be determined whether all or only some are necessary in diagnosis. This is particularly relevant, as some of the identifiers also may be present in other acutely presenting shoulder disorders of differing pathology.

The recent suggestion that attempting to place diagnostic labels on groups of patients in clinical research trials is of little value[22] may overstate the case. Arguably, one of the aims of establishing diagnostic criteria is to identify a homogenous subgroup of patients with which to evaluate treatment outcomes and make comparisons across trials more meaningful. Although there is some evidence that the outcomes of treatment may be similar in heterogeneous groups,[24–27] it remains to be seen whether subgroups of patients with common clinical features experience greater benefits with particular interventions.

The Delphi technique, and its application in this study, has a number of limitations. However, it was chosen because it enabled the engagement of a large number of musculoskeletal experts from a range of relevant professions and across a wide geographical area. One limitation often described is that there may be a poor response rate to the questionnaires.[35,36] In this study, the initial round had a moderate response rate of 48.1%, whereas the second and third rounds had high response rates of 84.3% and 93.3%, respectively. It has been suggested that a poor response rate may characterize the final rounds[35]; however, this did not occur in the current study. The overall response rate for this study was 37.8%, which compares favorably with recent studies that also had a large sample but achieved a response rate of only 8.4%.[38,39] Researcher bias also has been proposed as a weakness of the Delphi technique. The use of an open initial response in round 1 achieved a richness of collected data; however, this required care in reducing data to a more manageable volume for the subsequent rounds.

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Strict operational definitions were used by the 3 researchers to minimize bias. Furthermore, following round 3, rather than just using simple descriptive statistics as in many earlier studies, a more rigorous analysis was used to provide a more independent insight into the data.

Composition and size of the expert panel in Delphi studies vary across the literature. In an article discussing the methodology of the Delphi technique, Williams and Webb[51] noted that there is no agreement regarding the optimal size of an expert panel. They commented that the panel size of studies reported in the earlier literature varied from 10 to 1,685 participants. In the current study, the inclusion criteria for potential participants determined the size of the expert panel. These inclusion criteria were established to recruit musculoskeletal practitioners and leaders in several fields with expertise in clinical, research, and educational facets of shoulder pain. Although medical practitioners were represented, omission of rheumatologists, who may assess and treat musculoskeletal disorders, could be regarded as a limitation of this study. This omission occurred because it was not possible to identify a defined special interest group in musculoskeletal medicine or orthopedics within the Australian Rheumatology Association. Regional differences in prevalence or characteristics of adhesive capsulitis are not described in the literature. However, as the participants in this study were recruited from Australian and New Zealand experts, the results may reflect only views held in this region.

The present study not only addressed the difficulty faced by clinicians in the diagnosis of shoulder disorders as described by Mitchell and colleagues,[32] but also is the first of its kind to establish a set of clinical identifiers for the early stage of primary adhesive capsulitis. Although a specific diagnostic test or negative findings that may contribute to differential diagnosis did not achieve consensus in this study, several parameters of patient presentation have been established. These agreed-upon clinical identifiers should assist in the clinical decision-making process and aid in the early recognition of this disorder. They also represent the first step in the longer process of identification and validation of the agreed diagnostic criteria for this disorder.

Conclusions

The results of this study provide a framework for the validation of clinical identifiers for early primary adhesive capsulitis in further studies, as well as potentially facilitating comparisons across future clinical trials. Although the identifiers established in this study do not constitute an exclusive or discriminatory set of diagnostic criteria, they may be of assistance to the clinician confronted with the diagnostic dilemma of recognizing the early stage of primary adhesive capsulitis.

All authors provided concept/idea/research design and data analysis. Ms Walmsley and Dr Rivett provided writing. Ms Walmsley provided data collection. Dr Rivett provided institutional liaisons. Dr Rivett and Mr Osmotherly provided consultation (including review of manuscript before submission).

This study was approved by The University of Newcastle Human Research Ethics Committee.

An interactive poster presentation of selected findings of this study was given at the International Federation of Orthopaedic Manipulative Therapists (IFOMT) Conference; June 8–13, 2008; Rotterdam, the Netherlands.

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Adhesive Capsulitis: Establishing Consensus on Clinical Identifiers for Stage 1 Using the Delphi Technique

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Early diagnosis of primary/idiopathic adhesive capsulitis: Can imaging contribute?

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Adhesive capsulitis is a frequently presenting shoulder disorder in musculoskeletal medicine. It is recognized as consisting of three stages, and is often difficult to diagnose in its early stage and differentiate from other shoulder disorders. Treatment of this disorder has been proposed to be dependant on the stage, with early treatment suggested to decrease the overall morbidity. Arguably therefore, recognition in this early stage is desirable. The purpose of this paper is to review the current evidence that may support the role of imaging facilitating a diagnosis of adhesive capsulitis and to discuss this in relation to the contemporary understanding of the pathology of this disorder. The emerging role of Doppler ultrasound in the diagnosis and management of inflammatory arthropathies is discussed, and in particular its potential to contribute to the early diagnosis of adhesive capsulitis. While the diagnosis of adhesive capsulitis is presently largely based on clinical examination, this review outlines the current and future role that radiology may be able to contribute to the clinical presentation.

Keywords: Adhesive capsulitis, Diagnosis, Shoulder, Ultrasonography, Magnetic resonance imaging

Introduction

Adhesive capsulitis is a disorder of the shoulder which is frequently encountered in the primary health care setting. This disorder is characterized by gradually worsening pain and stiffness of the glenohumeral joint.[1,2] Traditionally, it has been reported to affect 2–5% of the normal population though, with advancing understanding of the pathology through arthroscopic examination it has been recently suggested that incidence may actually be as low as 0.75%.[3] Adhesive capsulitis is generally described as primary or secondary.[4,5] Primary or idiopathic adhesive capsulitis results from an unknown cause, whereas secondary adhesive capsulitis is due to a known cause such as trauma or surgery. It is recognized that adhesive capsulitis progresses through three stages and the natural history is towards resolution.[5–7] The three stages have been described as the painful stage (first) lasting between 3 and 9 months, the adhesive stage (second) lasting between 4 and 12 months, and the resolution stage (third) lasting from 5 to 26 months.[6] While various treatment options have been reported with variable results, it has been proposed that treatment implemented in the first or early stage may decrease the overall morbidity of the disorder.[1,8] Arguably, therefore, diagnosis and treatment in this early stage are most important.

The diagnosis of adhesive capsulitis is clinical and often one of exclusion.[1,9–12] It is acknowledged that diagnosis of adhesive capsulitis in its early stage can be difficult as the symptoms may be non-specific and easily confused with other pathologies, such as rotator cuff tendinopathy or subacromial bursitis.[9,10] While the diagnosis of established adhesive capsulitis is straightforward and essentially clinical, it is likely that confusion with coexisting impingement syndrome is common as features of both conditions may be present. In an attempt to address the lack of clearly defined diagnostic criteria for the early stage of adhesive capsulitis a Delphi study was conducted resulting in eight clinical identifiers being established for this early stage.[11] These identifiers remain to be validated and currently there is no definitive test or investigation for the early diagnosis of this disorder. The use of radiology as an adjunct to diagnosis in musculoskeletal medicine is well established, however, its role in the recognition of early stage adhesive capsulitis has yet to be determined. The current and potential future contribution of radiology in the diagnosis of adhesive capsulitis will be discussed in the light of the contemporary understanding of the anatomical and pathological evidence for the disorder.

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Pathology of adhesive capsulitis

An appreciation of the pathology of adhesive capsulitis provides a rationale behind the selection and timing of appropriate radiological investigation. While there has been controversy as to whether the disorder primarily represents an inflammatory or fibrotic process, it is now largely recognized that a mechanism involving capsular inflammation followed by fibrosis is responsible for the symptoms.[12] Historically, both inflammation[12–14] and fibrosis[15] have been microscopically described in adhesive capsulitis. Although histological examination has not identified inflammatory cells in the glenohumeral joint capsule in some studies,[15,16] others describe a visual appearance of synovitis consistent with inflammation.[1,2,17]

The surgical examination of patients believed to have adhesive capsulitis has identified the rotator interval area of the glenohumeral joint capsule as the anatomical location predominantly involved in this disorder.[14,18,19] As seen in Fig. 1, the rotator interval is a triangular space bounded superiorly by the anterior aspect of the supraspinatus tendon and inferiorly by the superior aspect of the subscapularis tendon. It is bordered medially by the lateral margin of the coracoid process and laterally by the transverse humeral ligament. Its contents include the coracohumeral and superior glenohumeral ligaments, together with the long head of biceps tendon.[20] Both arthroscopic[14,15,17] and open surgical studies[18,21] assessing the role of the rotator interval in adhesive capsulitis have demonstrated inflammation of the extra-articular tissue in this area, synovitis of the anterosuperior glenohumeral joint capsule, and thickening of the coracohumeral ligament. Histologically, the rotator interval has also been demonstrated to be an area of pathological significance.[15] Arthroscopic findings of adhesive capsulitis have also described the presence of red, inflamed synovium in the rotator interval, surrounding and in some instances indistinguishable from the intra-articular portion of the biceps tendon and coracohumeral ligament.[22] Macroscopic appraisal of the tissue in this study suggested the presence of chronic inflammation as demonstrated by high vascularity.[22]

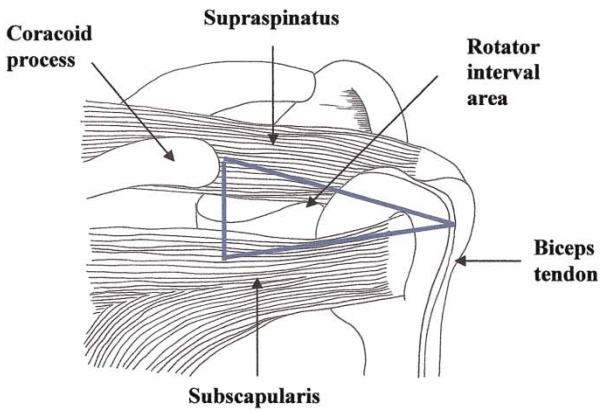

Figure 1 The rotator interval area of the shoulder.

The controversy and confusion regarding the exact pathogenesis of adhesive capsulitis has been proposed by Hand *et al.*[12] to stem from the fact that many published studies have examined groups of patients who were resistant to conservative treatment, and thus in the later stages of the disorder. It does, however, also appear from the surgical evidence that the pathology in the early stage of the disorder is inflammatory and this is supported by the clinical observation that intra-articular corticosteroid injections provide short-term improvement in symptoms.[23–29] In summary, the pathological evidence suggests that adhesive capsulitis in the early stage involves inflammatory changes of the glenohumeral joint capsule associated with increased vascularity in the synovium initiating at the rotator interval area, which then progresses to thickening and fibrosis of the capsular tissue.

Current radiology in the diagnosis of adhesive capsulitis

The radiological investigations most commonly performed for patients presenting with shoulder pain in the primary health care setting are X-ray and ultrasound examinations. These imaging investigations may confirm a diagnosis or be useful to eliminate other various possible pathologies.[10] While the various imaging modalities have described numerous findings in adhesive capsulitis, no one investigation to date is regarded as superior to clinical examination for the diagnosis of this disorder. Although invasive, conventional arthrography has been suggested as the preferred imaging investigation for adhesive capsulitis as it is able to demonstrate reduced glenohumeral joint volume.[2,30] Arthrographic evaluation of glenohumeral joint volume has, however, been suggested to provide misleading information in the presence of full-thickness rotator cuff tears which allow contrast material to flow into the subacromial space.[31]

While becoming increasingly more common and potentially providing superior diagnostic capabilities for shoulder pain, magnetic resonance imaging (MRI) continues to remain a less accessible and expensive imaging modality and is therefore used less frequently, though it is regarded by some as the gold standard for shoulder imaging.[32] Magnetic resonance arthrography (MRA) has been reported to demonstrate enhancement of the rotator interval and thickening and enhancement of the axillary recess.[33] Nuclear medicine bone scans are less frequently used and their contribution to the diagnosis of adhesive capsulitis is not regarded as significant.[30] Although the early stage of adhesive capsulitis has not received particular attention in most reported radiological investigations,

findings later in the course of the disorder may provide valuable information.

Ultrasound imaging

Ultrasound investigation of the shoulder has become increasingly utilized over recent years with the introduction of better imaging equipment, more advanced understanding of ultrasound anatomy, and a more defined examination technique.[34] This imaging modality is attractive as it has the advantages of being safe, non-invasive, and using non-ionizing radiation,[35] as well as being fast, inexpensive, and well-tolerated by the patient.[36,37]

The use of gray-scale ultrasound imaging in the assessment of rotator cuff tendons is widely accepted.[37] Conversely, only a small number of published studies report its application in assisting the diagnosis of adhesive capsulitis.[22,38,39] Indeed, it has been suggested that with the use of ultrasound there is no single finding that may be regarded as diagnostic or consistently present in all cases of adhesive capsulitis.[40] Using arthrography as the gold standard for diagnosis against which the sonographic findings were compared, Ryu *et al.*[39] described limitation of movement of the supraspinatus tendon as a reliable criteria for diagnosis of this disorder. While the duration of the symptoms of participants in this study was not reported, it is unlikely that they were in the early stage of adhesive capsulitis, and probably were at the stage when limitation of range of movement facilitated clinical diagnosis. As a means of assisting the diagnosis of adhesive capsulitis, the coracohumeral ligament was assessed by Homsi *et al.*[38] with ultrasound to determine if it was thickened in patients with arthrographic evidence of the disorder. They concluded that a thickened coracohumeral ligament may be suggestive of adhesive capsulitis, but it was recognized that further studies are needed to validate these results. However, the patients examined were likely at a later stage of the disorder when a clinical diagnosis may be more apparent and arthrography was utilized as the diagnostic reference which, may have lead to an incorrect interpretation in some cases.[41] A further recent suggestion that may assist in the diagnostic dilemma in early diagnosis has been a proposal that dynamic ultrasound assessment of posterior shoulder capsular compliance and joint synovial proliferation may correlate well with the various stages of adhesive capsulitis.[42] The ability of ultrasound to assess dynamically has been highlighted by this author together with the importance of early diagnosis.

