Solving the Enigma of Frozen Shoulder

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AUTHOR DECLARATION

This is to certify that to the best of my knowledge, the content of this thesis is my own work. This thesis has not been submitted for any degree or other purposes.

I certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged.

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ABSTRACT

Frozen shoulder is a common shoulder condition affecting 2-5% of the population. It is characterised by the spontaneous onset of pain, stiffness and range of motion (ROM) loss at the shoulder. The exact pathophysiology of frozen shoulder is unclear. However, it is commonly believed that a combination of capsular contracture and fibrosis of the rotator cuff interval, the subscapular recess and the coracohumeral ligament lead to global movement restriction of the glenohumeral joint.

There is no gold standard clinical test for frozen shoulder. Frozen shoulder is therefore a diagnosis of exclusion and relies on the accurate assessment of active and passive ROM. The generally accepted diagnostic criteria for frozen shoulder are active as well as passive movement restriction in at least two planes of shoulder range of motion, one being external rotation. However, the accuracy of active and passive ROM assessment has not been tested in people with frozen shoulder. Further, the evidence of the effectiveness of treatments for frozen shoulder that aim to stretch the presumed tight shoulder structures has been questioned recently. The overall aim of this thesis was to analyse the effectiveness of stretch-based treatments for frozen shoulder and to investigate if capsular contracture is responsible for movement loss in frozen shoulder.

Chapter 2 of this thesis contains a systematic review of stretch based treatments for frozen shoulder. The aim of the review was to analyse the current evidence regarding the effectiveness of interventions that aim to stretch the tissues of the shoulder region or release the presumed capsular fibrosis. The findings of six high quality randomised controlled clinical trials were reported and discussed. The RCTs included in the study evaluated the effectiveness of manipulation under general anaesthetic (MUA), manual therapy, distension and stretching & strengthening exercises on pain, ROM and function in frozen shoulder. Overall, it was found that mobilisation combined with stretching may result in small gains in passive ROM in the short term compared to stretching and strengthening exercises. Physiotherapy after capsular distension consisting of manual therapy and stretching and strengthening exercise provides no additional benefit in terms of pain, function, or
quality of life over sham-ultrasound, but may result in improved active ROM in the short term. However, these improvements may not be clinically significant. Distension, regardless of the medium used to distend the glenohumeral capsule, had no benefit with respect to pain, disability or shoulder abduction and flexion ROM over cortisone injection alone in the short term. Distension with hyaluronic acid lead to a small increase in passive external rotation ROM compared to a glenohumeral corticosteroid injection. MUA did not confers any additional benefit over a home exercise program in terms of pain, function and ROM in people with frozen shoulder.

Chapter 3 contains a cohort study investigating external rotation ROM in healthy shoulders. The effects of sex, handedness, shoulder and body position on active and passive ROM were investigated in twenty healthy participants. The results indicate that passive external rotation ROM was significantly greater than active ROM in people with healthy shoulders. Both active and passive shoulder external rotation ROM were greater when the arm was abducted at 90 degrees compared to lower positions of abduction. There was no difference in active or passive external rotation ROM between dominant and non-dominant shoulders. Female subjects demonstrated significantly more passive external rotation ROM than males. This study also found that measuring external rotation ROM with the arm by the side yields similar results to external rotation ROM measured in side-lying in 45 degrees of abduction. The latter is not commonly utilised in clinical practice but was the position required for external rotation ROM measurement for the study in Chapter 4 as dictated by the participant position in preparation for shoulder surgery.

Finally, Chapter 4 contains a case series of five subjects with global restriction of active and passive shoulder movement of greater than 50% of normal ROM in external rotation and at least one other plane of movement. This study demonstrates that capsular contracture is not a major contributor to movement restriction in all patients who exhibit classical clinical features of frozen shoulder. Although all five cases presented with painful, global restriction of passive shoulder movement, four subjects demonstrated significantly greater abduction range of motion (ROM) and three
demonstrated significantly greater external rotation ROM under anaesthesia. These findings highlight the need to reconsider the diagnostic process used for frozen shoulder as well as our understanding of the pathology of frozen shoulder and offers an explanation for why treatments aimed at stretching tight passive structures have not proven to be more effective.
Publications and presentations from this thesis

The following paper has been submitted for publication to the New England Journal of Medicine:

‘Capsular contracture is not a major contributor to range of motion loss in some patients with frozen shoulder.’

Hollmann L., Halaki M., Haber M., Ginn K.

The following manuscript has been prepared for submission to the British Journal of Sports Medicine:

‘Are stretching techniques effective in the treatment of frozen shoulder? A systematic review’

Hollmann L., Halaki M., Ginn K.

At the time of submitting this thesis the following abstracts had been published and oral presentations given:


World Congress of Physiotherapy, Singapore 2015 – Platform Presentation: Determining the contribution of active stiffness to reduced range of motion in frozen shoulder. (Presented by L Hollmann)

Shoulder and Elbow Physiotherapists Australasia, Sydney 2015 – 5x5 Presentation: Determining the contribution of active stiffness to reduced range of motion in frozen shoulder. (Presented by L Hollmann)

International Congress of Shoulder and Elbow Therapists, Edinburgh 2016: Contribution of ‘Active Stiffness’ to the Clinical Presentation Known as Frozen Shoulder. (Presented by K Ginn)

European Society for Shoulder and Elbow Rehabilitation, Gothenburg 2016: ‘Frozen Shoulder – Is it really frozen.’ (Presented by L Hollmann)
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Frozen shoulder, also termed adhesive capsulitis, is a common shoulder condition affecting 2-5% of the population (A. S. Neviaser & Hannafin, 2010). It is characterised by the spontaneous onset of pain, progressive stiffness and range of motion loss at the shoulder accompanied by significant disability (R. Buchbinder et al., 2007; Kelley et al., 2013). People who experience the condition usually complain of pain near the deltoid insertion, severe night pain, pain with sudden movements, and severe movement restriction (Lewis, 2015; Reeves, 1975). Frozen shoulder can be described as either primary, if the aetiology is unknown, or secondary, when it can be attributed to another cause such as trauma or surgery to the affected shoulder (Kelley et al., 2013). For the treating clinician, frozen shoulder presents a challenge both in terms of diagnosis and treatment.

Who gets frozen shoulder?
In China and Japan frozen shoulder is referred to as “50 year old” shoulder as a result of the condition primarily affecting people in the 5th decade of life (Lewis, 2015). There is no certainty about whether men or women are more commonly affected (Lewis, 2015). Frozen shoulder has a strong association with diabetes mellitus, occurring in 20% to 36% of the diabetic population (T. D. Bunker & Anthony, 1995). Arthroscopic observations have revealed an appearance of the shoulder capsule similar to that found in the finger flexor tendons of patients with Duputren’s disease and reports suggest an association between the two conditions with Duputren’s contracture being eight times more common in people with frozen shoulder compared to the normal population (T. D. Bunker & Anthony, 1995; Smith, Devaraj, & Bunker, 2001). Risk factors for frozen shoulder also include hypothyroidism, family history and genetic predisposition (Lewis, 2015).

Natural History
Frozen shoulder is generally described as a self-limiting condition; i.e. it resolves spontaneously even without treatment. The literature frequently describes frozen shoulder as passing through three
distinct stages; the freezing stage (most painful, gradually increasing stiffness), the frozen stage (characterised by severe stiffness and movement restriction) and the thawing (resolution) stage where pain and stiffness gradually diminish until a full resolution of symptoms is reached (Reeves, 1975). However, a recent systematic review found no studies that demonstrated a recovery pattern consistent with the theoretical pain, stiff and thawing recovery phases as suggested by Reeves (Wong et al., 2016). The average duration of symptoms is 30.1 months (Reeves, 1975). However, it has been reported that up to 50% experience ongoing pain and stiffness seven years post onset of symptoms (Shaffer, Tibone, & Kerlan, 1992). Whilst Reeves was the first document the different stages of frozen shoulder, this belief is still commonly held by many practitioners today even though evidence of distinct phases may be lacking. (Lewis, 2015; Shaffer et al., 1992; Wong et al., 2016)

Historical Perspective
Frozen shoulder was first described by Duplay in 1872 and termed peri-arthritis. The key symptoms as described earlier, i.e. gradual onset of shoulder stiffness, severe pain, especially at night, and restriction in active and passive range of movement of the shoulder, were initially attributed to inflammation of the subacromial and subdeltoid bursae (Codman, 1911). However, other investigators favoured the opinion that the joint capsule was the site of the pathological changes in frozen shoulder. In 1945, Neviaser was the first to described fibrosis and adhesions in the shoulder capsule in 10 cases and suggested the term ‘adhesive capsulitis’ as a more accurate description of the condition (J. S. Neviaser, 1945). Observational studies conducted since then concur with these findings and it is generally accepted that the shoulder capsule is the cause of symptoms in frozen shoulder (G. Hand, Athanasou, Matthews, & Carr, 2007; T. D. Bunker & Anthony, 1995).

Pathophysiology
The exact pathophysiology of frozen shoulder remains unclear. Acute inflammation as originally suggested, does not appear to occur in frozen shoulder (T. D. Bunker & Anthony, 1995; B. J.
Lundberg, 1969). However, Hand et al. described the presence of chronic inflammatory cells, including mast cells and macrophages (G. Hand, Athanasou, Matthews, & Carr, 2007). Other studies have noted hypervascularity of the shoulder capsule and the presence of fibroblasts (cells associated with initiating inflammation) and myofibroblasts (cells associated with contractile scar tissue) within the coracoacromial ligament (T. D. Bunker & Anthony, 1995; Bo J Lundberg, 1969; Simmonds, 1949). The presence of these cells may explain the process of pain and adhesions described in frozen shoulder.

Arthroscopic evaluations of the shoulder have revealed the presence of fibrosis particularly in the rotator cuff interval (the space between the tendons of subscapularis, supraspinatus, and the base of the coracoid process), the subscapular recess and the coracohumeral ligament (Uitvlugt, Detrisac, Johnson, Austin, & Johnson, 1993; A. M. Wiley, 1991). In summary, it is suspected that a process of chronic inflammation leads to scarring and fibrosis of the capsule and it is believed that this process is responsible for pain and range of motion loss in patients with frozen shoulder. It is unclear, however if or how the fibrosis and scarring of the glenohumeral capsule resolves in people who experience a resolution of their frozen shoulder symptoms.

**Diagnosis**

There is no gold standard clinical test for frozen shoulder. The generally accepted diagnostic criteria for frozen shoulder are active as well as passive movement restriction in at least two planes of shoulder range of motion, one being external rotation. A plain X-ray is needed to exclude other pathologies, such as glenohumeral osteoarthritis, locked dislocations and tumours, that can present with active and passive movement restriction and therefore, mimic frozen shoulder. The diagnosis therefore, relies on accurate clinical assessment of active and passive range of motion and the exclusion of other pathologies.
Accuracy of active and passive range of motion assessment in the clinic has not been tested in people with frozen shoulder. It is well documented in other conditions, including lumbar spine pain, that people with pain can exhibit significant muscle guarding which is presumed to be a protective mechanism to avoid pain (Roland, 1986). Recent research into chronic pain has also revealed reorganisation within the primary motor cortex consistent with a guarding-type response at a motor planning level (Moseley, 2004; Schabrun, Christensen, Mrachacz-Kersting, & Graven-Nielsen, 2015). These factors may make accurate assessment of range of motion difficult in the presence of pain in people with frozen shoulder and therefore, poses a diagnostic challenge. Since the glenohumeral joint capsule is strongly reinforced by the rotator cuff tendons which serve to provide dynamic shoulder stability by tightening the capsule during movement, we hypothesise that “active stiffness”, that is that rotator cuff muscle contraction, is contributing to stiffness and range of motion loss in people with frozen shoulder.

In addition to the difficulty of conducting a passive range of motion assessment in the presence of pain, it is unknown how patient or shoulder position may affect assessment findings. Testing shoulder range of motion in different positions may yield different results and therefore, affect diagnostic and treatment decisions. To date, no one has investigated the relationship between external rotation range of motion and patient positioning.

Treatment

The treatment of frozen shoulder is challenging. Following arthroscopic evidence of capsular fibrosis in patients with frozen shoulder, some authors speculated that the enigma of frozen shoulder had been solved i.e. that the release of contracted structures via surgery or manipulation would bring about a full resolution of the patients’ symptoms. (TD Bunker, 1997) Over the years, a number of treatments have been suggested for frozen shoulder – most of them aimed at addressing the fibrosis of the shoulder capsule by either stretching or surgically releasing it.
Treatments for frozen shoulder generally aim to reduce pain and to restore range of motion. The most commonly prescribed treatments for frozen shoulder in Australia include physiotherapy (stretching exercises and/or manual techniques to the glenohumeral joint with the goal of lengthening muscle or soft tissues), joint distension (a technique where a combination of saline and a corticosteroid is injected into the shoulder joint until the shoulder capsule ruptures), manipulation under general anaesthetic (a forceful manipulation of the glenohumeral joint by an orthopaedic surgeon), surgery to release the capsule (an arthroscopic operation in which fibrotic tissue cut and removed); and corticosteroid injections into the glenohumeral joint with the aim of reducing inflammation and pain. There is conflicting evidence as to the effectiveness of these treatments for frozen shoulder (Favejee, Huisstede, & Koes, 2011; Lewis, 2015).

In summary, many aspects of the pathophysiology, diagnosis and treatment of frozen shoulder are poorly understood. Specifically, it is unclear whether passive range of motion measurements, the definitive diagnostic tests for frozen shoulder, are an accurate representation of the shoulder joint’s available range of motion, thus challenging the validity of these tests. Further, it is unknown how effective the most commonly used treatments for frozen shoulder are in terms of reducing pain, and improving shoulder range of motion and function. This thesis aims to aid in our understanding of diagnosis and treatment in frozen shoulder by addressing these knowledge gaps. Our aim is:

(1) To investigate whether current evidence supports the efficacy of treatments for frozen shoulder aimed at stretching the shoulder capsule or tissues in relieving pain, improving range of motion or reducing disability in patients with frozen shoulder.

(2) To establish normal active and passive shoulder external rotation range of motion in people without shoulder pain taking into account the effect of patient and shoulder position.
(3) To investigate whether active stiffness (muscle guarding) contributes to range of motion loss in people with frozen shoulder.

The effectiveness of stretch-based treatments for frozen shoulder will be investigated in a systematic review. Shoulder external rotation range of motion in subjects without shoulder pain will be investigated in a cross-sectional study. The effect of sex, handedness and patient position will be investigated. Finally, a further study will investigate the contribution of active stiffness to movement restriction in people with frozen shoulder. Passive abduction and external rotation range of motion will be compared before and after general anaesthesia to establish whether passive range of motion is affected by pain or muscle guarding in the awake patient.
References


CHAPTER 2 – Literature Review

Publication Title: Stretching a frozen shoulder: a systematic review of the evidence

This Chapter has been formatted for submission as a manuscript to the journal, British Journal of Sports Medicine. As co-authors of the manuscript, ‘Stretching a frozen shoulder: a systematic review of the evidence’, we confirm that Luise Hollmann has made the following contributions:

- Conception and design of the research
- Database search
- Data extraction and processing
- Data Analysis and interpretation of findings
- Writing the paper and critical appraisal of content
- Final editing of article for publication

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ABSTRACT

Aim to summarise the current evidence regarding the effectiveness of interventions aimed at stretching the tissues of the shoulder region to improve range of motion (ROM), pain and function in individuals with frozen shoulder.

Design Systematic review.

Data sources Medline via Ovid, EMBASE, CINAHL, PEDro and Scopus databases.

Eligibility criteria for selecting studies Randomised controlled trials (RCTs) investigating treatments that stretch or release tissues of the shoulder region for frozen shoulder on pain, function or range of motion (ROM) were included.

Results Six high-quality RCTs were included. There is moderate evidence that glenohumeral joint mobilisation combined with stretching results in small gains in passive ROM in the short term compared to stretching and strengthening exercises. There is no benefit of shoulder distension, regardless of the medium used to distend the glenohumeral joint capsule, with respect to pain, disability or shoulder abduction and flexion ROM over cortisone injection alone in the short term. Distension with hyaluronic acid increases passive external rotation ROM compared to a glenohumeral corticosteroid injection. Physiotherapy after capsular distension consisting of manual therapy and stretching and strengthening exercise provides no additional benefit in terms of pain, function, or quality of life over sham-ultrasound but results in improved active ROM in the short term. There is moderate evidence from one RCT that manipulation under anaesthesia confers no additional benefit over exercise in pain, function and ROM in people with frozen shoulder.

Conclusions Distension, manual therapy and stretching lead to small short-term improvements in ROM in people with frozen shoulder but they do not appear to significantly alter the natural course of frozen shoulder.

INTRODUCTION

Frozen shoulder is a common shoulder condition characterised by the spontaneous onset of pain, progressive stiffness and range of motion (ROM) loss accompanied by significant disability. (R. Buchbinder et al., 2007; Tim Bunker, 2009; Kelley et al., 2013) It affects 2-5% of the general population and up to 36% of the diabetic population. (T. D. Bunker & Anthony, 1995; A. S. Neviaser & Hannafin, 2010) People who experience the condition usually report pain near the deltoid insertion, severe night pain, pain with sudden movements and severe, global movement restriction of the glenohumeral joint. (Tim Bunker, 2009; Lewis, 2015; Reeves, 1975) Frozen shoulder is generally described as a self-limiting condition; i.e. it resolves over time even without intervention. However, the course of frozen shoulder is very protracted with an average duration of symptoms of 30.1 months. (Reeves, 1975) Further, it has been reported that up to 50% of patients experience ongoing pain and stiffness seven years post onset of symptoms. (Shaffer et al., 1992)

The condition was first described by Duplay in 1872 and termed peri-arthritis. (Duplay, 1872) At the time, it was thought that the symptoms were due to inflammation of the subacromial and subdeltoid bursae. (Codman, 1911) As the understanding of the condition evolved, the glenohumeral capsule was identified as the source of pathology. (Lewis, 2015)

The pathoetiiology of frozen shoulder is not fully understood. Histological and arthroscopic studies of frozen shoulder suggest a process of chronic inflammation, fibrosis and glenohumeral joint capsule contracture is responsible for the pain and restricted ROM characteristic of frozen
Commonly reported arthroscopic findings include contracture of the glenohumeral capsule and the presence of fibrosis in the rotator cuff interval, the subscapular recess and the coracohumeral ligament. The appearance of the glenohumeral joint capsule has been compared to that found in the finger flexor tendons of patients with Duputren’s disease. Consequently, treatment is most commonly aimed at stretching glenohumeral joint structures to restore shoulder ROM while managing pain.

Diagnosis of frozen shoulder is difficult. A gold standard diagnostic test for frozen shoulder does not exist, so the diagnosis is generally made by excluding other pathology. Due to lack of understanding of the exact pathophysiology of frozen shoulder, it has been described as a “waste can diagnosis”, applying the terminology to any stiff and painful shoulder. Diagnostic criteria are often not uniform or not well described in studies investigating the efficacy of frozen shoulder. Overall, there appears to be consensus that a “true” frozen shoulder is a chronic condition that is characterised by global active and passive movement restriction and that a plain X-ray is essential to rule out other conditions that may masquerade as frozen shoulder, including osteoarthritis, locked dislocations fractures or avascular necrosis.

Treatments for frozen shoulder generally aim to reduce pain and to restore ROM. The most commonly prescribed treatments for frozen shoulder include physiotherapy (stretching exercises and/or manual techniques to the glenohumeral joint with the goal of lengthening muscle or soft tissues), distension (a technique where a combination of saline and a corticosteroid is injected into the shoulder joint until the shoulder capsule ruptures), manipulation under general anaesthetic (a forceful manipulation of the glenohumeral joint by an orthopaedic surgeon), capsular release surgery (an arthroscopic operation in which fibrotic tissue cut and removed); and corticosteroid injections into the glenohumeral joint with the aim of reducing inflammation and pain.

This review aims to summarise and analyse the current evidence regarding the effectiveness of interventions that aim to stretch the tissues of the shoulder region or release the presumed capsular fibrosis to improve ROM, pain and function in individuals with frozen shoulder. To achieve this goal, this review included available high quality randomised controlled clinical trials (RCTs) that applied a consistent diagnostic criterion for frozen shoulder.

**METHODS**

The PRISMA statement and Cochrane Collaboration guidelines were followed for this systematic review.