Color Doppler ultrasound has also been sporadically reported to provide valuable information in the diagnosis of adhesive capsulitis.[22] Enhanced vascularity and hypoechoic change in the rotator interval have been correlated with vascular synovial fronds visualized with arthroscopic investigation.[22] Though an unblinded assessment, ultrasound appraisal of the rotator interval compared with arthroscopic findings suggested that color Doppler ultrasound was able to provide an early and accurate diagnosis of adhesive capsulitis by assessing for hypoechoic vascular soft tissue.[22] In contrast to the previous studies, this study examined a group of patients who had experienced symptoms for less than 12 months, therefore reflecting the earlier stage of the disorder. Color Doppler ultrasound has also been proposed by other authors to show capsulosynovial hyperemia at the rotator interval early in the disorder, as well as tenderness to probing over the glenohumeral joint capsule.[40]

MRI

Unlike ultrasound, the use of MRI, and MRA has received wide attention in the literature in the diagnosis of adhesive capsulitis. A summary of studies using MRI is given in Table 1 and a summary of MRA studies is provided in Table 2. Comparison of these studies demonstrates that inclusion criteria for subjects vary and may not always include subjects in the early stage of adhesive capsulitis, but rather more likely in the later stages when the clinical presentation may be more apparent. Further, individual studies describe differing endpoints and as a result it has been suggested that drawing conclusions on the role of these radiological investigations in the diagnosis of this disorder may be difficult.[54] Despite these limitations, however, the reported studies using MRI and MRA provide consistent findings and therefore valuable diagnostic indicators.

Consistent with the surgical and histological findings, the area of most interest in both MRI and MRA investigations has been the rotator interval.[14,15] Some studies report a difference in rotator interval dimensions visualized with MRA,[52,53] while other authors were unable to demonstrate statistically significant differences.[49,50] Enhancement of tissue in this area has also been reported in both MRI and MRA investigations, indicating the presence of inflammation (Fig. 2).[33,45–47,52] Interestingly, Connell *et al.*[46] surgically correlated rotator interval and synovial inflammation using MRI with respect to the various stages of adhesive capsulitis. Thickening of the joint capsule and the coracohumeral ligament in the rotator interval area have also been reported (Fig. 3).[45,51] Obliteration of the subcoracoid fat between the coracoid process and the coracohumeral ligament has further been described as a useful MRA finding.[51] Using a variety of methods including both enhanced and unenhanced MRI and direct (intra-articular) and indirect (intravenous) MRA, capsular thickening of the axillary recess has been suggested by several authors as a useful sign of

Table 1 Summary of MRI studies on adhesive capsulitis

Study	Number of shoulders	Inclusion criteria	Duration of symptoms	Investigation	Summary of findings
Emig[43]	10 AC 15 asymptomatic	9 subjects diagnosed by arthrography, 1 confirmed at surgery	Not stated	MRI measuring thickness of capsule, synovium and CHL, volume of articular fluid	Capsule and synovium thickness >4 mm was specific (95%) and sensitive (70%) for AC. No significant difference in volume of fluid or thickness of CHL. RI not useful for assessing AC
Tamai[44]	18 AC 8 IS 3 healthy volunteers	>1 month history of shoulder pain and stiffness, <135° forward elevation, recognizable limitation of IR and ER. Monitored until pain free and near normal ROM	1–18 months (7 months)	Dynamic gadolinium enhanced MRI assessment of the synovium in AC subjects	Obvious enhancement of the GHJ synovium in AC subjects clearly distinguishable from that of normal shoulders
Carrillon[45]	25 AC 15 with RCT's	Gradually increasing shoulder pain at least 1 month duration, anterior elevation <135°, ER < 20°, normal X-rays	2–10 months (6 months)	MRI involving two spin-echo T2-weighted sequences with fat saturation and two spin-echo T1 weighted post-gadolinium sequences	Post-gadolinium enhancement of the GHJ capsule and synovium was seen in the RI in all 25 AC subjects (in only 1 of the RCT subjects) and in the AR in 22 out of 25
Connell[46]	24 AC 22 RC pathology	Insidious onset of shoulder pain and dysfunction. Pain and stiffness >15 weeks, increasing in nature, most severe at rest, restriction of PROM > 30° in 2 or more planes	15 weeks – 26 months (10.2 months)	MRI prior to arthroscopic capsulotomy. Routine intravenous gadolinium	Presence of enhancing fibrovascular scar tissue in the RI, soft tissue thickening around the biceps anchor and thickening of the axillary pouch on MRI are suggestive signs of AC
Lefevre-Colau[47]	26 AC 14 contralateral pain free, non restricted shoulders	Gradually increasing shoulder pain more severe at rest, for at least 1 month, limitation of PROM mainly in forward elevation and ER, normal X-ray, non-responsive to normal Rx	At MRI 3–26 months (9.5 ± 5.4 months)	MRI with gadolinium enhancement measuring GHJ capsule and synovial thickness in the RI and AR	Mean thickness of AR and RI greater in AC shoulders compared to controls
Sofka[48]	46 AC (47 shoulders)	Presumptive clinical diagnosis or MRI findings suggestive of AC. Patients with MRI's and detailed clinical information that allowed stage to be determined	Clinical diagnosis of stage 1 (0–3 mths), 8 subjects; stage 2 (3–9 mths), 23 subjects; stage 3 (9–15 mths), 8 subjects; stage 4 (15–24 mths), 8 subjects	MRI measuring capsular and synovial thickness at the AR, scarring in the RI, signal intensity in the capsule	All subjects demonstrated scarring of the RI; 29 subjects had hyperintensity of the GH capsule; capsular and synovial thickening measured in the AR correlated with clinical stage of AC; hyperintense capsular signal correlated with stage 2

AC, adhesive capsulitis; ADL, activities of daily living; AR, axillary recess; CHL, coracohumeral ligament; ER, external rotation; FE, forward elevation, GHJ, glenohumeral joint; h/o, history of; IR, internal rotation; IS, impingement syndrome; MRA, magnetic resonance arthrography; MRI, magnetic resonance imaging; mths, months; PROM, passive range of movement; RC, rotator cuff; RCT, rotator cuff tear; RI, rotator interval; ROM, range of movement; Rx, treatment; VAS, visual analog scale.

adhesive capsulitis.[33,43,47,48,50,52] However, conflicting results have, however, also been reported.[45,49,51]

Despite the findings reported in the literature, Petchprapa *et al.*[54] have recently suggested that the

Table 2 Summary of MRA studies on adhesive capsulitis

Study	Number of shoulders	Inclusion criteria	Duration of symptoms	Investigation	Summary of findings
Manton[49]	9 AC 19 without signs of AC	Retrospective arthrographic diagnosis based on having two or more of the following: joint volume <10 ml, poor or absent filling of the AR of the joint or biceps tendon sheath, irregularity of the capsule insertion, pain after injection of <10 ml of contrast, or extravasation of contrast prior to injection ≥10 ml	Not stated	MRA assessing relative amount of fluid in the biceps tendon sheath and AR, corrugation at the margin of the capsule, capsule synovium thickness, abnormalities of the RI, and the presence of RCT's	Concluded no useful MRA signs of AC. Capsule/synovium thickness, static fluid, and the presence of corrugation are inconclusive signs distinguishing shoulders with AC from those without
Lee[50]	16 AC 11 controls	Arthroscopically proven AC with at least two of the following: vascular synovitis, capsular contracture, tightness of the humeral head against the glenoid, difficult penetration of the GHJ capsule with the arthroscope. Excluded AC diagnosed clinically	Not stated	MRA measuring thickness of GHJ capsule and synovium, filling ratio of AR to determine relative volume, width of the RI	Thickening of the GHJ capsule and synovium and diminished filling ratio of the AR to posterior joint cavity appeared to be useful diagnostic criteria for AC
Mengiardi[51]	22 Rx arthroscopic capsulotomy for AC 22 age- and sex-matched controls	Surgical confirmation of AC (thickened GHJ capsule and synovitis in the area of the RI) and treatment with arthroscopic capsulotomy < 3 months after MRA	3–24 months (11 months)	Pre-operative MRA compared with age- and sex-matched control subjects without AC	Thickening of the CHL and joint capsule in the RI. Synovitis-like abnormalities at the superior border of the subscapularis tendon significantly more common in AC subjects than in controls
Jung[52]	14 AC 14 controls	Injected GHJ volume <WITH pain. Pain and stiffness >15 weeks, restriction of PROM of >30° in two or more planes, normal X-ray	Not stated	MRA measuring mean thickness of GHJ capsule and synovium, width of the AR and RI	In the absence of a full thickness RCT, thickness of the GHJ capsule, and synovium >3 mm at the level of the AR is a practical MR criterion for the diagnosis of AC on oblique coronal T2 weighted MRA without fat suppression
Kim[53]	26 AC 47 controls	Painful stiff shoulder for at least 4 weeks, severe pain interfering with ADL, night pain, painful restriction of active and passive elevation to <100°, 50% restriction of ER. AC confirmed arthroscopically in 11 shoulders	Not stated	Retrospective review of patients undergoing MRA. Estimated the height, base RI area, width, RI index, and RI ratio	Shoulders with AC differed significantly in height, base, RI area, RI index, and RI ratio from those without AC
Song[33]	35 AC 45 controls	Painful stiff shoulder for at least 4 weeks, severe shoulder pain that interfered with ADL, night pain, painful restriction of active and passive elevation <100°, 50% restriction of ER, normal X-ray	Not stated	Indirect MRA comparison with control subjects. Measured joint capsule thickness in AR; thickness of enhancing portion of the AR and RI	AC subjects had significantly thickened joint capsule in the AR and a thickened enhancing portion in the AR and RI

AC, adhesive capsulitis; ADL, activities of daily living; AR, axillary recess; CHL, coracohumeral ligament; ER, external rotation; FE, forward elevation, GHJ, glenohumeral joint; h/o, history of; IR, internal rotation; IS, impingement syndrome; MRA, magnetic resonance arthrography; MRI, magnetic resonance imaging; PROM, passive range of movement; RC, rotator cuff; RCT, rotator cuff tear; RI, rotator interval; ROM, range of movement; Rx, treatment; VAS, visual analog scale.

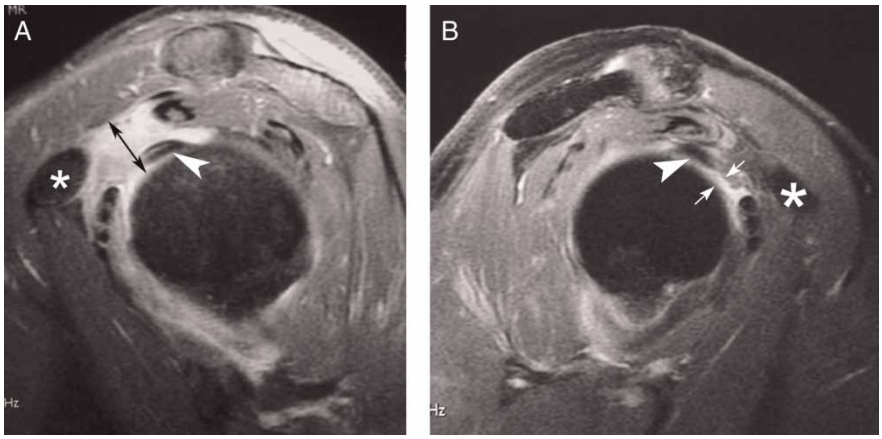

Figure 2 MRI of a 61-year-old woman with clinical evidence of right adhesive capsulitis and a contra lateral healthy shoulder. Sagittal fat-suppressed T1-weighted spin-echo sequence after IV Gd-chelate enhancement (TR/TE = 600/15 ms). Note the marked enhancement of the joint capsule and synovial membrane in the rotator cuff interval (*black opposed arrow*) in the right AC shoulder (A) and the lack of enhancement in the contra lateral healthy shoulder (*white double arrow*) (B). Biceps tendon (*arrowhead*) and coracoid process (*asterisk*) are shown. (image reproduced with permission from Ref. 47).

clinical role of MRI may be limited due to the variability of methodology in the studies reported to date. While some authors may draw certain conclusions from their studies, they are not always supported by others using differing methodologies. Further, as adhesive capsulitis is a disorder that progresses through a series of stages, reported results should be considered within the context of the duration of symptoms of the subjects. Some authors acknowledge the various stages of adhesive capsulitis in their studies,[44,46,48] however, it should be noted that generalized conclusions where the stage of the disorder has not been identified may need to be drawn with caution. Although findings have been described that may be useful indicators of adhesive capsulitis, plain MRI, and MRA are not investigations routinely utilized in the primary health care setting and therefore their practical application to this disorder may be limited.[31] Nonetheless the diagnosis of adhesive capsulitis is essentially clinical, and while not routinely performed in the early stage of adhesive capsulitis, MRI may facilitate a diagnosis at that stage which may be subsequently confirmed clinically.[54]

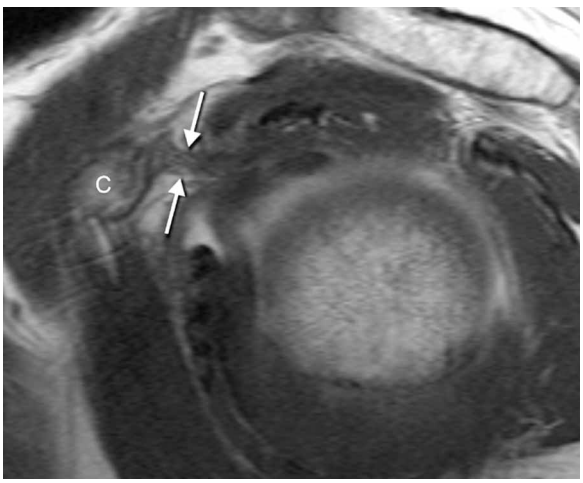

Figure 3 Sagittal oblique T1-weighted (700/12) image shows thickened CHL (arrows) in a 57-year-old patient with adhesive capsulitis. C, coracoid process (image reproduced with permission from Ref. 51).

The future of ultrasound in the diagnosis of adhesive capsulitis

As discussed earlier there is evidence that various radiological investigations have identified several features that may assist in the diagnosis of adhesive capsulitis. Other imaging modalities, notably power Doppler ultrasound, with the potential to assist diagnosis, have received little attention. This modality will be discussed in light of the current pathological understanding and existing radiological evidence.