**Selection of studies**

RCTs that compared surgical and non-surgical interventions that aimed to stretch or lengthen tissues of the shoulder region were included. Articles in English were accepted.

Studies which evaluated patients with a diagnosis of frozen shoulder and symptom duration greater than 3 months were included. The clinical diagnosis of frozen shoulder needed to be confirmed by documented active and passive range of shoulder motion restriction in at least two planes and a normal plain radiograph.

All interventions that aimed to stretch the shoulder tissues, including the glenohumeral joint capsule and shoulder region muscles were included. This included manual therapy (passive accessory or
passive physiological techniques to the glenohumeral joint to the end of available range, therapist assisted or self-stretching, continuous passive motion, devices aimed at stretching the shoulder, manipulation under general anaesthetic (MUA), glenohumeral joint (capsular) distension and capsular release surgery. Interventions could be compared to a control group with no intervention, placebo or any other intervention. The intervention could be the only treatment or an add-on treatment. Studies that did not include a treatment component directly aimed at stretching or lengthening shoulder region tissues were excluded.

Studies were included if at least one primary outcome measure investigated pain, ROM or shoulder function. Studies with any length of follow up period were included.

**Data Sources**

The following databases were searched electronically: Medline via Ovid, EMBASE, CINAHL, PEDro and Scopus with no restriction on the date of publication. All keywords were searched independently and then combined using relevant Boolean terms. The following Medical Subject Heading terms and keywords were used: (frozen shoulder OR adhesive capsulitis) AND (physiotherapy OR physical therapy OR manual therapy OR mobilization OR manipulation OR continuous passive motion OR stretch OR stretching OR hydrodilatation OR distension OR hydroplasty OR capsular release OR capsulotomy OR arthrolysis OR microadhesiolysis). Reference lists from included full-text articles and from other relevant systematic reviews were screened for additional relevant papers.

**Study selection and quality assessment**

All studies identified from the database search were assessed for eligibility by title to exclude those that were not relevant to the research question. Abstracts of the remaining studies were analysed to determine whether the study met the inclusion criteria in regards to design, diagnosis, intervention and outcomes. If it was unclear if the study met the inclusion criteria, full text articles were obtained. Two independent reviewers (LH and KG) performed the selection process and a third reviewer (MH) was consulted in cases of disagreement.

Studies that met the inclusion criteria were scored using the PEDro scale. The PEDro scale is a rating scale designed for rating methodological quality of RCTs based on the Delphi list.(Maher, Sherrington, Herbert, Moseley, & Elkins, 2003) It contains one item assessing external validity of a study, eight criteria assessing internal validity and two criteria assessing sufficiency of the statistical information reported. Each item except for the external validity item contributes one point to the rating scale with a possible maximum score of 10 points. The PEDro scale has been shown to be a valid and reliable measure of the methodological quality of clinical trials.(de Morton, 2009; Maher et al., 2003)

PEDro scores of indexed articles in the PEDro database were maintained. Methodological quality assessment of the remaining articles was conducted by two independent reviewers (LH and KG), and inconsistencies of the rating were solved by a consensus with a third reviewer (MH). Only studies with a high methodological quality defined as a PEDro score of 5 or higher(Cruz-Ferreira, Fernandes, Laranjo, Bernardo, & Silva, 2011; Haik, Alburquerque-Sendin, Moreira, Pires, & Camargo, 2016) were considered in the final summary of evidence.

**Data extraction and management**

The following data were extracted from selected studies using a data extraction form: participants, interventions, types of outcome measures, frequency of the intervention, duration of follow-up, loss
to follow-up, outcome measures and results. The included outcome measures were categorised: ROM (active or passive shoulder flexion, abduction and external rotation), pain (during movement or global pain score) and function. Missing data were either requested from the authors or calculated. Effect sizes (Cohen’s d) not reported were calculated from means and standard deviations. (Cohen, 1988) Due to heterogeneity of outcome measures used, a meta-analysis could not be conducted.
Figure 1: Flow Diagram for Literature Search Results

Records identified through database searching (n= 2067)
- Medline = 372
- Embase = 434
- CINAHL = 257
- PEDro = 76
- Web of Science = 443
- Scopus = 485

Additional records identified through reference lists (n= 0)

Records after duplicates removed (n= 915)

Records screened by title (n= 915)
Records excluded (n=668)

Records screened by abstract (n= 247)
Records excluded (n=173)

Full text articles assessed for eligibility (n= 74)
Records excluded (n= 68)
- Insufficient diagnostic criteria for frozen shoulder 42
- Not randomised 7
- Other interventions 7
- Low methodological quality 4
- Conference abstract 3
- Follow-up studies of same study 2
- Other diagnosis included 1
- Other outcomes 1
- Other language 1

Studies included in qualitative synthesis (n= 6)
RESULTS

This review considered articles published before September 2016. Six studies fulfilled the inclusion criteria and were included in this systematic review. A flow chart detailing the reasons for exclusion can be found in Figure 1.

Quality of included studies

The quality of included studies ranged from 5 to 9 out of 10 on the PEDro scale. None of the studies had a blinded therapist as this is not possible with the interventions studied. Subject blinding is also challenging in the interventions studied but one study (R. Buchbinder, Green, Forbes, Hall, & Lawler, 2004) blinded subjects by injecting the shoulders of subjects in the placebo group with a low volume contrast medium and compared them to subjects that received a shoulder distension. The remaining five studies did not utilise subject blinding.

Four out of the six included studies incorporated concealed allocation and three out of six utilised intention-to-treat analysis and a blinded assessor to minimise bias. Five out of six studies had acceptable loss to follow-up (>85% of subjects initially allocated to the groups completed the study), while one study (Kivimäki et al., 2007) only achieved adequate follow-up at 6 weeks but at 3, 6 or 12 months. Overall the quality of included studies was moderate to high (see Table 1).

Effectiveness of Interventions

Manipulation under general anaesthesia

One RCT (Kivimäki et al., 2007) investigated the effectiveness of MUA combined with a home exercise program versus a home exercise program alone in 125 patients. The exercise intervention consisted of two supervised sessions with a physiotherapist and a daily stretching program of pendulum and stretching exercises performed within pain limits. The effects of the interventions on shoulder passive ROM, pain and function (measured with the Shoulder Disability Questionnaire) were evaluated. There was no difference in pain intensity, self-reported shoulder disability, passive shoulder abduction, external rotation, or internal rotation ROM at 1.5, 3, 6 or 12 months post treatment. The MUA plus exercise group did demonstrate a small but statistically significant increase in passive shoulder flexion ROM (144°) at 3 months compared with 136° in the exercise alone group. This RCT provides moderate evidence that MUA confers no additional benefit in pain, function and ROM in people with frozen shoulder. (Kivimäki et al., 2007)

Glenohumeral joint distension

Three RCTs (R. Buchbinder et al., 2004; Park, Nam, Lee, Kim, & Park, 2013; Tveitå, Tariq, Sesseng, Juel, & Bautz-Holter, 2008) investigated the effectiveness of glenohumeral joint distension in the treatment of frozen shoulder. One RCT compared distension to a placebo intervention (arthrogram) in 48 patients. (R. Buchbinder et al., 2004) The distension procedure, consisted of injection of 30-90ml of 40mg methylprednisolone acetate (1 ml) plus normal saline until capsular rupture was achieved or the patient requested termination of the procedure. The effects of the interventions on pain measured using a VAS, active ROM and function measured with the SPADI (a questionnaire assessing shoulder pain and function) and Problem Elicitation Technique (PET), a measure of function, were reported. Significant improvements were seen in the distension group three weeks post treatment in function measured with both the SPADI and PET, overall pain and active shoulder abduction and hand behind back ROM. At 12 weeks there was a statistically significantly greater improvement in the PET but not the SPADI score in the distension group compared to placebo. There was no difference in overall pain or active ROM between groups at 12 weeks. Four subjects dropped
out of the placebo group. Statistical analysis excluding these subjects lead to a significant improvement in pain and disability measures favouring the distension group at 12 weeks. (R. Buchbinder et al., 2004)

Two RCTs (Park et al., 2013; Tveitå et al., 2008) compared the effectiveness of distension using either corticosteroids or hyaluronic acid to a corticosteroid injection. In one study (Tveitå et al., 2008) 76 patients received an intra-articular glenohumeral joint injection of either 3-4 ml contrast medium, 2 ml corticosteroid (triamcinolone acetonide) and 3-4 ml local anaesthetic or the same injection plus saline to achieve rupture of the glenohumeral joint capsule. (Tveitå et al., 2008) All patients received a total of three injections with two week intervals between injections and the effects on active and passive ROM, pain and function (SPADI) were measured. There were no differences in active or passive ROM, or SPADI scores between intervention groups at follow-up 6 weeks after the final injection. (Tveitå et al., 2008)

Park et al. (Park et al., 2013) compared a glenohumeral joint distension procedure using hyaluronic acid to an intra-articular corticosteroid injection. One hundred subjects received either 0.5% lidocaine (18 ml) with sodium hyaluronate (10 mg/ml; 2ml) for the distension procedure or 0.5% lidocaine (4 ml) plus triamcinolone (40 mg/ml; 1ml) under ultrasound guidance. All subjects received three intra-articular injections at two week intervals and a simple exercise program. The effects of the interventions on pain (Verbal Numerical Scale, VRN), function and pain (SPADI) and passive ROM were evaluated. No difference was found between groups with respect to pain and function, or passive shoulder flexion or abduction ROM at 2 and 6 weeks follow-up. The study reported a statistically significant increase in passive external ROM in the distension group at 2 and 6 weeks follow-up. (Park et al., 2013)

From the limited evidence available, it appears that regardless of the medium used to distend the glenohumeral capsule, there is no benefit with respect to pain, disability or shoulder abduction and flexion ROM over cortisone injection alone in the short term.