Power Doppler ultrasound

The radiological assessment of vascularity has been made possible with technological improvements and, in particular, with both color and power Doppler ultrasound. In contrast to color Doppler ultrasonography, which is better suited to evaluate high velocity flow in large blood vessels, power Doppler ultrasound is better suited to detect low velocity blood flow in small vessels as in the synovium.[55] Although power Doppler ultrasound has its origins in cardiac investigations, it has since been applied to other diagnostic situations including musculoskeletal medicine.[56,57] In musculoskeletal inflammatory disease, power Doppler ultrasound has the potential to detect soft tissue hyperemia.[56] Power Doppler has also been described as an efficient tool to measure and monitor disease activity and progression.[58]

While most musculoskeletal ultrasound is performed using gray-scale ultrasound alone, the detection of hyperemia with both color and power

Doppler is reported to be becoming increasingly common.[59] Power Doppler ultrasound has been demonstrated to provide a reliable and accurate method for visualizing blood flow in the synovial tissue of patients with osteoarthritis and rheumatoid arthritis of the knee joint.[60] With respect to the shoulder, several studies that assessed biceps tendon pathology give evidence that this modality provides important diagnostic information.[57,61,62] Notably, power Doppler ultrasound has been able to distinguish between inflammatory and non-inflammatory shoulder pain through assessment of the biceps tendon sheath in patients with rheumatoid arthritis, compared with patients with degenerative diseases of the shoulder.[61] However, Wamser *et al.*[57] conclude that while power Doppler ultrasonography is able to detect active inflammatory changes in the soft tissues of the shoulder, it is less capable than MRI in determining the degree of synovitis and distinguishing synovitis from fluid. The suggestions that a negative Doppler signal does not exclude the possibility of synovitis, but rather a positive signal is an indication of active synovitis has also been proposed.[63] Histopathologically, a minor color signal in the synovium has been shown to be an important marker for synovitis, though the amount of color may not correlate strongly with the severity of the histopathological synovitis.[63]

Both the current pathological and surgical evidence, together with findings on ultrasound and MRI imply the rotator interval is the area of initial synovial hyperemia in adhesive capsulitis. It has been proposed that increased signal intensity of the joint capsule and synovium in the early stage is likely to reflect the active synovial and capsular response at this stage of the disorder.[48] It would appear logical therefore that an imaging modality with the ability to detect synovitis may have potential to identify the early stage of adhesive capsulitis. Fig. 4 illustrates a power Doppler examination of a patient with clinically diagnosed adhesive capsulitis showing an area of increased vascularity in the rotator interval area. Evidence of enhanced vascularity in the rotator interval using color Doppler ultrasound[22] has been demonstrated, however, the role of power Doppler ultrasound in the diagnosis of adhesive capsulitis remains to be investigated.

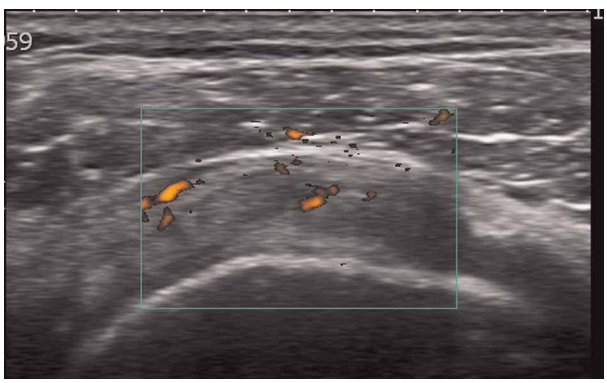

Figure 4 Power Doppler ultrasound of 54-year-old female with a 6 month history of adhesive capsulitis demonstrating increased vascularity at the rotator cuff interval.

Although the use of Doppler ultrasound is promising in musculoskeletal medicine, a number of limitations require consideration. Application of Doppler ultrasound is influenced by the skill of the examiner, sensitivity of the machine, as well as technical artifacts.[60] The technique is highly motion sensitive and even minimal soft tissue motion can make differentiation of blood flow from motion difficult to discern.[64] Further, excessive pressure from the transducer may also result in vessel occlusion, although a stand-off gel pad may minimize this issue.[55] It has also been demonstrated that the selection of the ultrasound machine used for investigation is important as an inability to detect a signal at the capillary flow level may be due to flow in synovium being under the detection threshold of some machines.[63]

As ultrasound is safe, inexpensive, non-invasive, and relatively accessible it may contribute in the future in diagnostically combining clinical signs and symptoms with objective radiological findings.[60] Power Doppler is an emerging technology that may, by measurement of vascularity of the musculoskeletal system provide an indication of disease processes and progression.[65] Arguably therefore, there is merit in assessing the shoulders of patients with acute pain with respect to vascularity of the capsule and particularly the rotator interval to determine whether an increase in vascularity may be present, potentially assisting in the early diagnosis of adhesive capsulitis.

Conclusion

Ultrasound and MRI findings in adhesive capsulitis have been described and may be useful diagnostically, most notably demonstrating increased vascularity in the rotator interval.[22,47] Despite reports of radiological examinations potentially being of some value in the diagnosis of adhesive capsulitis, it has also been argued that to date these investigations do not provide any real contribution over that of standard clinical assessment.[34] Notably, however, most studies have involved severe cases or those at a later stage of the disorder. With this imaging modality becoming increasingly popular in the clinical setting[55] power Doppler ultrasound may enable the clinician to combine imaging with the history and examination findings to facilitate early diagnosis of adhesive capsulitis. Future studies are required to explore these potential benefits.

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Power Doppler Ultrasonography in the Early Diagnosis of Primary/Idiopathic Adhesive Capsulitis: An Exploratory Study

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Abstract

Objective: The purpose of this exploratory study was to determine if increased vascularity in the rotator interval area of the glenohumeral joint capsule could be visualized with power Doppler ultrasonography (PDUS) in patients with a clinical diagnosis of early-stage adhesive capsulitis.

Methods: Demographic and clinical characteristics from a consecutive series of 41 patients diagnosed with early-stage adhesive capsulitis were recorded and examination with PDUS was undertaken. Images were reviewed by 3 musculoskeletal radiologists, and consensus was determined on the presence of increased signal in the rotator interval area.

Results: Consensus was achieved on the presence of increased signal in 12 (29%) of the 41 cases. Participants with an increased PDUS signal did not demonstrate a characteristic set of identifying features, suggesting that those with increased vascularity may not constitute a distinct subgroup.

Conclusion: This study found that some patients diagnosed with early-stage adhesive capsulitis demonstrated increased vascularity in the rotator interval area when examined with PDUS. These findings suggest that PDUS may have the potential to assist in the identification of increased vascularization in early stages of this disorder. Further research in the use of PDUS in diagnosing early-stage adhesive capsulitis is warranted. (J Manipulative Physiol Ther 2013;36:428-435)

Key Indexing Terms: *Shoulder Pain; Adhesive Capsulitis; Diagnosis; Ultrasonography*

Shoulder pain commonly presents in the musculoskeletal primary care setting and may arise from many potential sources. Differential diagnosis frequently poses a dilemma, as many disorders may present with similar symptoms and physical examination findings. Adhesive capsulitis of the shoulder has been typically reported to have an incidence of 2% to 5%[1,2] and is described as being either primary or secondary.[1] Primary or idiopathic adhesive capsulitis has an unknown cause, in contrast to secondary that results from a known event including trauma and surgery.[1] This disorder has been described as consisting of 3 stages. The first or early stage is generally described as the painful stage and is considered to last up to 9 months.[3] Adhesive capsulitis has been reported to be characterized by pain and progressive restriction of both active and passive shoulder movement as the patient progresses to the later stages.[3] It has also been reported to occur more commonly in women[4] and in up to 30% of the diabetic population, and has also been associated with thyroid disorders, autoimmune diseases,[5] and Dupuytren disease.[6] The age at which this disorder is reported to most frequently occur is between 40 and 60 years.[1,2] The early stage of adhesive capsulitis is acknowledged as the most difficult to diagnose because the clinical presentation at this stage may be confused with other shoulder disorders.[7]

It has been contended that treatment of adhesive capsulitis in its early stage may minimize the morbidity of the disorder.[1] In order that treatment may optimally be implemented, accurate and timely diagnosis is therefore required. The pathology of adhesive capsulitis has recently become better understood, and it is now acknowledged that

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the process involved is initial inflammation followed by subsequent fibrosis of the glenohumeral joint capsule.[8] The site at which the process is predominantly involved has been identified as the rotator interval area of the glenohumeral joint capsule.[9-11]

Musculoskeletal health care frequently relies on diagnostic imaging, together with clinical findings to inform the diagnosis of many conditions. Diagnostic imaging may be useful in contributing to a diagnosis, as well as to rule out other potential diagnoses. Although there is no clear criterion standard for the diagnosis of early-stage adhesive capsulitis,[7] diagnostic imaging using ultrasonography (US)[12-14] and magnetic resonance imaging (MRI)[15-23] has recently been suggested to assist the diagnosis of this disorder. Notably, enhancement or hypervascularity of the rotator interval area has been demonstrated with MRI in adhesive capsulitis.[18,21,24,25] However, most of the imaging findings that have been reported in these reports are in patients in the later stages of adhesive capsulitis when the clinical presentation more clearly indicates the diagnosis.

Assessment of the vascularity of soft tissues may also be achieved using both color (CDUS) and power Doppler ultrasonography (PDUS).[26] There is preliminary evidence that CDUS has the potential to identify characteristics of early-stage adhesive capsulitis.[12,27] With more sensitivity to detect low blood flow such as occurs in inflammation of synovial tissue, PDUS has more recently gained popularity in the diagnosis and management of diseases of the musculoskeletal system.[28] Its use is becoming more widespread in the clinical setting because, unlike some other imaging modalities, Doppler ultrasonography is a noninvasive, generally accessible and relatively inexpensive nonionizing imaging modality. Nonetheless, the use of PDUS in the diagnosis of early-stage adhesive capsulitis remains unexplored. Therefore, the aim of this study was to examine the rotator interval area of the shoulder with PDUS in a series of consecutive patients clinically diagnosed with early-stage primary adhesive capsulitis to explore its potential use as a tool to assist clinicians. The goals of this study included assessing if it were possible to visualize with PDUS an area of increased vascularity in the rotator interval area of patients in the early stage of adhesive capsulitis and if there is an association between clinical presentation or demographic variables and a reported increase in vascularity in the rotator interval area as seen with PDUS in these patients.

Methods

Design

A consecutive case series of 41 patients diagnosed with early-stage primary adhesive capsulitis on the basis of clinical presentation and attending an orthopedic clinic specializing in upper limb disorders in New South Wales, Australia, was invited to participate in the study. Power Doppler US examination was performed, and clinical measures of pain and shoulder range of movement and demographic information were collected in the clinic.

Participants

Potential participants were referred to the clinic by various medical practitioners with the clinical diagnosis of early-stage adhesive capsulitis. In the absence of a validated set of clinical identifiers or diagnostic criteria for early-stage adhesive capsulitis,[7,29] the clinical decision of the referring medical practitioner was pragmatically considered appropriate. However, to ensure a homogeneous sample and consistent with the diagnosis often being one of exclusion,[1,30] strict inclusion and exclusion criteria were used. As the study was investigating the early stage of primary or idiopathic adhesive capsulitis, potential participants were required to have a history of less than 9 months of shoulder pain that did not result from significant trauma, fracture, dislocation, or surgery. Potential participants were excluded if either they had not undergone recent radiographic and US investigation to exclude other pathologies or these investigations revealed other pathologies including osteoarthritis, calcific tendonitis, or a full-thickness rotator cuff tear. The presence of a neurological disorder, rheumatoid arthritis, and any systemic inflammatory joint disease, or an injection into the glenohumeral joint in the preceding 6 weeks was a further exclusion criterion. The Human Research Ethics Committee of The University of Newcastle granted ethical approval for this study. All participants provided written informed consent before the examination procedure.

Measurement

Participants first had a standard clinical history taken including recording of various pain descriptors relevant for adhesive capsulitis such as current level of pain and night pain measured on a visual analog scale (0-100 mm). Further recorded descriptors included presence of pain aggravated by movement, pain with rapid or unguarded movement, a feeling of nausea with movement, pain settling quickly after movement, and pain worse toward the end of range, as well as waking due to pain.[4,31-34] The Shoulder Pain and Disability Index (SPADI)[35] was also administered before the scanning procedure.

The rotator interval of all participants was examined using a 12-MHz linear transducer with a commonly clinically used diagnostic US system (Model M5; Shenzhen Mindray Bio-medical Electronics Co, Ltd, China). Although more sophisticated US systems may be available in specialist radiology practices, the system chosen was considered appropriate and sufficiently sensitive enough for this study, as the aim was to determine whether a tool

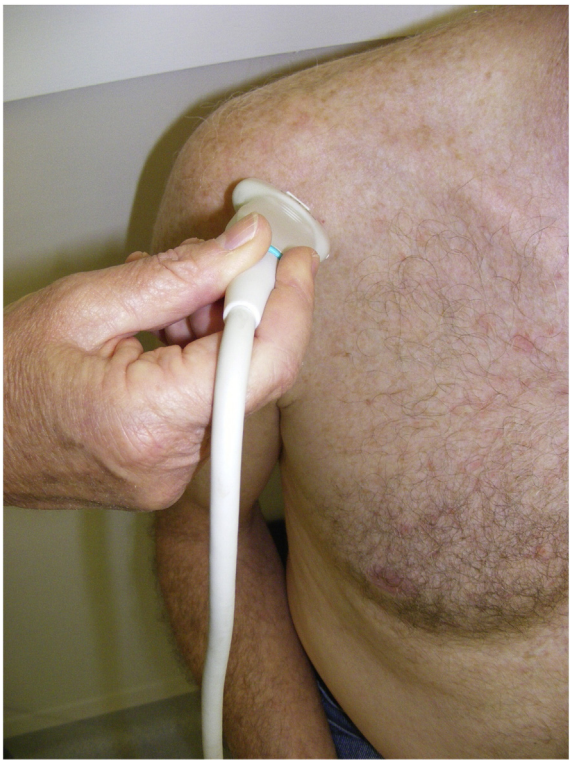

Fig 1. *The position of the participant for the examination, with the hand of the affected shoulder held in supination beside the patient's thigh and transducer over the anterior shoulder.*

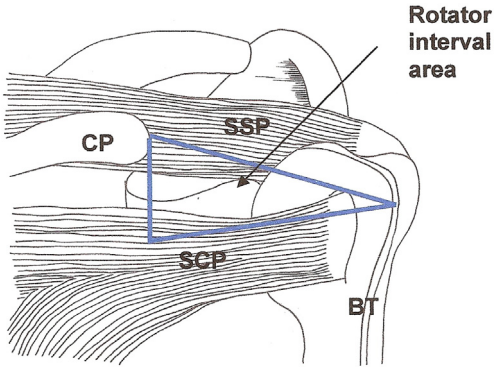

Fig 2. *The rotator interval area of the glenohumeral joint capsule. BT, biceps tendon; CP, coracoid process; SCP, subscapularis muscle; SSP, supraspinatus muscle.*

commonly found in the primary care setting was of clinical utility in the diagnosis of early-stage adhesive capsulitis. The examination was performed in the clinic by one of the researchers who had been individually trained in the use of the machine by both a musculoskeletal sonographer and an experienced musculoskeletal radiologist.

The participant was seated for the examination with the affected arm relaxed. The elbow was flexed with the forearm of the affected shoulder held in supination beside the patient's thigh, as has been previously described [12,36] (Fig 1). The transducer was positioned on the anterior shoulder with the biceps tendon visualized in its groove and the rotator interval identified. The rotator interval was visualized in the oblique plane as in previously published work. [12] This triangular area is located in the anterior portion of the glenohumeral joint capsule and is defined by the bordering structures. [37] Superiorly, the rotator interval area is bordered by the leading edge of the supraspinatus tendon, the superior edge of the subscapularis tendon inferiorly, the base of the coracoid medially, and the long head of biceps tendon laterally [37] (Fig 2). The PDUS assessment was performed with settings standardized to a Doppler frequency of 6.6 MHz, and pulse repetition frequency and wall filters were set at a value determined by the system to be optimum according to the characteristics of the tissue being scanned. Still images were recorded and stored for later review. The operator's pressure on the probe was minimized to avoid compression of the small vessels. A pilot study of 10 patients was completed before the investigation to ensure technical aspects of the examination were optimized.

Following the PDUS examination, participants underwent clinical examination including measurement of passive, total shoulder flexion and abduction, glenohumeral joint flexion and abduction, external rotation in neutral and 90° abduction, and internal rotation in 90° abduction using a Baseline digital inclinometer (Fabrication Enterprises Incorporated, Irvington, NY). Hand behind back range of movement was evaluated by measuring the distance between the radial styloid process and the spinous process of T1. Pain at the end of each passive movement was also recorded on a visual analog scale. Both the examiner and the participant were blinded to the results of the US examination during the actual clinical examination, as this was performed before the radiologists' review of the recorded US scans.

Three blinded radiologists, each with a minimum of 17 years of experience in musculoskeletal radiology, independently reviewed the recorded still images for the presence of a signal within the rotator interval area indicative of increased vascularity. The presence of increased signal in the rotator interval area was scored dichotomously as either absent or present. Although electronic quantification of power Doppler signal has recently become available, to date it has been reported less frequently than scoring as present or absent. [28] Consensus was determined when 2 or more of the radiologists agreed on the presence of an increased signal in the rotator interval area. Consensus interpretation of US images has been used in previously published studies. [12]

Data Analysis

Data were analyzed using Stata 11.0 statistical software (Stata Corporation, College Station, TX). Values for each clinical examination variable were analyzed by the

Table 1. *Demographic and clinical characteristics of the participants*

Characteristic	Total sample (N = 41)	Positive PDUS (n = 12)	Negative PDUS (n = 29)	*P* value for difference between groups
Age, y (mean ± SD)	56.0 ± 7.2	59.2 ± 6.5	54.8 ± 7.2	.08
Female, n (%)	19 (46.3)	6 (50.0)	13 (44.8)	.76
Duration of symptoms, mo (mean ± SD)	5.4 ± 1.8	4.8 ± 1.7	5.7 ± 1.8	.15
Preceding minor trauma, n (%)	14 (34.2)	5 (41.7)	9 (31.0)	.51
Affected shoulder dominant, n (%)	19 (46.3)	4 (33.3)	15 (51.7)	.28
Dupuytren disease, n (%)	7 (17.1)	3 (25.0)	4 (13.8)	.39
Diabetes, n (%)	3 (7.3)	0 (0)	3 (10.3)	N/A
Thyroid disorders, n (%)	3 (7.3)	1 (8.3)	2 (6.9)	.66
SPADI score (mean ± SD)	48.9 ± 18.1	43.3 ± 19.3	51.3 ± 17.3	.11

PDUS, power doppler ultrasound; *SPADI*, shoulder pain and disability index.

Table 2. *Comparison of reported descriptors of pain in the positive PDUS and negative PDUS groups*

Descriptor	Total sample (N = 41)	Positive PDUS (n = 12)	Negative PDUS (n = 29)	*P* value for difference between groups
Current pain, VAS (mean ± SD)	24 ± 26	16 ± 28	27 ± 26	.08
Pain during preceding night, VAS (mean ± SD)	54 ± 24	51 ± 25	55 ± 24	.71
Waking at night >2×, n (%)	32 (78.0)	10 (83.3)	22 (75.9)	.70
Pain aggravated by movement, n (%)	35 (85.4)	10 (83.3)	25 (86.2)	.58
Pain settles quickly after movement, n (%)	32 (78.0)	10 (83.3)	22 (75.9)	.60
Pain with rapid movement, n (%)	37 (90.2)	11 (91.7)	26 (89.7)	.67
Nausea with movement, n (%)	20 (48.8)	3 (25)	17 (58.6)	.05 [a]
Pain worse toward the end of range, n (%)	38 (92.7)	11 (91.7)	27 (93.1)	.66

PDUS, power doppler ultrasound; *VAS*, visual analog scale (0-100 mm).
[a] $P \leq .05$.

reported presence (positive group) or absence (negative group) of increased PDUS signal in the rotator interval area. The differences between group mean values or medians were evaluated with the independent *t* test or Mann-Whitney tests for continuous variables, and χ^2 or Fisher exact tests were used for categorical variables. A difference with a *P* value of less than or equal to .05 was considered statistically significant.

Results

Characteristics of Participants

The demographic and clinical characteristics of the participants are shown in Table 1.

The age of participants in the positive PDUS group was higher than that of participants in the negative PDUS group, although this did not quite achieve statistical significance ($P = .08$). There were a slightly higher proportion of female participants, a shorter mean duration of symptoms, and a slightly higher incidence of Dupuytren disease and thyroid disorders in the participants with a positive scan. There were also a lower SPADI score and complete absence of diabetic participants in the positive PDUS group, as well as a trend for the nondominant shoulder to be more frequently affected. The positive PDUS group also had a greater proportion of participants who reported preceding minor trauma to the affected shoulder. Despite these differences, there was no statistically significant disparity between the groups of participants with a positive PDUS signal and a negative PDUS signal with respect to any of these variables.

Patient-Reported Findings

The comparison of the various pain descriptors in the positive and negative groups is shown in Table 2. Reported descriptors of pain, including severity of night pain and waking due to pain, were not significantly different between the groups of participants with and without a positive PDUS scan. The only exception to this was the descriptor of the feeling of nausea with movement, which was reported less frequently in the positive group ($P = .05$). Levels of pain at rest before the examination (current pain) were less in the positive group, approaching statistical significance ($P = .08$).

Physical Examination Findings

Measurements of passive range of movement and pain at the end of range of passive movement are shown in Table 3. There was an overall tendency to report less pain at the end of range of passive movement in the positive PDUS participants, but this generally failed to reach statistical significance. The exception was pain at the end of glenohumeral joint flexion, which was significantly less in the positive PDUS group ($P = .03$). None of the measured ranges of passive movement showed significant differences

Table 3. *Comparison of passive range of movement (degrees) and pain (VAS) at the end of ranges of passive movement (mean ± SD) in the positive and negative PDUS groups*

	Total sample (N = 41)	Positive PDUS (n = 12)	Negative PDUS (n = 29)	*P* value for difference between groups
Range total shoulder flexion, deg (mean ± SD)	126.4 ± 20.3	124 ± 21.7	131.3 ± 16.1	.33
Pain total shoulder flexion, VAS (mean ± SD)	67 ±23	65 ± 26	67 ± 22	.98
Range glenohumeral joint flexion, deg (mean ± SD)	103.9 ± 18.6	101.2 ± 18.0	110.4 ± 16.8	.15
Pain glenohumeral joint flexion, VAS (mean ± SD)	49 ± 33	33 ± 32	56 ± 27	.03 [a]
Range total shoulder abduction, deg (mean ± SD)	92.1 ± 21.2	88.7 ± 23.9	100.6 ± 8.7	.080
Pain total shoulder abduction, VAS (mean ± SD)	68 ± 27	67 ± 26	68 ± 28	.67
Range glenohumeral joint abduction, deg (mean ± SD)	69.8 ± 18.2	67.4 ± 18.3	75.7 ± 17.1	.187
Pain glenohumeral joint abduction, VAS (mean ± SD)	66 ± 22	64 ± 22	67 ± 20	.69
Range external rotation in adduction, deg (mean ± SD)	43.3 ± 16.4	41.1 ± 16.6	48.6 ± 15.0	.186
External rotation in adduction, VAS (mean ± SD)	67 ± 25	60 ± 32	70 ± 21	.46
Range external rotation in abduction, deg (mean ± SD)	38.5 ± 17.5	36.3 ± 15.0	43.8 ± 22.3	.430
External rotation in 90° abduction, VAS (mean ± SD)	77 ± 18	74 ± 22	70 ± 21	.56
Range internal rotation in abduction, deg (mean ± SD)	53.0 ± 14.1	53.0 ± 14.6	52.8 ± 13.2	.785
Internal rotation in 90° abduction, VAS (mean ± SD)	49 ± 29	49 ± 35	49 ± 27	.93
Range hand behind back, cm (mean ± SD) [b]	43.5 ± 8.3	45.0 ± 9.1	39.9 ± 4.4	.055
Hand behind back, VAS (mean ± SD)	74 ± 22	69 ± 28	76 ± 19	.57

deg, degrees; *PDUS*, power doppler ultrasound; *VAS*, visual analog scale.
[a] $P \leq .05$.
[b] Note that a larger distance indicates a more restricted range.

between the 2 groups of participants, although "hand behind back" demonstrated a strong trend to be less restricted in the positive PDUS group ($P = .055$).

Following review of the recorded images by the radiologists, 12 (29%) of the 41 patients were considered to demonstrate the presence of an increased signal in the rotator interval area, as shown in Figure 3.

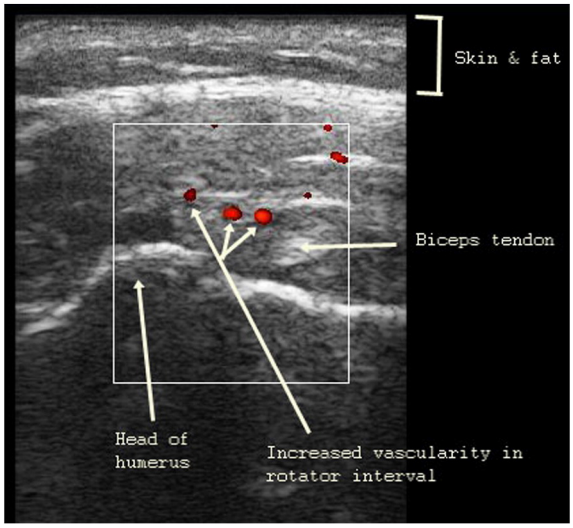

Fig 3. *Power Doppler US image of the right shoulder of a 60-year-old woman demonstrating the presence of increased signal in the rotator interval area.*

Discussion

This is the first study to examine the rotator interval area of the shoulder using PDUS in a group of patients diagnosed clinically with early-stage primary adhesive capsulitis. The findings of this study can be considered hypothesis generating with regard to the potential value of PDUS in demonstrating increased vascularity in the rotator interval area of the shoulder in patients diagnosed with early-stage adhesive capsulitis. An increase in vascularity was demonstrated in 12 (29%) of 41 participants, indicating that it may be clinically possible to visualize an increased signal in the rotator interval area of the shoulder using PDUS examination. However, participants with an increased signal did not demonstrate a characteristic set of identifying features that differentiated them from those with a negative PDUS examination, suggesting that they do not constitute a distinct subgroup in this population.

Most of the reported descriptions of changes seen on US and MRI examination [12-18,20,21,38] have been concerned with the later stages of adhesive capsulitis when clinically recognizable signs and symptoms are quite obvious, essentially rendering medical imaging of little value. Nonetheless, rotator interval imaging abnormalities have been reported to correlate well with surgical and pathological findings. [18] Notably, in the early stage of adhesive capsulitis, hypertrophic vascular synovitis has been identified at arthroscopic examination. [1] It has therefore been suggested that Doppler US has the potential to identify this area of increased vascularity in the rotator interval area of the shoulder in patients with adhesive capsulitis. [12] Lee et al [12] examined participants with adhesive capsulitis with CDUS before arthroscopy who had symptoms for less than 12 months and demonstrated enhanced vascularity and hypoechoic change in the rotator interval that correlated well with the surgical findings. In particular, PDUS enables the

assessment of vascular tissues along with the detection of low-velocity blood flow at the microvascular level[39] and so is well suited to identify the inflammation reported to be present in the early stage of adhesive capsulitis.

The present study was able to demonstrate the presence of increased vascularity with PDUS in 29% of the participants examined, suggesting that this diagnostic imaging tool may be useful in identifying some patients with early-stage adhesive capsulitis. Some of the measured variables in this exploratory study have demonstrated early trends that, in future experimental studies, have the potential to be further investigated using a larger sample and suitable study design. Interestingly, although failing to reach statistical significance, the 12 participants who demonstrated the presence of increased vascularity in the rotator interval area reported a shorter mean duration of symptoms, consistent with observed inflammatory changes in the early stage of the disorder.[1] Adhesive capsulitis has been described in 3 stages, with the early stage lasting up to 9 months.[3] Participants in this study were required to have had symptoms for less than 9 months; however, it may be that this increase in vascularity is more pronounced or more easily observed with PDUS at an earlier stage of the disorder. The mean duration of symptoms for all participants was 5.4 (±1.8) months, which may be beyond the period when changes are most apparent using PDUS. Only 1 patient reported symptoms for less than 3 months when arguably it may be the best time to visualize an increase of vascularity in this area using PDUS because of the inflammatory nature of the disorder at that time.[1] Notably, this participant, with a history of symptoms of 2½ months, had a positive PDUS finding.

It is widely reported that the age at which adhesive capsulitis most frequently occurs is between 40 and 60 years.[2] The age of participants in the current study was consistent with this characteristic, although there was a trend for participants with a positive finding to demonstrate a greater mean age than those with a negative finding. Other findings include a greater percentage of women and a higher incidence of Dupuytren disease and thyroid disorders in the positive PDUS group, which are consistent with the frequently cited characteristics of this disorder.[30,40,41] In contrast, the lack of diabetic participants in the positive PDUS group is an unexpected finding considering the strong association that this disease has with adhesive capsulitis[42]; however, the group size was relatively modest. Although the clinic manages patients from a variety of demographic groups and socioeconomic backgrounds within its geographic region, it is possible that other populations may display different characteristics, such as a higher prevalence of diabetes. It has recently been argued that adhesive capsulitis may be clinically overdiagnosed,[31] which raises the possibility that some of the participants in this study may have had disorders other than adhesive capsulitis, potentially explaining some of the negative PDUS findings. Bunker[31] has also challenged several traditional associations including with female sex and thyroid disorders, while noting that associations with diabetes and Dupuytren disease have a more robust scientific basis.