Manual Therapy and Stretching

One RCT compared joint mobilisation and stretching to stretching alone. (Çelik & Kaya Mutlu, 2016) Thirty subjects were randomised to receive manual therapy, specifically glenohumeral joint mobilisations, and a home exercise program consisting of cyclic intermittent stretches and strengthening exercises or the home exercise program only over a period of six weeks. The primary outcome measure were the Disabilities of the Arm Shoulder Hand Score (DASH), a measure of upper extremity pain and function and the Constant-Murley Shoulder Outcome score, a measure of pain, ROM, strength and function. The study found a statistically significant improvement in Constant Score in favour of the manual therapy plus home exercise group but not in DASH scores at 6 weeks and 12 months. Further, there was a statistically significant improvement in passive shoulder abduction and external rotation ROM at the conclusion of 6 weeks treatment and at 12 months follow-up in the manual therapy plus home exercise group compared to the home exercise only group. There were no differences in passive shoulder flexion or internal rotation between groups at 6 weeks or 12 months. (Çelik & Kaya Mutlu, 2016)

The final RCT included in this systematic review investigated the effectiveness of manual therapy treatment for frozen shoulder after a glenohumeral distension procedure. A total of 156 subjects underwent glenohumeral joint capsular distension and were then randomised to either an active physiotherapy group or a placebo group. The effects of the interventions on shoulder function (SPADI), active shoulder ROM, and quality of life (SF-36 and AQoL) were investigated. The active
physiotherapy intervention consisted of twice-weekly physiotherapy treatments over a six-week period. Treatments included manual therapy techniques at the glenohumeral joint and the cervicothoracic spine as well as stretching and strengthening exercises for the shoulder that subjects were instructed to complete daily. The placebo group had the same number of visits but were treated with sham ultrasound. There was no difference in function and/or pain (SPADI questionnaire and VAS scores) or quality of life (AQoL) between the physiotherapy and placebo groups at 6, 12 or 26 weeks. The physiotherapy group did report significantly greater participant-perceived success of treatment at all time points and did have significantly greater improvements in active shoulder flexion, abduction, external rotation and hand behind back ROM at 6 and 12 weeks but not at 26 weeks. (R. Buchbinder et al., 2007)

In summary, from the limited evidence available, glenohumeral joint mobilisation combined with stretching may result in small gains in passive ROM in the short term compared to stretching & strengthening exercises. Physiotherapy after capsular distension consisting of manual therapy and stretching & strengthening exercise provides no additional benefit in terms of pain, function, or quality of life over sham-ultrasound but may result in improved active ROM in the short term. However, these improvements were small. All studies reported improvements in pain, range of motion and function in all groups from baseline to later follow-up periods (R. Buchbinder et al., 2004; R. Buchbinder et al., 2007; Çelik & Kaya Mutlu, 2016; Kivimäki et al., 2007; Park et al., 2013; Tveitå et al., 2008), indicating that there is a natural tendency for frozen shoulder to improve overtime.
<table>
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DISCUSSION

Distension, MUA and manual therapy are thought to have a positive effect in the treatment of frozen shoulder by improving glenohumeral mobility via stretching or rupturing of the joint capsule. However, the results of the current review indicate that joint distension confers some short-term benefit compared with placebo (arthrogram), but distension, MUA and passive mobilisation techniques do not incur additional benefit with respect to pain & functional ability over cortisone injection or a home-based stretching & strengthening program in the short term.

Glenohumeral capsular contracture, adhesions, coracohumeral ligament thickening and scarring of the rotator cuff interval have been demonstrated in people diagnosed with frozen shoulder(TD Bunker, 1997; G. Hand et al., 2007; J. S. Nevisaser, 1945; Uitvlugt et al., 1993; A. Wiley, 1991) Shoulder movement restriction associated with frozen shoulder has been attributed to these abnormalities found within the glenohumeral capsule. In 1997, Bunker wrote: “Thus the enigma of frozen shoulder has been unravelled. We have shown that the cause of frozen shoulder appears to be a fibrous contracture of the rotator interval and coracohumeral ligament of the shoulder joint. [...] Treatment must be aimed at releasing this contracture by manipulation or surgical release.”(TD Bunker, 1997)” The current available clinical trial evidence summarised in this review would not seem to support this statement.

There may be several reasons why surgical procedures to release contractures in the glenohumeral joint capsule have not been shown to be more effective in the treatment of frozen shoulder: The glenohumeral joint dilatation procedure is unspecific and may not be able to release the contracted structures, instead rupturing the weakest part of the capsule rather than necessarily the tissues responsible for the movement restriction. It has previously been reported that most capsular ruptures occur at the subscapularis recess or the sheath around the long head of biceps brachii, not at the thickened capsule.(Kim et al., 2011) In addition, intra-articular corticosteroid injection, even at low volumes, may have a distension effect on the glenohumeral joint capsule, making it more difficult to identify between group differences in the trials which compared distension to corticosteroid injection in this review.(J. S. Nevisaser, 1945; Tveitå et al., 2008) Nevisaser et al. has reported glenohumeral joint volumes to be as low as 5 ml in some people with frozen shoulder and injection volumes in the studies included in this review ranged from 5-10 ml in the corticosteroid injection only groups.(R. Buchbinder et al., 2004; R. J. Nevisaser & Nevisaser, 1987; Park et al., 2013; Tveitå et al., 2008) Tveita et al. in fact reported that in their trial 4 subjects belonging to the injection group experienced capsular rupture. (Tveitå et al., 2008)

Mobilisation and physiotherapy exercises are frequently prescribed for people with frozen shoulder.(Çelik & Kaya Mutlu, 2016; Hanchard et al., 2012) However, differing opinions exist regarding the appropriate intensity and degree of manual therapy and stretching exercises for people with frozen shoulder. It has been suggested that vigorous manual therapy, stretching and exercise is counterproductive in frozen shoulder,(Diercks & Stevens, 2004; R. J. Nevisaser & Nevisaser, 1987) while others have favoured more vigorous techniques .(Vermeulen et al., 2000; Yang, Jan, Chang, & Lin, 2012) The two trials included in this review investigated manual therapy and stretching exercises that aimed to utilise end range positions but were described as being low intensity and performed within patient comfort. It is uncertain if stretching exercises or manual therapy have a direct effect on the contracted tissues but the results of this review indicate they may have some benefit leading to small improvements in active ROM in the short term in patients with frozen shoulder. These improvements may be a result of stretching of the contracted tissues of the glenohumeral capsule. It is also possible that they are due to decreased activity/tightness in
surrounding shoulder muscles or as a result of increased patient confidence to move their arm further into range.

The role of inflammation in frozen shoulder remains debatable. (G. Hand et al., 2007) Nevertheless, results of a systematic review have shown short term benefit of intra-articular corticosteroid injection with respect to pain and ROM over placebo and physiotherapy in patients with frozen shoulder. (Rachelle Buchbinder et al., 2003) This suggests that it may be a reduction in pain, rather than a change in the glenohumeral capsule, that produces the increase in ROM observed in these patients. Therefore, it may be that the observed improvements in the distension group are partially or entirely due to the glenohumeral corticosteroid injection rather than the distension procedure.

Some evidence exists that factors other than adhesions of the glenohumeral joint capsule may be contributing to ROM loss in some people with frozen shoulder. In a case series, four out of five patients diagnosed with frozen shoulder demonstrated significantly greater passive shoulder abduction ROM when measured under general anaesthesia. (Hollmann et al., 2015) These authors suggested that protective muscle contraction as a result of shoulder pain was a major contributing factor to the ROM limitation in these patients making passive range of motion assessment unreliable in patients with frozen shoulder. (Hollmann et al., 2015) If pain and muscle guarding produce the perceived stiffness in some patients diagnosed with frozen shoulder rather than glenohumeral capsular contracture and adhesions, this may explain why the studies included in this review aimed at stretching/lengthening tight passive structures at the shoulder have demonstrated very little clinical benefit.

**Conclusion**

This systematic review has summarised the available evidence from six high quality RCTs for treatments that aim to stretch or release areas of contracture or fibrosis in frozen shoulder. While distension, manual therapy and stretching may lead to small short term improvements in ROM in people with frozen shoulder, they do not appear to significantly alter the natural course of frozen shoulder.
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INTRODUCTION

Knowledge of normal range of motion (ROM) is essential when assessing impairments and clinical pathology in the shoulder. The assessment of shoulder external rotation ROM in particular is of great importance as it provides diagnostic information for several common shoulder conditions. Passive external ROM restriction is a diagnostic feature of frozen shoulder (Tim Bunker, 2009). Excessive active and passive external rotation ROM is thought to contribute to anterior shoulder instability (Kuhn, Huston, Soslowsky, Shyr, & Blasier, 2005) and is also used as a measure to differentiate between capsular tightness/joint stiffness and muscle weakness, aiding in the diagnosis of conditions such as glenohumeral osteoarthritis. Active external rotation is commonly used as a measure of the function of the posterior rotator cuff (Dutton, 2008). Studies have examined shoulder ROM in healthy athletes, including elite tennis and baseball players (Baltaci, Johnson, & Kohl III, 2001; Ellenbecker, Roetert, Bailie, Davies, & Brown, 2002; Ellenbecker, Roetert, Piorkowski, & Schulz, 1996; Ellenbeckert, 1992). However, generalising these results to the normal population is problematic as it is well documented that high level throwers exhibit humeral retroversion affecting shoulder rotation ROM (Chant, Litchfield, Griffin, & Thain, 2007; R. Whiteley, Adams, Ginn, & Nicholson, 2010; R. J. Whiteley, Ginn, Nicholson, & Adams, 2009).

Several researchers have attempted to establish normative values for shoulder external rotation ROM in the general population and investigated factors such as sex and hand dominance on ROM. Female subjects have been reported to have greater active and passive shoulder external rotation ROM compared to male subjects (Allander, Björnsson, Olafsson, Sigfusson, & Thorsteinsson, 1974; Barnes, Van Steyn, & Fischer, 2001; Kronberg, Broström, & Söderlund, 1990; Murray, Gore, Gardner, & Mollinger, 1985). The findings of the impact of hand dominance on ROM, however, are not consistent. Some authors reported passive external rotation ROM to be similar in dominant and
nondominant shoulders (Allander et al., 1974; Kronberg et al., 1990). In contrast, two studies that investigated active and passive external rotation ROM reported conflicting findings. A study of 280 healthy subjects aged 4-70 demonstrated significantly greater active and passive external rotation ROM in the dominant shoulder (Barnes et al., 2001; Riddle, Rothstein, & Lamb, 1987). However, significantly less passive and active external rotation was observed in dominant shoulders compared non-dominant shoulders in a group of 1000 male military recruits (Gunal, Kose, Erdogan, Gokturk, & Seber, 1996).