It is now considered that capsular inflammation is a predominant pathological feature of the early stage of adhesive capsulitis[8] and therefore arguably may be considered responsible for the pain behavior seen at this stage. It was therefore surprising that analysis of various pain descriptors revealed lower scores in the positive PDUS group, although not statistically significant. Similarly, the severity of pain at the end of passive range of movement was less in the positive PDUS group, significantly so with glenohumeral shoulder flexion, which is somewhat difficult to explain.

Musculoskeletal medicine uses a combination of assessment tools, including patient-reported symptoms and physical examination findings, together with results of various diagnostic imaging and pathological investigations to achieve a diagnosis. It has been suggested that the diagnosis of adhesive capsulitis is essentially clinical[38]; however, the addition of a pathognomic diagnostic imaging finding may provide valuable information to support a diagnosis in some cases. The main finding of the current study is that we have confirmed that it may be possible to visualize the presence of vascularity using PDUS in the rotator interval area of the glenohumeral joint capsule in some patients diagnosed with early-stage adhesive capsulitis in the clinical setting. Ultrasonographic examination in the clinical setting is becoming increasingly more common, and the findings from this study provide preliminary evidence to suggest that it may be useful in cases of suspected early-stage adhesive capsulitis.

Limitations

Firstly, because of the requirement that patients have symptoms for less than 9 months, a comparison against a criterion standard was not possible. As acknowledged in other studies,[38] the lack of a criterion standard, such as surgical findings with which to make comparison, may limit the conclusions that can be drawn. The diagnosis of adhesive capsulitis was based on patient history and physical examination findings together with diagnostic imaging to exclude other pathologies. Thus, it is possible that some of the patients in this study did not have early-stage adhesive capsulitis. Secondly, the sample size was modest, as appropriate for an exploratory case series. A larger sample may have increased the overall power of the study to find statistically significant differences between patients with a positive PDUS finding and a negative PDUS finding with some of the variables measured. This may have helped identify the characteristics of a subgroup of patients for which this tool is able to assist the diagnosis of early-stage adhesive capsulitis. Slow recruitment of participants with adhesive capsulitis has been previously reported[43]; however, the strict but necessary criteria that were set for inclusion were required to ensure an appropriate sample. As this was an exploratory study, a control group was not included. An

experimental study with matched control participants would be required to confirm the results of this preliminary study. It would also be useful in future studies to compare these findings in patients with clinical signs of other pathologies.

Finally, there are potential technical limitations. Ultrasonography is known to be operator dependent,[44,45]; however, specific, individualized training was given to the researcher who performed the scans in examining the rotator interval area. Nonetheless, if this tool continues to be increasingly used in the primary care clinical setting, many clinicians will likely receive similar training to that of the researcher who performed the US examinations in the present study. Although this study has demonstrated the presence of an increased PDUS signal in 29% of patients with the clinical diagnosis of early-stage adhesive capsulitis, the lack of a signal in the others may be due to the blood flow in the synovium being under the detection threshold of the machine that was used.[46] With rapid advances in technology, however, this may not remain an ongoing issue. Although limiting the external generalizability of PDUS in the primary care clinical setting, further studies in a specialized diagnostic imaging clinic using machines with greater sensitivity and more experienced operators may provide different findings.

Conclusion

The findings of this exploratory study suggest that PDUS may have the potential to assist in identification of increased vascularization in early stages of adhesive capsulitis. Further research in the use of PDUS in diagnosing early-stage adhesive capsulitis using a study design involving a control group and larger patient numbers and including various other shoulders disorders is warranted.

Practical Application

- Examination of the rotator interval area of the shoulder with PDUS may be able identify increased vascularity consistent with the pathology of adhesive capsulitis in its early stage.

Funding Sources and Potential Conflicts of Interest

No funding sources or conflicts of interest were reported for this study.

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Movement and pain patterns in early stage primary/idiopathic adhesive capsulitis: a factor analysis

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Abstract

Objectives To evaluate patients clinically diagnosed with early stage primary/idiopathic adhesive capsulitis to determine the existence of any pattern of movement loss and associated pain that may facilitate early recognition.
Design Cross-sectional study.
Setting Private upper limb specialty clinic, Newcastle, Australia.
Participants Fifty-two patients clinically diagnosed with early stage adhesive capsulitis by a medical practitioner or physiotherapist.
Main outcome measures Percentage loss of active and passive ranges of eight shoulder movements and the pain level at the end of each movement. The reason for limitation of movement was also recorded.
Results Factor analysis clearly identified two groups for percentage loss of active range of movement. Notably external rotation movements grouped separately from other movements. A single group emerged for percentage loss of passive range of movement suggesting a non-specific global loss. For both pain at the end of active range of movement and passive range of movement two groups emerged, however the delineation between the groups was less clear than for percentage loss of active range of movement suggesting a pattern of end range pain may be less useful in identifying patients in this stage.
Conclusions External rotation movements in neutral and abduction generally group together and behave differently to other shoulder movements in patients clinically diagnosed with early stage primary/idiopathic adhesive capsulitis. In particular external rotation in abduction has emerged as the most painfully limited movement in this sample. This study provides preliminary evidence of patterns of range of movement and end range pain that require testing in a population of mixed shoulder diagnoses to determine their diagnostic utility for early stage adhesive capsulitis.
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Keywords: Shoulder patterns; Shoulder pain; Adhesive capsulitis; Range of motion; Factor analysis

Introduction

Adhesive capsulitis is a shoulder disorder that is recognised as consisting of three stages and reported to last from one to three years [1]. The disorder is described as either primary or idiopathic when the onset is insidious, and secondary when a known event precedes the onset [2]. Adhesive capsulitis has a number of reported associations that include, but are not limited to, diabetes [3], Dupytren's disease [4] and thyroid dysfunction [5], as well as a reported higher incidence in females [6]. The first or early stage is generally agreed to last up to nine months [7] and is typically characterised by pain rather than marked loss of movement [2]. Whilst adhesive capsulitis is usually recognisable in the later stages due to distinct restriction of both active and passive ranges of movement [8], it is considered difficult to identify and differentiate from other shoulder disorders in its early stage [9].

Routine assessment of patients with musculoskeletal disorders generally includes measurement of both active and

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passive ranges of movement, as well as any pain associated with each movement. Patterns of movement deficit and the behaviour of pain often assist in diagnosis [10]. As a means of differentiating joint capsular pathology from other causes of symptoms, James Cyriax described what is called the 'capsular pattern' [11]. This capsular pattern suggests a fixed proportion of movement loss is present and that each joint has a characteristic pattern [11]. The pattern for the glenohumeral joint proposed by Cyriax is that the proportional passive loss of external rotation will be greater than the proportional loss of abduction, which will be greater than the proportional loss of internal rotation. Although the literature on adhesive capsulitis frequently acknowledges this 'capsular pattern' [1,12], recent studies have demonstrated that it may not be consistently present [13–15]. Notably, however, these studies have involved populations in the latter stages of the disorder. No studies have examined the presence of the 'capsular pattern', nor any other recognisable pattern of movement loss in the early stage of adhesive capsulitis.

Recent research into the pathology of adhesive capsulitis has identified that initial inflammation of the glenohumeral joint capsule is followed by fibrosis and contracture [16]. This understanding of the pathology provides an explanation for the temporal behaviour of the symptoms, which are reported to initially manifest with pain followed by subsequent progressive movement restriction [17]. Surgical and radiological investigations have identified that anterior structures of the glenohumeral joint are predominantly affected [18,19], which may help explain the observed pattern of movement loss or pain reported in adhesive capsulitis, notably in external rotation [20]. However, the contribution of other active and passive shoulder movements to diagnosis have not been similarly considered.

As well as the lack of investigation of any pattern of either active or passive movement loss in early stage adhesive capsulitis, any associated pain pattern has also not been described to date. As pain is reported to be a key component of the early stage, it would therefore be potentially valuable to evaluate any contribution it may make to the clinical presentation of this disorder.

It has been suggested that treatment in the early stage of adhesive capsulitis may reduce the overall morbidity of the disorder [17]. The mixed results of treatment reported however, have been suggested to be at least partially as a result of the inability to define or classify sub-groups of patients likely to respond to physiotherapy and other interventions [21]. Although a set of clinical identifiers that may assist diagnosis in the early stage have been proposed, including global loss of active and passive ranges of movement and pain at the end-range in all directions, they have yet to be validated [22]. The recognition of any pattern of movement restriction or pain that may assist early diagnosis or identify sub-groups of patients would therefore be valuable. The overall aim of this study was to evaluate patients with a clinical diagnosis of early stage adhesive capsulitis to determine if it was possible to identify a pattern of movement loss and/or associated end range pain that may facilitate recognition of this diagnostically challenging stage of the disorder. The findings of this preliminary study will enable future studies of mixed diagnosis populations to determine whether any patterns that may emerge are unique to the early stage of primary/idiopathic adhesive capsulitis.

Materials and methods

Participants

Fifty-two participants attending an upper limb specialty clinic diagnosed with early stage adhesive capsulitis on the basis of clinical presentation by various health care practitioners, including orthopaedic surgeons, a shoulder physician, general practitioners and physiotherapists were included in the study. In the absence of any validated criteria for the diagnosis of early stage primary/idiopathic adhesive capsulitis the clinical decision of the referring practitioner was considered pragmatically appropriate. Participants were required to have had symptoms for less than nine months, consistent with the reported duration of the early stage of the disorder [7]. As primary/idiopathic adhesive capsulitis was being investigated, patients with a history of major trauma or surgery of the shoulder were excluded. Potential participants were also required to have had recent shoulder X-rays and ultrasound examinations which did not demonstrate potential alternate diagnoses. Further exclusion criteria included a diagnosis of any systemic inflammatory joint disease, as well as neurological or current cervical spine disorders. Glenohumeral joint injection in the preceding six weeks was also an exclusion criterion.

Procedure

Each participant underwent routine clinical examination including measurement of active and passive shoulder ranges of movement. These included total shoulder flexion (TSF) and abduction (TSA), glenohumeral joint flexion (GHF) and abduction (GHA), and external rotation in neutral (ERN), together with external and internal rotation in 90° abduction (ERA and IRA respectively). Hand behind back (HBB) range was also measured. Measurement was performed by one of the researchers, an experienced musculoskeletal physiotherapist, using a Baseline digital inclinometer (Fabrication Enterprises Incorporated, Irvington, NY, USA) for all movements with the exception of HBB which was measured with a tape measure. Digital inclinometry has been demonstrated to have a measurement error of ±1° [23]. The range of movement was recorded in degrees for all movements other than HBB which was recorded in millimetres.

Measurement of shoulder ranges of movement was based on the method described by Green *et al.* [24]. The following movements were performed in sitting: TSF, GHF, TSA, and GHA. The starting position for these movements was with

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the palm of the hand facing medially. The inclinometer was held on the mid shaft of the humerus by the researcher and the participant maintained an extended elbow [24]. In order to stabilise the scapula and isolate the glenohumeral joint for GHF and GHA, a device was developed that provided an arm that rested on the acromion, preventing upward rotation of the scapula (Supplementary Fig. 1).

The following movements were performed in the supine lying position:

- ERN: The shaft of the humerus was placed beside the participant's trunk in 0° of abduction and rotation. A towel was placed under the humerus to ensure it rested parallel to the plinth. The elbow was flexed to 90° and the forearm was in neutral rotation. The inclinometer was placed on the dorsal surface of the participant's forearm.
- ERA: The arm was abducted to 90° where possible, or if not possible due to either movement restriction or pain, abduction was taken to the limit of movement. The position of the humerus and placement of the inclinometer was the same as measurement of ERN.
- IRA: The arm was placed as described for ERA and internally rotated until either the posterolateral acromion was visualised to rise off the plinth [25], or the movement was limited by pain.

HBB was measured in standing as the distance between the spinous process of T1 and the radial styloid process. This has been demonstrated to have excellent intrarater reliability [26].

In order not to aggravate the participant's pain, each movement was performed only once. All active movements were performed prior to passive movements and in the same sequence for each participant. The order of measurement was: TSF, GHF, TSA, GHA, ERN, ERA, IRA, HBB. Active range of movement was performed by asking the participant to move their arm in the required direction until it was not possible to move any further or the pain became intolerable. Similarly, passive range of movement was performed by the researcher to the point of resistance limitation or when the participant reported the pain was intolerable. The limiting factor to movement was recorded simply as pain or inability to move for active movements and resistance or pain for passive movements. Regardless of the cause of limitation, each participant scored their level of pain at the end of each movement on a 100 mm visual analogue scale.

Statistical analysis

The data were analysed initially using descriptive statistics. The affected shoulder's percentage of movement of the unaffected shoulder was calculated for each of the eight active and eight passive movements.

For all movements with the exception of HBB:

$$\frac{\text{unaffected shoulder range of movement} - \text{affected shoulder range of movement}}{\text{unaffected shoulder range of movement}}$$

Table 1
Demographic characteristics of the participants ($n = 52$).

Characteristic	
Age (yrs), mean (SD)	55.2 (6.9)
Duration of symptoms (months), mean (SD)	5.5 (1.9)
Gender (% female)	51.9
Dominance (% right)	84.6
History of diabetes (%)	9.6
History of Dupytren's disease (%)	13.5

For HBB:

$$\frac{d1 \text{ affected shoulder} - d1 \text{ unaffected shoulder}}{d1 \text{ unaffected shoulder}}$$

($d1$ = distance between T1 spinous process and radial styloid process).

Factor analysis was then used to determine if it was possible to identify any relationships between the ranges of movement loss and similarly the pain behaviour at the end of each of the ranges of movement. Any such relationships, or movements grouping together, may denote the formation of patterns. Exploratory factor analysis was performed using the principal components method for extraction of factors followed by Varimax rotation. A combination of an eigenvalue of >1.00 and inspection of the scree plot was used to determine the optimum number of factors within each range of movement or pain score. Item loadings of ≥0.60 were considered to contribute strongly to that factor. Factors with four or more variables ≥0.60 were considered strong factors. All statistical analyses were performed using JMP 9.0 (SAS Institute Inc., Cary, NC, USA).

Results

Demographic characteristics of the participants are presented in Table 1. The mean (SD) shoulder ranges of active and passive movement (affected and unaffected), percentage loss of range of movement and pain scores at the end of range of movement are reported in Tables 2A and 2B.

Percentage loss of movement

Active range of movement

The mean percentage loss of active range of movement ranged between 68% (HBB) and 26% (GHF).

Two factors were extracted which accounted for 68% of the variance of the eight measured ranges of active movement (Table 3). These two factors represented a pattern comprising two groups of movements. The first group of movements (movement group 1), accounting for 52% of the variance

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Table 2A
Mean (SD) shoulder ranges of active movement (unaffected and affected), percentage loss of active ranges of movement and pain scores at the end of range of each movement.