External rotation ROM is limited by different structures in different shoulder positions. Many ligaments of the glenohumeral joint have significant roles in restraining external rotation (Kuhn et al., 2005). A cadaveric study by Ferrari et al. reported that the coracohumeral ligament provides the primary passive constraint to shoulder external rotation between 0 and 60° of shoulder abduction. Between 60° and 90° of shoulder abduction, the middle glenohumeral ligament becomes the primary passive restraint to shoulder external rotation range of motion (Ferrari, 1990). At 90° of abduction and above, the inferior glenohumeral ligament develops the most strain, therefore restricting external rotation ROM in these positions (O'Connell, Nuber, Mileski, & Lautenschlager, 1990). Active and passive external rotation ROM is also dependent on the function of the rotator cuff, with infraspinatus and teres minor acting concentrically as shoulder external rotators and subscapularis eccentrically providing a dynamic restraint to external rotation ROM in both adducted and abducted shoulder positions (Kuhn et al., 2005; Palastanga, Field, & Soames, 2006). Kuhn et al. also demonstrated that the long head of biceps provides a dynamic restraint to shoulder external rotation in the abducted position (Kuhn et al., 2005). It is therefore expected that different shoulder positions will yield different ranges of shoulder external rotation ROM as different anatomic structures are stressed.

The impact of shoulder position when testing shoulder external rotation ROM has been a lesser focus in previous research. Three studies measured active and passive external rotation ROM in two
positions of shoulder abduction (0 and 90°), two studies carried out both measures with the patient supine (Barnes et al., 2001; Kronberg et al., 1990) and one in sitting and supine (sitting with the shoulder at 0° abduction and supine with 90° abduction) (J.-S. Roy et al., 2009). All three studies found significantly greater active and passive ROM in the 90° of abduction position, as would be expected based on the shoulder anatomy described above. However, the studies had conflicting findings regarding the impact of hand dominance in the two positions. Barnes et al. demonstrated greater active and passive external rotation ROM in the dominant arm regardless of position whereas Kronberg et al. found no difference in external rotation ROM in dominant and non-dominant shoulders regardless of position. Roy et al. found significantly increased ROM in the dominant shoulder when external rotation was measured in supine but no difference between dominant and non-dominant shoulders when measured in sitting. In addition, Roy et al. found that female subjects had significantly more active and passive external rotation ROM compared to male subjects when ROM was measured in sitting but not in supine (J.-S. Roy et al., 2009). No studies have examined external rotation in other positions of abduction.

The purpose of this study was to examine the effect of sex, handedness, and shoulder position on active and passive shoulder external rotation ROM. The positions were chosen to reflect the testing positions most commonly used in clinical practice: shoulder external rotation in 0° of shoulder abduction with the subject seated and shoulder external rotation with the shoulder abducted to 90° and the subject supine. Additionally, a side lying position with the shoulder abducted to 45° was chosen to provide comparison data to external rotation ROM measurements of frozen shoulder subjects where a side-lying position was necessary (Thesis Chapter 4).
METHODS

SUBJECTS

Twenty subjects were recruited by advertisement at the University of Sydney on physical and online notice boards. Power analysis for a dependent sample t-test was conducted in G*Power based on the results of a study by Gunal et al. (Gunal et al., 1996) To determine a sufficient sample size to detect a 10° difference between groups, using an alpha of 0.05, a power of 0.80, an effect size (dz = 0.8), and two tails, the desired sample size is 10. Interested staff and students of the University contacted the research team by phone or email. Potential subjects were screened for eligibility at this time. Subjects were eligible to participate if they were over 18 years old, have not had any shoulder pain in the past two years and have never had shoulder surgery.

Potentially eligible subjects were screened just prior to testing to ensure they did not have any current shoulder symptoms. Subjects were asked to perform active shoulder flexion, abduction, and external rotation in standing as well as a maximal isometric contraction of internal and external rotation. One of the researchers, an experienced physiotherapist, then performed a passive shoulder external rotation movement with over pressure with the subjects in supine and the arm abducted to 90°. Subjects were excluded if they exhibited abnormal scapulohumeral rhythm (Lucas, 1973) or experienced shoulder pain on any of the shoulder assessments.

ETHICS AND CONSENT

Ethics approval was obtained from The University of Sydney Human Research Ethics Committee (Ethics protocol number: 2015/001). Following confirmation of eligibility subjects were given the opportunity to ask questions relating to the study before giving written consent to participate (Appendix A).
OUTCOME MEASURES

The primary outcome measures were active and passive external rotation ROM.

Active External Rotation Range of Motion

Active shoulder external rotation ROM was measured bilaterally with a goniometer in two positions, seated and supine lying in a random order.

Sitting (0° shoulder abduction): The subject was seated with the arm by the side and the elbow flexed to 90°. The subject was then asked to maximally externally rotate their shoulder. The centre of the goniometer was positioned above the axis of the glenohumeral joint. ER ROM was measured as the angle between a line representing the sagittal plane and a line through the longitudinal axis of the forearm, using the acromioclavicular joint and the radial styloid process as landmarks for the alignment of the goniometer (Figure 3.1).

Figure 3.1: Measurement of Active Shoulder External Rotation in sitting.
Supine (90° shoulder abduction): The subject was lying supine with the shoulder abducted to 90° and the elbow flexed to 90°. The centre of the goniometer was aligned with the olecranon process of the elbow. The angle between the vertical line and the line of subjects’ forearm, along a line from the olecranon process of the elbow to the ulna styloid process was measured (Figure 3.2).

![Measurement of Active Shoulder External Rotation in supine.](image)

**Figure 3.2: Measurement of Active Shoulder External Rotation in supine.**

**Passive External Rotation Range of Motion**

A custom-built arm frame was used to measure passive external rotation ROM. The frame was instrumented with a potentiometer (Vishay Model 357, Germany) to measure the external rotation angle and a force transducer (XTran, Model S1W 250N, Applied Measurement PTY. LTD., Australia) attached 0.33 m from the axis of rotation was used to standardise the torque that was applied to the subject’s arm when assessing maximal range. The angle and force signals were recorded using a 32-bit analogue to digital converter (cDAC 9171, National Instruments, TX, USA) and LABVIEW software at a sample rate of 100 Hz. With elbow maintained in 90° of flexion, the subject’s arm was strapped firmly into the arm frame using velcro straps. Passive external rotation ROM was measured in sitting,
side lying and supine. For the seated measurement, external rotation was measured with the arm by the side. In side-lying, the arm was abducted to 45° and supported with a cushion between the subject’s trunk and upper arm. For the supine position, the shoulder was positioned in 90° of abduction in the coronal plane with the upper arm supported on a treatment table.

For each movement, the subject was asked to relax their arm as much as possible. The arm was then moved into external rotation by one of the researchers until a torque of 5 Nm was reached. The torque target used was established from pilot testing of the force normally applied by two of the researchers who were experienced physiotherapists when testing passive external rotation ROM.

PROCEDURE

Each subject’s age and handedness were recorded. Prior to commencing active and passive ROM testing, subjects performed a short warm up of 5-10 repetitions of active external rotation in neutral and in 90° shoulder abduction. This was to ensure that subjects understood how to perform the movements without the use of compensatory strategies and to reduce the risk of injury. Both shoulders were tested in random order.

The order of tests was block randomised for subject position using the random number generator function in Microsoft Excel. All measurements were repeated three times. The subjects position was stabilised by the arm frame and by using a chairs with back support to prevent compensatory movement strategies. The average of the three trials for each active and passive ROM measurement was used for analysis.

STATISTICAL ANALYSIS

Descriptive statistics for ROM, age and sex were calculated. Three factor Mixed-model analysis was used to determine the effect of body position, hand dominance and sex on active and passive ROM. Multiple pairwise comparisons with Bonferroni adjustment were used for identifying differences
between levels when significant effects were found using SPSS software (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp).

RESULTS

Ten female and ten male subjects entered the study. The average age of subjects was 45 years (range 25-69). Seventeen subjects were right hand dominant. None of the subjects reported shoulder pain or discomfort during testing and all subjects completed the study.

Active vs Passive Range of Motion

Passive ROM was significantly greater than active ROM (mean 95° vs 70°, p<0.001, F(1,143)=118.65).

Active Range of Motion

Subjects had significantly greater active ROM in supine compared to sitting (mean=81° vs 59°, p<0.001, F(1,72)=67.14, Figure 3.3). There was no significant difference in active ROM between male and female subjects (p=0.08, F(1,72)=3.16) or between the dominant and non-dominant shoulder (p=0.46, F(1,72)=0.56). No significant interactions were found (p>0.48).

Figure 3.3: Active shoulder external rotation range of motion.

Passive Range of Motion
The results for passive external rotation range of motion measurements are displayed in Figure 3.4. There was a significant effect of body position (p<0.001, F(2,107)=21.53). Subjects had significantly greater passive ER in supine (mean=106°) compared to sitting (mean=84°, p<0.001) or side-lying (mean=86°, p<0.001) positions, with no difference between sitting and side lying (p=1.00). Females had significantly more passive ROM compared to males (mean=98° vs 86°, p<0.001, F(1,107)=17.13, Table 3.1). There was no significant difference in passive ROM between the dominant and non-dominant side (p=0.22, F(1,107)=1.51). No significant interactions were found (p>0.28).

**Figure 3.4:** Passive shoulder external rotation range of motion.
Table 3.1: Effect of sex, body position and handedness on active and passive external rotation ROM

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<th>Mean Passive ROM (degrees)</th>
<th>95% CI (degrees)</th>
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*significant difference between sexes

*significant difference compared to other positions (<0.001)
DISCUSSION

This study investigated the effect of sex, handedness, shoulder and body position on active and passive ROM. The main results can be summarised as follows: Passive external rotation ROM was significantly greater than active ROM in people with healthy shoulders. Both active and passive shoulder external rotation ROM was greater when the arm was abducted at 90° compared to lower positions of abduction. There was no difference in active or passive external rotation ROM between dominant and non-dominant shoulders. Female subjects demonstrated significantly more passive external rotation ROM than males. Both active and passive external rotation ROM was greater at 90° of shoulder abduction compared to 0° abduction in both males and females and both dominant and non-dominant sides. These findings are consistent with previous research (J.-S. Roy et al., 2009).

Anatomically, the primary passive constraint to external rotation of the shoulder between 0 and 60° of shoulder abduction is the coracohumeral ligament, between 60° and 90° of shoulder abduction is the middle glenohumeral ligament (Ferrari, 1990) and above 90° of shoulder abduction is the inferior glenohumeral ligament (O’Connell et al., 1990). Therefore, the testing position of ER has an influence on which structures are assessed and their ability to act as a restraint to ER ROM.