Movement	Unaffected shoulder ROM (°), Mean (SD)	Affected shoulder ROM (°), Mean (SD)	% loss ROM, Mean (SD)	Pain score end of range (mm), Mean (SD)
Total shoulder flexion	161.9 (12.8)	116.4 (22.8)	28 (13)	62 (25)
Glenohumeral joint flexion	126.8 (12.8)	93.6 (18.2)	26 (14)	50 (28)
Total shoulder abduction	146.0 (16.4)	81.4 (28.3)	46 (18)	69 (25)
Glenohumeral joint abduction	114.9 (21.0)	55.6 (23.2)	52 (18)	59 (28)
External rotation in neutral	67.3 (9.9)	38.5 (14.6)	42 (21)	57 (30)
External rotation in abduction	83.2 (12.9)	36.0 (17.6)	57 (20)	71 (22)
Internal rotation in abduction	77.1 (9.1)	51.7 (14.6)	33 (19)	45 (29)
Hand behind back (mm)	28.3 (5.3)	46.4 (9.4)	68 (43)	6 (28)

Table 2B
Mean (SD) shoulder ranges of passive movement (unaffected and affected), percentage loss of passive ranges of movement and pain scores at the end of range of each movement.

Movement	Unaffected shoulder ROM (°), Mean (SD)	Affected shoulder ROM (°), Mean (SD)	% loss ROM, Mean (SD)	Pain score end of range (mm), Mean (SD)
Total shoulder flexion	170.4 (9.4)	129.7 (21.1)	24 (11)	63 (25)
Glenohumeral joint flexion	132.3 (11.1)	105.7 (18.4)	20 (12)	48 (31)
Total shoulder abduction	153.9 (14.4)	97.0 (25.0)	37 (16)	63 (29)
Glenohumeral joint abduction	118.8 (14.0)	72.8 (19.8)	39 (16)	64 (23)
External rotation in neutral	73.2 (9.6)	42.3 (16.8)	42 (21)	68 (24)
External rotation in abduction	92.4 (12.8)	38.9 (16.0)	58(17)	77 (18)
Internal rotation in abduction	84.1 (8.8)	55.8 (15.7)	34 (18)	45 (29)
Hand behind back (mm)	24.7 (4.3)	42.2 (9.0)	72 (36)	71 (22)

ROM, range of movement.

Table 3
Factor loadings for the factor models for the percentage loss of active and passive ranges of movement.

Movement	Active		Passive
	Factor 1: movement group 1 (eigenvalue = 4.13)	Factor 2: movement group 2 (eigenvalue = 1.31)	Factor 1: global loss of movement (eigenvalue = 4.76)
Total shoulder flexion	0.90[a]	0.08	0.85[a]
Glenohumeral joint flexion	0.83[a]	0.15	0.83[a]
Total shoulder abduction	0.73[a]	0.17	0.87[a]
Glenohumeral joint abduction	0.75[a]	0.35	0.84[a]
External rotation in neutral	0.15	0.66[a]	0.51
External rotation in abduction	0.25	0.97[a]	0.58
Internal rotation in abduction	0.48	0.18	0.62[a]
Hand behind back	0.55	0.22	0.68[a]

[a] Loadings ≥ 0.60.

included TSF, GHF, TSA and GHA. The second group of movements (movement group 2), accounting for 16% of the variance included ERN and ERA. The loadings of the eight movements on the two factors are shown in Table 3.

Passive range of movement

The mean percentage loss of passive range of movement ranged between 72% (HBB) and 20% (GHF).

A single factor with an eigenvalue of 4.76 was extracted for the measured ranges of passive movement which accounted for 60% of the variance suggesting a global loss of passive range of movement rather than an identifiable pattern. Six of the eight loadings (TSF, GHF, TSA, GHA, IRA, HBB) were >0.6 (range 0.62 to 0.87). The loadings of the eight movements are shown in Table 3.

Pain at the end of range of movement

Active range of movement

The active range of movement scoring the highest mean (SD) pain score for all participants was ERA (71 mm (22)).

A two factor structure accounted for 66% of the variance of the pain scores at the end of active range of movement. These two factors represented a pattern of two groups of movements. The relative weights of the eight movements are shown in Table 4, which provides factor loadings for each of the ranges of active movement in the two-factor solution. The first group of movements (movement group 1), accounting for 53% of the variance included TSF, TSA and GHA. The second group of movements (movement group 2), accounting for 13% of the variance included ERA and IRA.

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Table 4
Factor loadings for two factor models for pain at the end of active and passive ranges of movement.

Movement	Active		Passive	
	Factor 1: movement group 1 (eigenvalue = 4.20)	Factor 2: movement group 2 (eigenvalue = 1.06)	Factor 1: movement group 1 (eigenvalue = 4.60)	Factor 2: movement group 2 (eigenvalue = 1.01)
Total shoulder flexion	0.71[a]	0.23	0.76[a]	0.21
Glenohumeral joint flexion	0.50	0.33	0.51	0.24
Total shoulder abduction	0.86[a]	0.22	0.78[a]	0.26
Glenohumeral joint abduction	0.70[a]	0.39	0.72[a]	0.46
External rotation in neutral	0.47	0.54	0.22	0.98[a]
External rotation in abduction	0.22	0.73[a]	0.41	0.72[a]
Internal rotation in abduction	0.21	0.67[a]	0.32	0.53
Hand behind back	0.36	0.58	0.60[a]	0.44

[a] Loadings ≥ 0.60.

Table 5
Reason for limitation of movement.

Movement	Active		Passive	
	Pain limited, *N* (mean % loss ROM)	Movement limited, *N* (mean % loss ROM)	Pain limited, *N* (mean % loss ROM)	Resistance limited, *N* (mean % loss ROM)
Total shoulder flexion	26 (28)	26 (28)	45 (23)	7 (28)
Glenohumeral joint flexion	18 (25)	34 (26)	29 (22)	23 (18)
Total shoulder abduction	30 (49)	22 (38)	37 (40)	15 (29)
Glenohumeral joint abduction	26 (55)	26 (48)	42 (39)	10 (37)
External rotation in neutral	30 (42)	22 (42)	44 (45)	8 (30)
External rotation in abduction	37 (55)	15 (62)	49 (58)	3 (50)
Internal rotation in abduction	19 (33)	33 (32)	24 (31)	28 (36)
Hand behind back	34 (60)	18 (84)	48 (74)	4 (53)

Passive range of movement

The passive range of movement scoring the highest mean (SD) pain score for all participants was ERA (77 mm (18)).

A two factor structure accounted for 70% of the variance for pain scores at the end of passive range of movement. These two factors suggested a pattern of two groups of movements. The relative weights of the eight movements are shown in Table 4, which provides factor loadings for each of the ranges of passive movement in the two-factor solution. The first group of movements (movement group 1), accounting for 58% of the variance included TSF, TSA, GHA and HBB. The second group of movements (movement group 2), accounting for 13% of the variance included ERN and ERA.

The factor loading plots for percentage loss of active range of movement, and for the pain level scores at the end of each of the active and passive ranges of movement are presented in Supplementary Fig. 2. These plots demonstrate that only percentage loss of active movement resulted in a clear separation of the two groups of movements (ERN and ERA with the other group of movements comprising TSF, GHF, TSA and GHA) (Supplementary Fig. 2A). Similar separation is not observed for pain at the end of both active and passive movements (Supplementary Fig. 2B and C) suggesting a recognisable pattern for pain at the end of range did not emerge.

Limitation to movement

Descriptive statistics describing the reason for limitation to movement are presented in Table 5. The movement most frequently limited by pain, rather than an active inability to move or passive resistance was ERA for both active (71%) and passive (94%) ranges of shoulder movement. The movement least frequently limited by pain was GHF (35%) for active movement and IRA (46%) for passive movements.

Discussion

This is the first study to investigate the presence of any recognisable pattern of movement loss that may exist in a group of participants clinically diagnosed with early stage primary/idiopathic adhesive capsulitis. Unlike earlier studies, this study has utilised factor analysis to determine relationships or patterns that may exist within the percentage loss of both active and passive ranges of movement and pain experienced at the end of each range of movement. It is also unique as it has considered the reason for limitation to movement in a larger sample than previously reported. The results of this study have demonstrated that in this group of patients diagnosed clinically with early stage primary/idiopathic adhesive capsulitis, the percentage loss of both active and passive ranges of movement does not fit the 'capsular pattern' previously reported by Cyriax to be characteristic of this disorder [1,12]. The selection of factor analysis has enabled the detection of groups, rather than isolated shoulder movements that may involve common anatomical,

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pathological or biomechanical characteristics. In this study the movements that have grouped together as a result of the factor analysis may be reflecting the underlying pathological process in the glenohumeral joint capsule. In particular, the grouping together of the two external rotation movements may indicate an area of capsular involvement leading to restriction or pain different from the other measured shoulder movements.

The clearest pattern to emerge from this study was from the analysis of the percentage loss of active range of movement which identified a pattern with two distinct groups (Table 3 and Supplementary Fig. 2A). One group included the shoulder movements TSF, GHF, TSA and GHA, whilst the other comprised the two measured external rotation movements (ERN and ERA). The two groups of movements show a degree of correlation with each other and this is demonstrated by the acute angle between each of the groups of variables in Supplementary Fig. 2A. The two external rotation movements are not completely independent from the other group of movements suggesting there is a small amount of similarity between the two. Although perhaps not surprising, external rotation in both neutral and in abduction appeared to behave differently from the other measured shoulder movements. However the classic 'capsular pattern' of proportional loss of external rotation being greater than the proportional loss of abduction, which in turn is greater than the proportional loss of internal rotation, did not emerge. Although not entirely consistent with 'the capsular' pattern previously described for loss of passive range of movement [11], this is in accordance with the reported pathological involvement of the anterior glenohumeral structures in adhesive capsulitis and the previously recognised involvement of external rotation [27].

Percentage loss of passive range of movement grouped differently to active movement and demonstrated only one pattern of approximately equivalent loss across all movements (Table 3). Again the 'capsular pattern' did not emerge and in contrast to active movement, this would suggest a non-specific global loss of passive shoulder movement. Whilst not clearly emerging as a second group, ERN appeared least related to the other movements. Similarly an earlier study of passive range of movement loss in adhesive capsulitis, reported loss in all measured ranges, with no 'capsular pattern' evident in their sample of 30 participants [15]. That study measured abduction as well as internal and external rotation in 45° of abduction. They demonstrated that external rotation was significantly limited in comparison to abduction and internal rotation, with the latter two movements not differing from each other. Whilst direct comparison with the current study is problematic due to methodological differences the trend for global passive movement loss appears to be consistent with a greater loss in external rotation.

The early stage of adhesive capsulitis has been reported to be characterised by pain rather than movement restriction [2], and to our knowledge there are no other reported studies that have quantified and analysed pain at the end of range of movement in this stage of the disorder. Pain at the end of active movement suggested two groups of movements (Table 4 and Supplementary Fig. 2B). The first group contained only three movements with loadings $\geq$0.60, suggesting only a weak association. This group comprised the movements of TSF, TSA and GHA, while the second suggested a relationship between two of the rotational movements (ERA and IRA). Consideration of the descriptive data would suggest that when ERA recorded a high level of pain at the end of range, IRA conversely recorded a low level of pain. Interestingly, of the two groups that emerged in analysing pain at the end of passive range of movement (Table 4 and Supplementary Fig. 2C), the first contained HBB as well as TSF, TSA and GHA. While active HBB has been used clinically to assess shoulder internal rotation, it has been reported that it is not solely related to internal rotation at the glenohumeral joint [28]. This might help explain HBB grouping with the other movements. Notably the second factor again consisted of the two external rotation movements (ERN and ERA). Despite the presence of this grouping, inspection of the factor loading plots (Supplementary Fig. 2B and C) would suggest that a clear pattern did not emerge. This indicates that whilst pain reportedly is a feature of early adhesive capsulitis, the absence of a pattern may make this symptom less useful than percentage loss of active range of movement in identifying patients at this stage.

It would be reasonable to expect that the limitation to movement in early stage adhesive capsulitis may be more likely due to pain rather than resistance or weakness. Interestingly, for both active and passive movements, ERA and HBB were those movements most frequently limited by pain. ERA is reportedly limited by anterior capsular structures [29], which suggests those structures may be responsible for pain experienced with that movement. As pain not only from the capsule, but also from muscle spasm has been previously suggested as a reason for limitation of movement [14], it could potentially be that spasm from the scapulothoracic musculature is responsible for at least some of the pain limiting the HBB movement in these participants.

There are some limitations to this study. The sample size was modest although it compares favourably with earlier studies [13–15]. Interpretation of factor analysis with this sample has suggested findings that require confirmation with a larger sample. The participants in this sample were recruited from a limited number of practice environments and it is possible this may have led to biased estimates due to participants not being representative of other patient sources. The absence of a gold standard for diagnosis of adhesive capsulitis in its early stage remains a limitation in all related research. Heterogeneity of participants has previously been reported as a limitation of similar studies [14], however strict inclusion and exclusion criteria were applied in the current study to minimise participants with potentially alternate diagnoses. Although based on previously reported reliable measurement

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methods, intrarater reliability was not specifically determined in this study due to the clinical nature of the research and the ethical requirement to minimise any worsening of each participant's pain. The order of testing was not randomised which may have resulted in greater pain scores for the later measured movements due to aggravation by earlier movements.

Conclusion

This study has specifically investigated patients clinically diagnosed with early stage primary/idiopathic adhesive capsulitis to determine whether any recognisable movement patterns may be present which could assist diagnosis. The main finding of the study was that active external rotation movements in both neutral and in abduction grouped together and behaved differently to the other measured active shoulder movements. Percentage loss of passive ranges of movement identified a non-specific global loss. Unlike the percentage loss of active range of movement, a clear pattern for pain at the end of range of movement did not emerge. Interestingly, ERA has emerged as both the most painful active and passive movement and the movement most frequently limited by pain, rather than weakness or resistance. Clinically this indicates the involvement of this movement in the early stage as has been previously recognised in the later stages, and suggests that careful assessment of movement range and pain at the end of range of external rotation in both neutral and 90° abduction should be undertaken in patients with suspected early stage adhesive capsulitis. Whilst percentage loss of active and passive ranges of movement, pain at the end of range of movement and limitation to movement have highlighted the involvement of external rotation, further studies are required to investigate the inter-relationships among these parameters. The findings of this preliminary study therefore, will direct future studies of mixed populations comprising patients with varying shoulder diagnoses, to test the patterns that have emerged, and determine if they are unique to the early stage of adhesive capsulitis.

Ethical approval: The Human Research Ethics Committee of The University of Newcastle (No. H-2009-0234).

Conflict of interest: None declared.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.physio.2014.02.001.

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Research Report

Clinical Identifiers for Early-Stage Primary/Idiopathic Adhesive Capsulitis: Are We Seeing the Real Picture?

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Background. Adhesive capsulitis is often difficult to diagnose in its early stage and to differentiate from other common shoulder disorders.

Objective. The aim of this study was to validate any or all of the 8 clinical identifiers of early-stage primary/idiopathic adhesive capsulitis established in an earlier Delphi study.

Design. This was a cross-sectional study.

Methods. Sixty-four patients diagnosed with early-stage adhesive capsulitis by a physical therapist or medical practitioner were included in the study. Eight active and 8 passive shoulder movements and visual analog scale pain scores for each movement were recorded prior to and immediately following an intra-articular injection of corticosteroid and local anesthetic. Using the local anesthetic as the reference standard, pain relief of ≥70% for passive external rotation was deemed a positive anesthetic response (PAR).

Results. Sixteen participants (25%) demonstrated a PAR. Univariate logistic regression identified that of the proposed identifiers, global loss of passive range of movement (odds ratio [OR]=0.26, P=.03), pain at the end of range of all measured active movements (OR=0.06, P=.02), and global loss of passive glenohumeral movements (OR=0.23, P=.02) were associated with a PAR. Following stepwise removal of the variables, pain at the end of range of all measured active movements remained the only identifier but was associated with reduced odds of a PAR.

Limitations. The lack of a recognized reference standard for diagnosing early-stage adhesive capsulitis remains problematic in all related research.

Conclusions. None of the clinical identifiers for early-stage adhesive capsulitis previously proposed by expert consensus have been validated in this study. Clinicians should be aware that commonly used clinical identifiers may not be applicable to this stage.

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There is a strong component of night pain
There is a marked increase in pain with rapid or unguarded movements
It is uncomfortable to lie on the affected shoulder
The patient reports the pain is easily aggravated by movement
The onset generally occurs in people older than 35 years of age
On examination, there is pain at the end of range in all directions
On examination, there is global loss of active and passive range of movement
There is global loss of passive glenohumeral joint movement

Figure 1.
Clinical identifiers achieving consensus.

Adhesive capsulitis is a diagnostic label attributed to a disorder of the glenohumeral joint capsule that has been reported to affect up to 5% of the population.[1,2] Primary adhesive capsulitis is due to an unknown cause, as opposed to secondary adhesive capsulitis, which results from a known cause or extrinsic event.[3] The condition is generally described as consisting of 3 stages.[3] These have been identified as the painful stage (first), the adhesive stage (second), and the resolution stage (third).[4] The first (or painful) stage, which was considered in this study, is generally considered to last 3 to 9 months.[4] Although the later stages are easily recognized, often due to marked restriction of movement, the early stage of this disorder is commonly difficult to identify and correctly diagnose.[5] It has been proposed, however, that treatment in the early stage of adhesive capsulitis may decrease the overall morbidity,[1] arguably suggesting that early recognition of this disorder is desirable.

Musculoskeletal health care frequently relies on recognition of patient-reported and physical examination findings, together with special tests and medical imaging, to inform diagnosis and direct management. Determining the clinical features considered necessary to establish a diagnosis frequently is achieved through research using various types of consensus methods.[6–8] Several studies using this approach have attempted to identify clinical characteristics of adhesive capsulitis in general,[9,10] as well as clinical characteristics specific to the early stage[5]; however, validation of these characteristics is lacking. As well as routine clinical assessment, musculoskeletal assessment often relies on a gold standard that may include a particular diagnostic test, imaging procedure, or even surgical findings with which to determine a diagnosis. Because surgery is not indicated and imaging procedures in the early stage of adhesive capsulitis have yet to be systematically explored,[11] a gold standard for diagnosis remains problematic in this population. Clinical tests have recently been described that may assist the diagnosis of adhesive capsulitis[12,13]; however, the duration of symptoms of participants in these studies was not reported, resulting in difficulty determining the stage of the disorder and whether the findings are valid for patients in the early stage.

A set of clinical identifiers considered necessary and sufficient by a group of experts to diagnose early-stage adhesive capsulitis[5] (Fig. 1) has been proposed as a framework with which to begin the process of addressing this diagnostic dilemma. The identifiers established in that study by our research group included both patient-reported and physical examination findings and, interestingly, clustered into 2 discrete dimensions of pain and movement. As pain is reportedly a significant feature of the early stage,[1] it was not surprising that several dimensions in pain were reported to achieve consensus. Night pain, a marked increase of pain with rapid or unguarded movements, discomfort lying on the affected shoulder, and pain easily aggravated by movement were all identified as required to achieve diagnosis. These descriptors were suggested to reflect the inflammatory nature of the disorder in the early stage.[14]

Although often unquantified, recognition of the later stages of adhesive capsulitis through marked movement restriction, in particular external rotation, has been reported.[15] Conversely, there is a lack of description of movement dysfunction in the early stage of the disorder. Physical examination findings achieving consensus in our Delphi study[5] similarly lacked quantification, but it was suggested global loss of both active and passive ranges of movement and pain at the end of range in all directions were necessary characteristics. Although the clinical identifiers proposed for early-stage adhesive capsulitis by expert consensus[5] were suggested as a starting point for future validation studies, it was recognized that they could not at this time be regarded as a gold standard or provide a certain differential diagnosis, but potentially could be used to assist in clinical decision making.

The aim of this study, therefore, was to validate any or all of the 8 clinical identifiers previously proposed for the early stage of adhesive capsulitis.[5]

Materials and Method

Participants

Participants were recruited from a private upper limb physical therapy clinic in Newcastle, Australia, over a 3-year period between May 2010 and April 2013. Patients clinically diagnosed with adhesive capsulitis by various health care practitioners, including orthopedic surgeons,

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shoulder physicians, general practitioners, and physical therapists, were invited to participate in the study.

To be considered for inclusion, potential participants were required to have been referred for an intra-articular glenohumeral joint corticosteroid and local anesthetic injection using radiological guidance to confirm correct placement of the needle as part of routine clinical care. Consistent with the reported duration of the early stage of adhesive capsulitis,[4,16] potential participants were excluded from the study if they had a symptom duration of greater than 9 months. As primary/idiopathic adhesive capsulitis was being investigated, individuals with a history of previous major trauma or surgery on the affected shoulder also were excluded. Reported minor trauma was not an exclusion criterion. Potential participants were required to have had a recent unremarkable radiographic examination to eliminate glenohumeral osteoarthritis, calcific deposits, or other potentially confounding diagnoses. They also were required to have had a recent ultrasound examination that excluded a full-thickness rotator cuff tear. Potential participants who had undergone an intra-articular corticosteroid injection into the glenohumeral joint in the preceding 6 weeks or had a history of inflammatory arthropathies or of cervical spine pathology that may refer into the shoulder joint also were excluded from the study. Because the contralateral shoulder was being used to determine percentage loss of range of movement, the presence of pain or restriction of movement in that shoulder was a further exclusion criterion. All participants signed an informed consent form prior to entering the study.

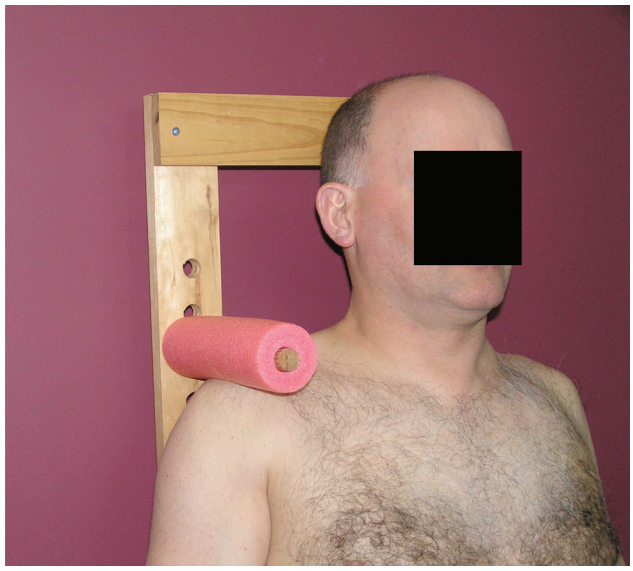

Figure 2.
Device to stabilize the scapula for measurement of glenohumeral joint movement.

Procedure

Immediately prior to the injection, each participant attended the clinic to complete routine assessment, including measurement of active and passive ranges of movement and pain at the end of ranges of movement. Additional questions were asked to determine the presence of the 8 clinical identifiers being validated. To provide baseline measurements of shoulder pain and disability, the Shoulder Pain and Disability Index (SPADI)[17,18] was administered. This instrument is a validated questionnaire measuring shoulder pain and impairment and has a high level of internal consistency and good test-retest reliability.[19] General health status was measured using the 36-Item Short-Form Health Survey (SF-36).[20] This instrument is easy to administer, has been demonstrated to be reliable and valid,[20] and has been used previously to describe study samples with adhesive capsulitis.[21,22] Upon completion of the assessment, participants attended a radiology practice to undergo the intra-articular glenohumeral corticosteroid and local anesthetic injection under radiological guidance. Within 1 hour of administration of the injection,[23] participants returned for reassessment, which included measurement of active and passive ranges of movement and pain at the end of ranges of movement. Following the measurement of range of movement and recording of postinjection pain levels, the participants continued with routine clinical management.

Shoulder movement measurement. A comprehensive series of shoulder active and passive ranges of movement were evaluated. Seated upright in a chair to limit trunk extension, measurement of the following ranges of movement were performed based on the method described by Green et al[24]: total shoulder flexion (TSF), glenohumeral flexion (GHF), total shoulder abduction (TSA), and glenohumeral abduction (GHA). The starting position for each of these movements was with the palm facing medially to ensure consistent rotation. The elbow was extended, and the inclinometer was placed along the shaft of the humerus.[24] As GHF and GHA were being measured, a device was constructed to limit movement of

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the acromion in order to provide consistent scapular stabilization (Fig. 2).

Each of the following movements was performed in the supine position based on previously described methods[24–26]: external rotation in neutral abduction (ERN), external rotation in 90 degrees of abduction (ERA), and internal rotation in 90 degrees of abduction (IRA). A towel was placed under the shaft of the humerus to ensure it was parallel to the plinth, with the elbow flexed to 90 degrees, and the inclinometer was placed on the dorsal surface of the participant's forearm. For ERA and IRA, the arm was abducted to 90 degrees, or, if this was not possible, it was taken to the limit of movement. Internal rotation in abduction was measured based on a method previously described whereby the end range was determined as the point at which the posterolateral acromion was visualized to rise off the plinth.[27] In addition, hand behind back (HBB) was measured in standing using the distance between the spinous process of T1 and the spinal level reached by the radial styloid process with the arm taken behind the back.[28]

All movements, with the exception of HBB, were measured in degrees using a Baseline digital inclinometer (Fabrication Enterprises Inc, Irvington, New York). Prior to each measurement, the digital inclinometer was reset to zero after placement on the participant to ensure consistency. Digital inclinometery has been demonstrated to have a measurement error of ± 1 degree.[29] Hand behind back was measured with a tape measure and recorded in millimeters. The order of measurement was standardized (TSF, GHF, TSA, GHA, ERN, ERA, IRA, HBB), and all active movements were performed prior to any passive movements.

The instruction to participants for all active movements was to move the arm as far as possible until they were no longer able to tolerate the movement due to pain or they were unable to move the arm any farther. For passive movements, the researcher performed each of the movements to the point of resistance or when the participant reported the pain was intolerable. To determine percentage of loss of active and passive ranges of movement, contralateral shoulder range of movement also was measured prior to the injection of corticosteroid and local anesthetic in an identical manner to the affected shoulder. In the absence of any documented deficit, a loss of range of movement of 10% or greater with respect to the contralateral shoulder was determined to constitute loss of movement. Such a loss exceeds the measurement error of shoulder range of movement of less than 7% previously reported,[26] as well as that reported for the commonly used universal goniometer (5°–7°),[30] thus affording some translation of the findings to the clinical setting.

Calculation of postinjection pain intensity. In the absence of a gold standard for the diagnosis of early-stage adhesive capsulitis, the response to the local anesthetic (administered concurrently with the corticosteroid injection) was used as the reference test standard. Local anesthetic injection has been previously proposed as a method of determining diagnosis.[31,32] To determine the anesthetic response, each participant was required to record their level of pain at the end of active and passive ranges of movement on a 100-mm visual analog scale (VAS) with 0 mm="no pain" and 100 mm="worst pain imaginable." The percentage change in pain intensity from before to after the injection was calculated for each active and passive movement. Pain relief of $\geq$70% for ERN was considered a positive anesthetic response (PAR). External rotation in neutral abduction was chosen because it is generally recognized as the most frequently affected movement in adhesive capsulitis.[33] The required $\geq$70% of pain relief obtained was chosen because it is considered clinically relevant and has been used in previous research.[34]

Data Analysis

Descriptive statistics were used to summarize the characteristics of the participants and presence of the 8 clinical identifiers. The participant characteristics together with the 8 identifiers were analyzed against anesthetic response using univariate logistic regression. As the clinical identifier describing pain at the end of range in all directions was nonspecific about whether this was active or passive range of movement; both dimensions were included in the analysis. Furthermore, although only global loss of passive glenohumeral joint movement was proposed as a clinical identifier, for completeness, active range of movement also was included in the model. Movements of the glenohumeral joint include GHF, GHA, ERN, ERA, and IRA. All factors with a P value of $\leq .2$ were included in a multiple logistic regression model. Outcomes were expressed as odds ratios (ORs) with 95% confidence intervals. A P value of $< .05$ was considered to be statistically significant. Data were analyzed using Stata 12.0 statistical software (Stata Corp, College Station, Texas).

Results

The flow of participants through the study is shown in Figure 3. In total, 255 patients were assessed for inclusion in the study, and 191 were excluded for either not meeting the inclusion or exclusion criteria (n=150) or being unwilling or unable to participate (n=41). Sixty-

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four participants were included in the study, and participant demographic characteristics are reported in Table 1.

The prevalence of the 8 clinical identifiers is presented in Table 2. All of the participants were aged over 35 years. Global loss of active and passive ranges of movement were the least prevalent of the 8 criteria (65% and 67%, respectively).

Sixteen participants (25%) demonstrated a PAR. The relationship between the demographic characteristics and the proposed 8 clinical identifiers of the participants with a positive PAR is reported in Table 3. Univariate logistic regression identified that none of the patient demographic characteristics were associated with a PAR. Of the 8 proposed clinical identifiers, pain at the end of range of all measured active movements (OR=0.06, P=.02), global loss of passive range of all measured movements (OR=0.26, P=.03), and global loss of passive glenohumeral movements (OR=0.23, P=.02) were associated with a PAR. Following stepwise removal of the variables, pain at the end of range of all measured active movements remained the only identifier but was associated with reduced odds of a positive response (OR=0.06, P=.018).