Active ROM was greater than passive ROM in both males and females and in dominant and non-dominant shoulders. This finding was expected and in agreement with other studies (Barnes et al., 2001; J.-S. Roy et al., 2009). Passive ROM may be greater as it is performed by the examiner with the subjects arm relaxed allowing the joint to be moved further into range and stretching elastic soft tissues.

This study confirms the findings of others that have demonstrated increased passive ER ROM in females compared to males (Allander et al., 1974; Barnes et al., 2001; Kronberg et al., 1990). However, the lack of difference in active ER ROM between males and females conflicts previous research which has shown females to have greater active ER ROM (Allander et al., 1974; Barnes et al., 2001; J.-S. Roy et al., 2009). Other factors such as occupation or level of sports participation that
have previously hypothesised to affect shoulder ROM (Allander et al., 1974) do not appear to play a role in the conflicting findings as, these, even though not recorded in our study, have previously shown not to have an effect on shoulder ROM (Barnes et al., 2001). Equally, the method of measuring ROM does not appear to be a factor as goniometry was used in all studies and has been demonstrated to be reliable for upper limb ROM assessment, particularly when the same observer is responsible for repeated measurements (Mayerson & Milano, 1984).

Dominant and non-dominant shoulders exhibited similar magnitudes of passive ROM in this study, supporting the findings of Allander et al. and Kronberg et al. and but conflicting the findings of studies by Barnes et al. and Gunal et al. that found significant, but opposite, differences in active and passive external rotation ROM between dominant and non-dominant shoulders (Allander et al., 1974; Barnes et al., 2001; Kronberg et al., 1990). It is unclear what causes these conflicting findings.

Normal shoulder external rotation ROM with the shoulder abducted at 45° has not previously been investigated. While healthy subjects exhibit significantly greater passive ROM in 90° degrees of shoulder compared to 0° abduction, there is no significant difference in external rotation ROM between 45° abduction and 0° abduction. This result might be expected as the coracohumeral ligament is the primary restraint between 0° and 60° abduction, therefore the primary structure limiting shoulder external rotation ROM in the 0° and 45° abducted positions. As external rotation ROM measures from both positions yield similar results, they can be used interchangeably in clinical practice.

The results of this study indicate that the position of side-lying with 45° of shoulder abduction in the operating theatre in the frozen shoulder study (as required in preparation for the shoulder surgery) can be used as it yields similar results to shoulder external rotation measured with the arm by the side which is the typical position used by clinicians to assess external rotation ROM limitations in people with frozen shoulder.
REFERENCES


CHAPTER 4 – Active Stiffness in Frozen Shoulder

Publication Title: Capsular contracture is not a major contributor to range of motion loss in some patients with frozen shoulder.

As co-authors of the paper, ‘Capsular contracture is not a major contributor to range of motion loss in some patients with frozen shoulder.’, we confirm that Luise Hollmann has made the following contributions:

- Conception and design of the research
- Ethics Application
- Data collection
- Data processing
- Analysis and interpretation of findings
- Writing the paper and critical appraisal of content
- Final editing of article for publication

Signature:  
Associate Professor Karen Ginn  
Date: 28.2.2017

Signature:  
Dr Mark Halaki  
Date: 28.2.2017
Submitted to the New England Journal of Medicine

Please review the Supplemental Files folder to review documents not compiled in the PDF.

Capsular contracture is not a major contributor to range of motion loss in some patients with frozen shoulder.

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<td>Abstract:</td>
<td>This case series of five subjects with frozen shoulder demonstrates that capsular contracture is not a major contributor to movement restriction in all patients who exhibit classical clinical features of frozen shoulder. Although all five cases presented with painful, global restriction of passive shoulder movement, four subjects demonstrated significantly greater abduction range of motion (ROM) and three demonstrated significantly greater external rotation ROM under anaesthesia. These findings highlight the need to reconsider our understanding of the pathology of frozen shoulder and offer an explanation for why treatment aimed at stretching tight passive structures has not proven to be more effective.</td>
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Capsular contracture is not a major contributor to range of motion loss in some patients with frozen shoulder.

ABSTRACT

This case series of five subjects with frozen shoulder demonstrates that capsular contracture is not a major contributor to movement restriction in all patients who exhibit classical clinical features of frozen shoulder. Although all five cases presented with painful, global restriction of passive shoulder movement, four subjects demonstrated significantly greater abduction range of motion (ROM) and three demonstrated significantly greater external rotation ROM under anaesthesia. These findings highlight the need to reconsider our understanding of the pathology of frozen shoulder and offer an explanation for why treatment aimed at stretching tight passive structures has not proven to be more effective.

INTRODUCTION

Frozen shoulder has puzzled the medical community since it was first described in the late 19th century. It occurs in 5–10% of the general population and up to 29% of the diabetic population.(Balci, Balci, & Tüzüner, 1999; Pal, Anderson, Dick, & Griffiths, 1986; Walker-Bone, Palmer, Reading, Coggon, & Cooper, 2004) It is characterized by spontaneous onset of pain with progressive, marked active and passive stiffness at the glenohumeral joint(Bo J Lundberg, 1969; Nash & Hazleman, 1989) usually resulting in gross loss of function.(Reeves, 1975) The condition is described as self-limiting with gradual return of painfree shoulder function after an average of 1-3 years.(C. Hand, Clipsham, Rees, & Carr, 2008; Reeves, 1975)

There is no definitive diagnostic test for frozen shoulder and diagnosis is based on physical examination following exclusion of osteoarthritis, locked dislocations, fractures or avascular necrosis as the cause of symptoms.(Tim Bunker, 2009) A clinical diagnosis of frozen shoulder is made if the patient has painful restriction of active and passive motion in at least two planes of shoulder movement one being external rotation.(Tim Bunker, 2009; Zuckerman & Rokito, 2011)

The pathoaetiology of frozen shoulder is not fully understood. Histological and arthroscopic studies of frozen shoulder suggest a process of chronic inflammation, fibrosis and glenohumeral joint capsule contracture is responsible for the pain and restricted range of movement (ROM) characteristic of frozen shoulder.(TD Bunker, 1997; G. Hand et al., 2007; J. S. Neviaser, 1945; Uitvlugt et al., 1993; A. Wiley, 1991) Consequently, treatment is most commonly aimed at stretching glenohumeral joint structures to restore shoulder ROM while managing pain.

Frozen shoulder is considered notoriously difficult to treat and there is no consensus regarding optimal management.(Lewis, 2015) Evidence suggests that corticosteroid injection confers significant short term benefit.(Rachelle Buchbinder et al., 2003) However there is little evidence to support the effectiveness of treatments aimed at lengthening the glenohumeral joint capsule. Physiotherapy aimed at increasing ROM is only slightly more effective than placebo injection in the short term(Carette et al., 2003); efficacy of arthroscopic capsular release is not supported by evidence from randomised control trials;(Lewis, 2015) and capsular hydrodilatation or distension is no more effective than corticosteroid injection alone.(Tveitå et al., 2008)

If frozen shoulder is caused primarily by capsular adhesions, it is surprising that treatment directed at presumed glenohumeral joint capsuloligamentous contracture has not proven to be more
successful. In addition, if the cause of movement restriction in frozen shoulder is primarily due to capsular fibrosis how can the spontaneous recovery of ROM, commonly seen with frozen shoulder after a protracted period of symptoms, be explained?

We hypothesise that factors other than adhesions of the glenohumeral joint capsule may be contributing to ROM loss in people with frozen shoulder. Protective muscle spasm, or guarding, is a common motor strategy in response to other painful musculoskeletal dysfunction, including back and neck pain, which results in decreased ROM. At the glenohumeral joint the capsule is strongly reinforced by the rotator cuff tendons and one of the normal functions of the rotator cuff muscles is to contribute to glenohumeral joint stability by tightening the capsule during movement. Given this intimate relationship between rotator cuff muscles and the glenohumeral joint capsule, it is possible that rotator cuff muscle contraction in response to pain is contributing to the movement restriction associated with frozen shoulder. (Roland, 1986) Relaxation of these muscles as pain subsides could explain why substantial improvement in shoulder ROM can be expected in most cases of frozen shoulder. Therefore, the aim of this case series was to test whether there is muscle guarding (active stiffness) component to movement restriction in patients with frozen shoulder by comparing passive shoulder ROM before and after the administration of general anaesthesia.

METHODS

PARTICIPANTS

The participating orthopaedic surgeon identified patients scheduled to undergo capsular release surgery for frozen shoulder. All potential participants had an X-ray and MRI to ensure the absence of shoulder joint osteoarthritis, fractures or dislocations. On the day of the surgery, the potential participants were screened for eligibility to participate. Patients were eligible if their shoulder pain was associated with global restriction of active and passive shoulder movement which was greater than 50% normal ROM in external rotation and at least one other plane of movement.

Patients were excluded if they had a history of trauma to the affected shoulder within the four weeks prior to surgery, previous surgery on the affected shoulder, shoulder pain referred from the vertebral column (defined as shoulder pain exacerbated during neck movement and/or palpation of the cervicothoracic vertebral column) or concurrent inflammatory or neurological disease involving the affected shoulder.

OUTCOME MEASURES

To minimise the time participants spent under general anaesthetic prior to surgery, only two passive shoulder ROM outcome measurements were compared before and after general anaesthesia: external rotation ROM because passive restriction in this direction is one of the diagnostic criteria for frozen shoulder (Tim Bunker, 2009); and abduction ROM because it could readily be measured in the side-lying position required by the orthopaedic surgeon. A portable custom built arm frame instrumented with a potentiometer (Vishay Model 357, Germany) and a force transducer (XTran, Model S1W 250N, Applied Measurement PTY. LTD., Australia) was constructed to standardise the force applied to each participant’s arm to achieve maximum passive external rotation ROM. The participant’s arm was strapped into the arm frame which maintained the elbow in 90 degrees of flexion and shoulder in 45 degrees abduction. Both shoulder external rotation angle and torque applied were recorded at a sample rate of 100 Hz using a 32-bit analogue to digital converter (cDAC 9171, National Instruments, TX, USA) and LABVIEW software. Abduction ROM was measured by passively moving the participant’s arm through range. Maximal achieved abduction ROM was measured from a digital photograph by measuring the angle at the intersection of a horizontal reference line and a line between the acromion process and the lateral epicondyle. (Figures 1-3).
PROCEDURE

On the day of the scheduled surgery, researchers met potentially eligible patients and described the aim and design of the study. For patients who were willing to participate, active and passive movements of shoulder flexion, abduction, external rotation with arm by the side and hand-behind-back were conducted on the affected shoulder to confirm eligibility. As is common clinical practice, these movements were performed with the patient standing and measured with a goniometer. Following confirmation that all inclusion and exclusion criteria were met, participants signed a consent form and demographic data were collected, including age, handedness and duration of symptoms. To determine the impact of frozen shoulder on their quality of life, participants completed the Shoulder Pain and Disability Index (SPADI).

With the participant in side-lying, passive shoulder abduction and external rotation ROM were measured three times in random order. Each participant was asked to relax their affected shoulder while the investigator slowly moved the arm through full available range. Movement was stopped when resistance to the movement was felt or severe pain prevented further movement.

Each participant then entered the operating theatre and was administered general anaesthesia. The researchers then entered the operating theatre and repeated the passive shoulder ROM measures. For external rotation ROM measurements which were not limited by severe pain preanaesthesia, the same maximum force achieved during the pre-anaesthetic condition was applied. For subjects who experienced severe pain which limited ER ROM preanaesthesia force was applied gradually until resistance to movement was felt. Following completion of passive external rotation and abduction ROM measurements, the participant was left under the care of the treating shoulder surgeon.

RESULTS

Three females and two males volunteered to participate in the study. Participants ranged from 51 to 64 years of age, with symptoms ranging from 6 to 30 months. None of the subjects were diabetic and the non-dominant shoulder was affected in three subjects. SPADI scores ranged from 67 to 87, indicating moderate to high levels of pain and disability.

Passive abduction ROM increased following anaesthesia in all subjects, with increases ranging from $53^\circ$ to $111^\circ$ (Figures 1-3). For one subject, passive external rotation ROM measured in the arm frame in a side-lying position at $45^\circ$ abduction was within normal limits ($75^\circ$) initially and did not increase following general anaesthesia (Figure 2). For the four subjects who demonstrated passive external rotation ROM restriction initially, the ROM increased in three subjects (by $20^\circ$, $27^\circ$ and $44^\circ$) following anaesthesia (Figure 1) and did not change in one subject (Figure 3).
Figure 1: Passive abduction and external rotation range of motion pre and post general anaesthetic. Subjects that exhibited significantly greater passive abduction and external rotation ROM under general anaesthesia compared to awake.

Subject 1

Abduction
External Rotation

Pre
Post

47° 152°

-4
0
2
4
6
8

-20 0 20 40 60 80

Applied Torque (Nm)

External Rotation angle (degrees)

Subject 2

Abduction
External Rotation

Pre
Post

70° 153°

-2
0
2
4
6
8

-20 0 20 40 60 80

Applied Torque (Nm)

External Rotation angle (degrees)

Subject 3

Abduction
External Rotation

Pre
Post

53° 164°

-2
0
2
4
6
8

-20 0 20 40 60 80

Applied Torque (Nm)

External Rotation angle (degrees)
**Figure 2:** Passive abduction and external rotation range of motion pre and post general anaesthetic. Subject that exhibited significantly greater passive abduction ROM under general anaesthesia compared to awake but demonstrated normal external rotation ROM under both conditions.

**Subject 4**

Premedication | Postmedication
--- | ---
Abduction | Abduction
Pre | Post
90° | 144°

**Figure 3:** Passive abduction and external rotation range of motion pre and post general anaesthetic. Subject that exhibited significant glenohumeral stiffness awake and under general anaesthesia.

**Subject 5**

Premedication | Postmedication
--- | ---
Abduction | Abduction
Pre | Post
63° | 116°
DISCUSSION

The accurate assessment of passive shoulder ROM is essential to determine the contribution of tight connective tissue structures to shoulder ROM deficits, as it is the critical criterion for frozen shoulder diagnosis in the clinic and guides treatment decisions. This is the first study to report passive ROM in patients diagnosed with frozen shoulder, without the confounding variables of pain and voluntary muscle contraction. All five subjects demonstrated an increase in passive shoulder abduction ROM following anaesthesia (Figures 1-3). As the scapula was not stabilised during measurement, these increases cannot be attributed solely to increased glenohumeral joint ROM. However, the large increases in passive abduction ROM (53° to 111°) indicate that the abduction movement restriction cannot be attributed solely to contracture of the glenohumeral joint capsule. Rather, active stiffness (muscle guarding) is likely to be a significant contributing factor.

Increases in passive shoulder external rotation ROM in this study further highlight the role of active stiffness to movement restriction in some patients diagnosed with frozen shoulder. In addition to increased abduction ROM, three of the five subjects demonstrated large increases in passive glenohumeral joint external rotation ROM under anaesthetic (Figure 1). At the same external rotation force level applied pre-anaesthetic, passive external rotation ROM increased by 20° to 44° (Figure 1).

For two subjects in this study, passive shoulder external ROM did not increase when measured during anaesthesia. However, only one of these subjects would have met the critical physical assessment criterion for a diagnosis of frozen shoulder (i.e. passive restriction in shoulder external rotation ROM) when measured under anaesthetic in the absence of pain and voluntary muscle contraction. This subject, who had the smallest increase in passive shoulder abduction ROM (53°) and had the longest duration of symptoms (30 months) in the small cohort examined, recorded passive external rotation ROM of 21°, which did not change under general anaesthesia (Figure 3). This result suggests that shortening of passive shoulder structures may be the result of protracted frozen shoulder signs and symptoms, warranting further research.

The remaining subject who did not record an increase in shoulder external rotation ROM following anaesthetic had a pre-anaesthetic external rotation ROM within normal limits. This subject satisfied the inclusion criterion of significantly restricted passive external rotation when measured with the arm by the side. However, when measured in side-lying position using the arm frame prior to anaesthesia, a passive shoulder external rotation range of 75° was recorded, and this range did not increase when repeated following general anaesthesia (Figure 2). If this subject was able to fully relax and/or experienced less pain when their arm was supported in the arm frame in the side-lying position, reduced muscle guarding could explain this result. Given that decreased passive external rotation ROM is the critical physical examination finding required to establish a diagnosis of frozen shoulder, current clinical practice appears to be inadequate to accurately assess this shoulder sign.

The results of this study have significant implications for understanding the pathophysiology, clinical assessment and treatment of frozen shoulder. In patients with painful, restricted shoulder movement, both tightness of passive structures and muscle guarding (active stiffness) have been shown to contribute to restricted ROM, with muscle guarding being the most significant factor in this small cohort. If movement restriction is largely due to muscle guarding, presumably in response to pain, then treatment aimed at stretching tight structures, which often causes pain, will be of limited benefit.

In addition, the accuracy of assessment of passive shoulder ROM in the presence of pain has been shown to be poor, drawing into question the validity of physical assessment procedures crucial to the diagnosis of frozen shoulder. As demonstrated by one subject in this study (Figure 2) a more
careful, thorough clinical assessment of passive ROM could identify some patients whose restricted, painful shoulder dysfunction is predominantly due to muscle guarding. However, the results of this study suggest that to definitively identify the cause of movement restriction in patients with frozen shoulder, and thus implement an appropriate care pathway, assessment of passive ROM under anaesthetic may be necessary.

REFERENCES

Chapter 4.1 Active Stiffness in Frozen Shoulder
– Additional Methods

SUBJECTS

Active and passive movements of flexion, abduction, external rotation with arm by the side and hand behind back were conducted on the affected shoulder. As is common clinical practice these movements were performed with the patient standing and measured with a goniometer. The neck was screened as a potential source of symptoms by asking the patient to perform active neck flexion, extension, rotation and lateral flexion as well as palpation of the cervicothoracic spine.

Patients were eligible to participate if they had a diagnosis of unilateral frozen shoulder defined by pain over the shoulder joint and/or into the proximal arm exacerbated by active shoulder movement and if their shoulder pain was associated with global restriction of active and passive shoulder movement which was greater than 50% normal ROM in external rotation and at least one other plane of movement.

Patients were excluded if they had a history of trauma to the affected shoulder within the past 4 weeks, a prior history of surgery on the affected shoulder, shoulder pain referred by the vertebral column (defined as shoulder pain exacerbated during neck movement and/or palpation of the cervicothoracic vertebral column) or concurrent inflammatory or neurological symptoms that may affect the shoulder.

ETHICS

Ethics approval was obtained from the Joint University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee and The University of Sydney Human Research Ethics Committee (Ethics number: H12/434, Appendix A).

CONSENT
Following confirmation of eligibility to participate patients were given the opportunity to ask questions relating to the study following which patients who agreed to participate signed a consent form (Appendix A).

**OUTCOME MEASURES**

The primary outcome measures were passive shoulder abduction ROM and passive shoulder external rotation ROM. All outcome measures were completed with the patient in side lying as this was the position required by the orthopaedic surgeon in preparation for the surgical procedure. All measures were recorded while the patient was awake and compared to the same measures recorded with the patient under general anaesthesia.

To avoid prolonging the time that each participant spent under general anaesthetic prior to their surgical procedure, only two passive ROM measurements were chosen. External rotation was chosen because passive restriction in this direction is one of the diagnostic criteria for frozen shoulder (R. Buchbinder et al., 2004; TD Bunker, 1997) Shoulder abduction was chosen because it could readily be measured in the sidelying position in the operating theatre.

A portable custom built arm frame instrumented with a potentiometer (Vishay Model 357, Germany) and a force transducer (XTran, Model S1W 250N, Applied Measurement PTY. LTD., Australia) was constructed to standardise the force applied to each participant’s arm to achieve maximum passive external rotation ROM. The participant’s arm was strapped into the arm frame which maintained the elbow in 90 degrees of flexion and shoulder in 45 degrees abduction. Both shoulder external rotation angle and torque applied were recorded at a sample rate of 100 Hz using a 32-bit analogue to digital converter (cDAC 9171, National Instruments, TX, USA) and LABVIEW software.