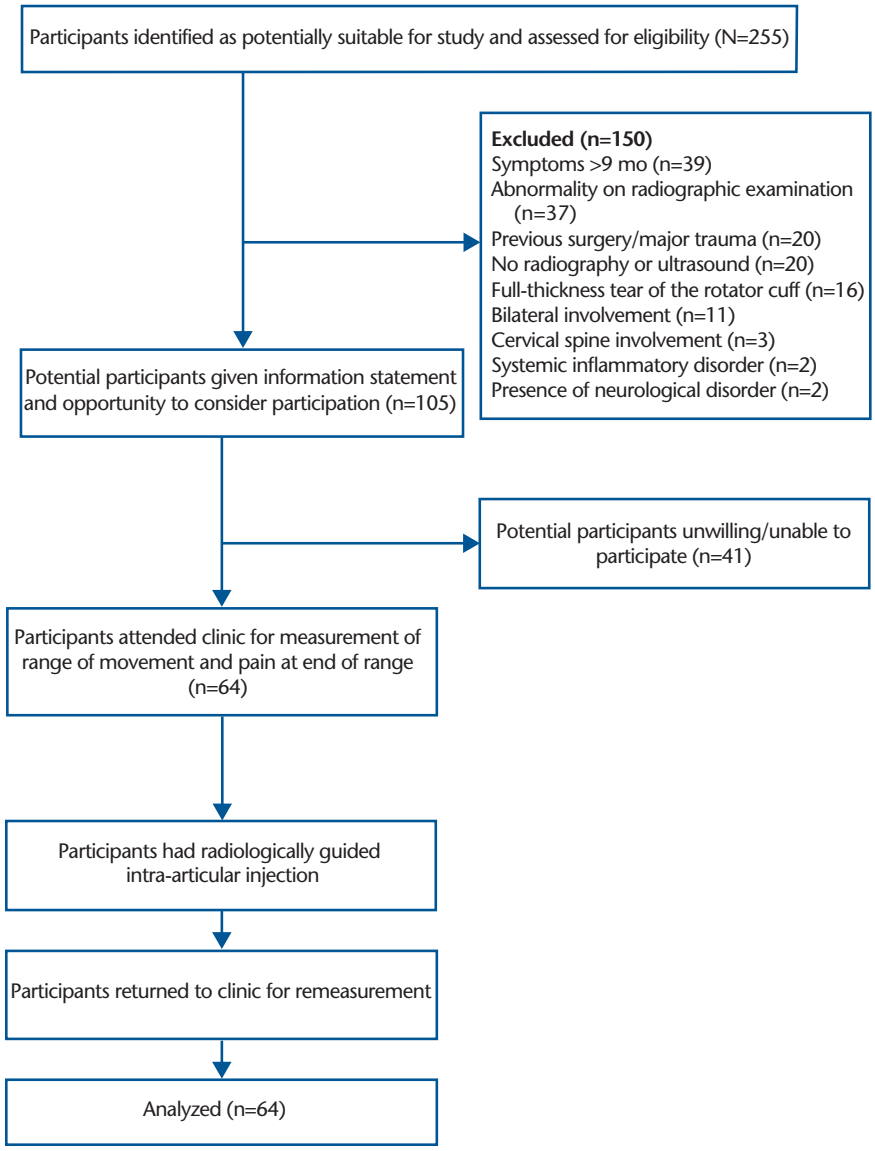

Figure 3.
Design and flow of participants through the study.

Discussion

This is the first study that has attempted to validate a set of clinical identifiers for the early stage of primary/idiopathic adhesive capsulitis. It is unique in that it used clinical identifiers previously established by expert consensus[5] and investigated only patients with symptoms for less than 9 months. Although the identifiers established by this consensus method have frequently been recognized in the literature,[35–37] none were validated in this study. Interestingly, of the 8 clinical identifiers, pain at the end of all active ranges of movement has emerged as the least likely to indicate a diagnosis of early-stage adhesive capsulitis. These results may suggest expert opinion, and possibly clinical practice may not be recognizing the appropriate clinical identifiers of patients in the early stage of this disorder. This study highlights the difficulty in quantitatively determining an exclusive set of criteria for the early stage of adhesive capsulitis.

Using the effect of intra-articular local anesthetic injection and associated pain relief of ≥70% in external rotation as the diagnostic reference standard, 25% of the participants in this study were determined to have early-stage adhesive capsulitis. This percentage was less than anticipated; however, it is in line with the proposal that this disorder is overdiagnosed, and the true incidence is much lower than generally reported.[38] A further consideration is

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Table 1.
Characteristics of the Study Participants (n=64)[a]

Variable	
Age (y), $\bar{X}$ (SD)	55.1 (6.5)
Female (%)	33 (51.6)
Duration of symptoms (mo), $\bar{X}$ (SD)	5.4 (1.9)
Affected shoulder dominant (%)	28 (43.8)
History of minor trauma (%)	23 (35.9)
History of diabetes (%)	6 (9.4)
History of Dupuytren disease (%)	8 (12.5)
SPADI, $\bar{X}$ (SD)	49.2 (1.9)
SF-36 PCS, $\bar{X}$ (SD)	41.2 (6.8)
SF-36 MCS, $\bar{X}$ (SD)	50.9 (10.6)

[a] SPADI=Shoulder Pain and Disability Index, SF-36=36-Item Short-Form Health Survey, PCS=physical component summary, MCS=mental component summary.

that every patient with a painful shoulder and apparent limitation of motion may not necessarily indicate a diagnosis of early-stage adhesive capsulitis.[39] It is likely that the clinicians assessing the patients in the current study used clinical identifiers similar to those used by the experts in the Delphi study,[5] given the specialist nature of the practice from which the participants were recruited. It is not surprising, therefore, that the prevalence of the identifiers in the participants was generally high, as demonstrated in Table 2.

Our results suggest that using these criteria may not be appropriate to identify the early stage of this disorder. The differences of opinion and lack of understanding of adhesive capsulitis in its early stage, as well as the general appreciation of the specific diagnostic criteria that distinguish it at this stage from other shoulder disorders, have been reported previously.[40] Furthermore, there is no consensus as to the exact range-of-motion restriction required for a patient to qualify for a diagnosis of early-stage adhesive capsulitis.[41] Although consensus exists regarding the presence of 3 phases of the disorder, controversy still arises regarding the diagnostic criteria that distinguish these stages.[42] The findings of this study are consistent with this confused picture.

Table 2.
Prevalence of the 8 Clinical Identifiers (n=64)

Criteria	No. of Participants (%)
There is a strong component of night pain	62 (96.9)
There is a marked increase in pain with rapid or unguarded movements	57 (89.1)
It is uncomfortable to lie on the affected shoulder	61 (95.3)
The patient reports the pain is easily aggravated by movement	55 (85.9)
The onset generally occurs in people older than 35 years of age	64 (100)
On examination, there is pain at the end of range in all directions	Active: 59 (92.2) Passive: 60 (93.8)
On examination, there is global loss of active and passive range of movement	Active: 42 (65.6) Passive: 43 (67.2)
There is global loss of passive glenohumeral joint movement	47 (73.4)

Recent understanding of the pathology of adhesive capsulitis has suggested that the behavior of the symptoms throughout the stages of the disorder may be explained by the underlying pathological process of initial inflammation followed by subsequent contracture.[14] In particular, inflammation of the anterior glenohumeral joint capsule[43,44] has been implicated in early adhesive capsulitis. It may be reasonable, therefore, to expect pain or restriction of movement to not be global in the early stage of adhesive capsulitis, given this reported pathology.[14] Despite these findings, consensus studies on diagnostic criteria or clinical identifiers previously reported (with the exception of the Delphi study[5]) notably omit consideration of the stages described when proposing diagnostic criteria.[9,33] Furthermore, the degree and directions of restriction required to constitute adhesive capsulitis have not been identified as necessary to determine appropriate diagnosis.[45] The fact that each of the 8 measured active and passive movements stresses various aspects of the glenohumeral joint capsule may provide an explanation for none of the clinical identifiers involving physical assessment being validated. It also may suggest that a "one size fits all" approach to diagnosis has been taken and, as the later stages reportedly are characterized by global restriction of movement and end-range pain,[37,46] this approach is likely to be similarly assumed in the early stage of the disorder. Potentially, it is the global rather than specific nature of these clinical identifiers that resulted in reduced odds of a PAR. The suggestion that limitation of external rota-

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tion may be the most recognizable feature[33] may warrant specific further exploration in a similar population.

The early stage of adhesive capsulitis has been reported to be frequently confused with impingement syndrome, with differentiation between the 2 disorders often difficult.[47,48] Compounding the confusion between these 2 disorders, impingement tests used clinically have been reported to lack specificity.[49] As well as recognition of groups of physical examination findings, the use of local anesthetic as a diagnostic tool in shoulder disorders has been reported previously.[50] The confusion between early-stage adhesive capsulitis and impingement syndrome may be better addressed with injection of local anesthetic into the subacromial space[51] to facilitate the diagnosis of adhesive capsulitis by exclusion.

The aim of musculoskeletal health care is to provide effective treatment of patients with various disorders. However, the lack of strong evidence for successful treatment of shoulder disorders reported in a systematic review[52] has been suggested to be a result of the lack of uniformity of the use of diagnostic labels or that the criteria used in determining diagnostic subgroups are not related to treatment success.[53] Establishing diagnostic criteria or clinical identifiers for various shoulder disorders allows identification of a homogeneous subgroup of patients with which to evaluate treatment outcomes and make comparisons across trials more meaningful.[5] However, in the shoulder, the validity of various shoulder examination procedures has recently been challenged,[54] with the lack of diagnostic accuracy possibly explained by the lack of anatomical validity of most shoulder tests.[55] Schellingerhout et al[53] proposed that alternate methods should be used to classify patients with shoulder disorders. The shoulder symptom modification procedure approach proposed recently to address rotator cuff tendinopathy/subacromial impingement syndrome[56] may be worthy of further exploration in the group of patients with presumed early-stage adhesive capsulitis.

Table 3.
Relationship Between Participant Characteristics and the 8 Clinical Identifiers and Positive Anesthetic Response (n=64)[a]

Variable	Univariate Association		Multivariate Association	
	Odds Ratio (95% CI)	*P*	Odds Ratio (95% CI)	*P*
Age	1.08 (0.98, 1.18)	.12		
Sex	0.92 (0.16, 0.78)	.89		
History of minor trauma	1.09 (0.34, 3.53)	.88		
History of diabetes[b]				
History of Dupuytren disease	1.98 (0.42, 9.44)	.39		
SPADI	0.38 (0.02, 8.09)	.54		
SF-36 PCS	1.02 (0.93, 1.11)	.69		
SF-36 MCS	1.02 (0.96, 1.08)	.46		
Presence of night pain	0.32 (0.02, 5.42)	.43		
Pain with rapid movement	2.14 (0.24, 19.30)	.50		
Uncomfortable lying on affected shoulder[b]				
Pain easily aggravated by movement	0.62 (0.14, 2.83)	.54		
Global loss of active movement	0.41 (0.13, 1.31)	.13		
Global loss of passive movement	0.26 (0.08, 0.85)	.03[c]		
Pain at the end of active range of movement	0.06 (0.01, 0.62)	.02[c]	0.06 (0.01, 0.62)	.02[c]
Pain at the end of passive range of movement[b]				
Global loss of active glenohumeral movements	0.43 (0.13, 1.40)	.16		
Global loss of passive glenohumeral movements	0.23 (0.07, 0.78)	.02[c]		

[a] 95% CI= 95% confidence interval, SPADI=Shoulder Pain and Disability Index, SF-36=36-Item Short-Form Health Survey, PCS=physical component summary, MCS=mental component summary.
[b] Omitted due to collinearity.
[c] $P<.05$.

There are a number of limitations that require consideration in this study. First, the lack of an agreed-on reference standard for early-stage adhesive capsulitis makes any validation investigation problematic. The selection of intra-articular local anesthetic, however, was based on its previously reported diagnostic utility as a method of determining the source of patient symptoms.[31,32] Although an alternative reference standard may be to provide follow-up of patients in the long term to confirm the diagnosis of adhesive capsulitis (as the characteristic loss of motion becomes evident), this approach was not feasible in the present study because the participants were concurrently clinically treated with a corticosteroid injection and stretching exercises.

Second, as this study investigated patients undergoing normal clinical

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management, it was not ethically possible to administer a local anesthetic injection without the simultaneous corticosteroid component. In some patients, the corticosteroid may have resulted in a reaction that was not sufficiently negated by the local anesthetic,[57] although all participants were remeasured within 1 hour.

A further limitation of this study was the large number (n=191) of potential participants who were excluded. The requirement to use strict inclusion and exclusion criteria to obtain a homogeneous sample resulted in recruitment being slower than projected and the sample size accordingly modest. Interestingly, earlier authors reported similar recruitment difficulties,[21,58] perhaps supporting recent opinions that the incidence of the disorder is overestimated.[38] Although intrarater reliability was not specifically determined for the measurements due to the ethical consideration of patient pain provocation, previous published reports support the reliability of the method on which it was based.[24–26,59]

Finally, the study might have been strengthened if participants had been randomly sampled over a wider area. The generalizability of the findings, therefore, may be limited if these patients are not representative of other areas.

In conclusion, the early diagnosis of adhesive capsulitis remains problematic. Clinicians should be aware that commonly used clinical identifiers may not be applicable to this stage, which also may explain some of the poor reported outcomes of treatment to date. Recognition that the features of adhesive capsulitis in its early stage are likely to differ from those of the later stages also is needed to correctly diagnose this disorder. This study raises 2 issues that may warrant exploration in future research. First, given the reported confusion with impingement syndrome,[47,48] it may be worthwhile to include patients with "general" shoulder pain and assess the presence of any of the agreed identifiers in a heterogeneous group. Second, analysis of subgroups of movement deficit and pain at the end of range of groups of movements, rather than global movement, also may be worthy of further exploration.

All authors provided concept/idea/research design and writing. Ms Walmsley provided data collection. Ms Walmsley and Dr Osmotherly provided data analysis. Dr Osmotherly provided facilities/equipment. Dr Osmotherly and Dr Rivett provided project management and consultation (including review of manuscript before submission).

The Human Research Ethics Committee of The University of Newcastle granted ethical approval for this study.

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Clinical Identifiers for Early-Stage Primary/Idiopathic Adhesive Capsulitis: Are We Seeing the Real Picture?

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