To measure passive abduction ROM, the arm was moved to maximal shoulder abduction by one of the researchers. The movement was stopped when the researcher felt that resistance to the
movement was felt. Maximal achieved abduction ROM was measured from a digital photograph by measuring the angle at the intersection of a horizontal reference line and a line between the acromion process and the lateral epicondyle (Figure 4.1.1). A software program, PhiMatrix Golden Ration Design and Analysis software (http://www.phimatrix.com/download-golden-ratio-design/) was used to draw lines between markers & measure abduction angle.

Figure 4.1.1: Passive Shoulder abduction ROM measurement

PROCEDURES

For all eligible participants enrolled in the study, a more comprehensive patient interview and physical examination were conducted to build a better clinical picture of each frozen shoulder case.

Each participants’ date of birth, handedness and complete history of shoulder pain, including details relating to the onset of shoulder pain, the duration of symptoms, pain levels at rest, pain levels at night, current use of pain medication and details of any previous episodes of shoulder pain were recorded. All participants completed the SPADI (Shoulder Pain and Disability Index) and PCS (Pain Catastrophizing Scale) questionnaires (Appendix B).
The SPADI was chosen as it is a commonly used clinical tool to assess a patient’s current shoulder pain and disability. It contains a total of 13 items, including a 5-item pain subscale and a 8-item disability subscale. Each subscale is summed and transformed to a score out of 100. A mean is taken of the two subscales to give a total score out of 100 with a higher score indicating greater shoulder disability. The SPADI has demonstrated good construct validity, high internal consistency and correlates well with other region-specific shoulder questionnaires (Paul et al., 2004; Roy, MacDermid, & Woodhouse, 2009).

The PCS is widely used instruments for measuring catastrophic thinking related to pain and is used extensively in clinical practice and in research. It was developed to quantify an individual’s pain experience. Pain catastrophizing is the tendency to magnify the threat value of a pain stimulus and has been found to be a significant factor in other chronic conditions, particularly in patients with nonspecific low back pain. The PCS has been validated and has shown to have adequate to excellent internal consistency (Osman et al., 1997; Sullivan, Bishop, & Pivik, 1995). The three subscale scores of the PCS assess rumination, magnification and helplessness and are added to a total score of 0-52 with a score of ≥30 indicating a clinically relevant level of catastrophizing (Sullivan et al., 1995).

To build a full clinical picture of each subject’s overall shoulder movement, active shoulder flexion, abduction and external rotation on the affected side were then recorded using digital photography. Small white marker stickers were attached to anatomical landmarks on the participants’ spine, shoulder and arm to allow accurate ROM measurements to be taken from the digital photographs. Hand behind back movement was measured with a tape measure. The order of tests was randomised using the Microsoft Excel random number generator function. The patient was instructed to move their arm as far as they could and, due to the painful nature of frozen shoulder, participants only performed each active movement once.

ROM measures to provide a clinical picture of each patient’s movement restriction:
Hand behind back movement was recorded with digital photography and measured with a tape measure. The patient was asked to move their hand behind their back and move it upwards as far as possible along their spine. The distance from the radial styloid process of the forearm to the spinous process of T1 was measured with a tape measure. Measurements were recorded for the affected and unaffected side (Figure 4.1.2).

**Figure 4.1.2:** Hand behind back ROM measurement

To measure active shoulder abduction ROM, a photograph was taken from behind the patient. The angle of shoulder abduction ROM was measured between a vertical line and a line from markers on the acromion process of the shoulder and the lateral epicondyle of the elbow.

Active shoulder flexion ROM was measured by taking a photograph taken side on to the patient’s affected shoulder. The angle of shoulder flexion ROM was measured at the intersection of a straight line drawn from the markers 6cm below the lateral angle of the acromion process and the olecranon
process and a straight line drawn from the end of the 12th rib and the marker 6cm below the lateral angle of the acromion process.

Active shoulder external rotation ROM was measured by taking a photograph was taken from above the patient. A long ruler was placed on the floor to indicate the neutral (starting) position of the patients arm at 0 degrees of rotation. The angle was measured between this straight line and another line drawn from the markers on the lateral angle of the acromion process and the radial styloid process.

Following these, passive abduction and external rotation ROM were measured as described in the outcomes section. Each measurement was repeated three times. During these measurements, the subject was asked to relax their affected shoulder and arm as much as possible while the investigator slowly moved the arm through full available range.

The subject then entered the operating theatre and was anaesthetised and positioned in side lying in preparation for surgery. The researchers entered the operating theatre once the subject was fully anesthetised to repeat the passive abduction and passive external rotation ROM measures as described earlier. At the conclusion of these tests, the patient was left under the care of the treating shoulder surgeon.
REFERENCES


Chapter 4.2 Active Stiffness in Frozen Shoulder – Additional Results

Three females and two males volunteered to participate in the study. Participants ranged from 51 to 64 years of age, with symptoms ranging from 6 to 30 months (Table 4.2.1). None of the subjects were diabetic and the non-dominant shoulder was affected in three subjects. SPADI scores ranged from 67 to 87, indicating moderate to high levels of pain and disability in all participants. PCS Scores ranged from 0 to 49, with two subjects (subject 1 and 4) indicating very low levels of pain catastrophizing while the others (subject 2, 3 and 5) exhibited very high levels of catastrophizing (Table 4.2.1).

Table 4.2.1: Participant demographic information, SPADI and PCS Scores

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<td>30</td>
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</table>

D= Dominant, ND=Non-dominant

All subjects demonstrated global restriction of active and passive ROM (Tables 4.2.2 and 4.2.3). The degree of passive abduction was variable between subjects but passive abduction ROM increased following anaesthesia in all subjects, with increases ranging from $53^\circ$ to $111^\circ$ (Table 4.2.3). For one subject, passive external rotation ROM measured in the arm frame in a side-lying position at $45^\circ$ abduction was within normal limits ($75^\circ$) initially and did not increase following general anaesthesia (Table 4.2.3). For the four subjects who demonstrated passive external rotation ROM restriction initially, the ROM increased in three subjects (by $20^\circ$, $27^\circ$ and $44^\circ$) following anaesthesia and did not
change in one subject (Table 4.2.3). The subject with the smallest increase in passive abduction and
passive external rotation under anaesthesia (subject 5) also exhibited the most significant
movement restriction actively. All subjects reported pain with active and passive ROM testing,
aranging from 3 to 10/10 on a numerical rating scale.

### Table 4.2.2: Active ROM measures

<table>
<thead>
<tr>
<th>Active Movement</th>
<th>Subject 1</th>
<th>Subject 2</th>
<th>Subject 3</th>
<th>Subject 4</th>
<th>Subject 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion (°)</td>
<td>86</td>
<td>83</td>
<td>78</td>
<td>107</td>
<td>40</td>
</tr>
<tr>
<td>External Rotation (°)</td>
<td>20</td>
<td>19</td>
<td>21</td>
<td>17</td>
<td>7</td>
</tr>
<tr>
<td>Hand behind back deficit (cm)</td>
<td>17</td>
<td>27</td>
<td>30</td>
<td>13</td>
<td>30</td>
</tr>
</tbody>
</table>

### Table 4.2.3: Passive Abduction and External Rotation ROM pre and post anaesthesia in degrees.

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>Change Pre vs Post</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Abduction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject 1</td>
<td>47</td>
<td>152</td>
<td>105</td>
</tr>
<tr>
<td>Subject 2</td>
<td>70</td>
<td>153</td>
<td>83</td>
</tr>
<tr>
<td>Subject 3</td>
<td>53</td>
<td>164</td>
<td>111</td>
</tr>
<tr>
<td>Subject 4</td>
<td>90</td>
<td>144</td>
<td>54</td>
</tr>
<tr>
<td>Subject 5</td>
<td>63</td>
<td>116</td>
<td>53</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>Change Pre vs Post</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External Rotation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject 1</td>
<td>20</td>
<td>64</td>
<td>44</td>
</tr>
<tr>
<td>Subject 2</td>
<td>26</td>
<td>46</td>
<td>20</td>
</tr>
<tr>
<td>Subject 3</td>
<td>16</td>
<td>43</td>
<td>27</td>
</tr>
<tr>
<td>Subject 4</td>
<td>75</td>
<td>74</td>
<td>1</td>
</tr>
<tr>
<td>Subject 5</td>
<td>19</td>
<td>21</td>
<td>2</td>
</tr>
</tbody>
</table>
CHAPTER 5 – CONCLUSIONS

SUMMARY OF PROJECTS

The aim of this thesis was to further the understanding of frozen shoulder by

(1) Investigating whether current evidence supports the efficacy of treatments for frozen shoulder aimed at stretching the shoulder capsule or tissues in relieving pain, improving range of motion or reducing disability in patients with frozen shoulder.

(2) Establishing the effect of body and shoulder position on active and passive shoulder external rotation ROM.

(3) Investigating whether active stiffness contributes to range of motion loss in people with frozen shoulder.

The following chapters addressed each of these research questions:

In Chapter 2, a systematic review of RCTs investigating stretch-based treatments for frozen shoulder was conducted. The results from six high quality trials that included participants based on the currently accepted diagnostic criteria for frozen shoulder were included. The treatments investigated in these studies were: Manipulation under general anaesthetic (MUA), distension, manual therapy and exercise. The effects of these treatments on range of motion, pain and function were summarized.

In Chapter 3, shoulder external rotation range of motion was investigated in 20 subjects (40 shoulders). The effect of sex, handedness, body and shoulder position on ROM were discussed and compared to the findings of previous research.

Finally, in chapter 4, the contribution of active stiffness to movement restriction in people with frozen shoulder was investigated. In a case series, passive shoulder ROM of five participants with a
diagnosis of frozen shoulder was assessed pre and post anaesthesia to establish whether passive range of motion is affected by pain or muscle guarding in the awake patient.

**SUMMARY OF MAIN FINDINGS**

*Chapter 2 – Literature Review*

Although the initial search of electronic databases yielded a large number results, including seventy-four papers that appeared to be eligible for inclusion in this review after screening their abstracts, many (fifty-five) were either not randomised, of low methodological quality (PEDro score <5) or did not state a clear diagnostic inclusion criteria for study participants with frozen shoulder. Considering that frozen shoulder is a common condition that is often addressed with a combination of physiotherapy and medical interventions, it is surprising that high quality evidence investigating the effectiveness of these treatments is scarce.

The results of the included RCTs suggest that joint distension confers some short-term benefit compared with a placebo intervention, but distension, MUA and manual therapy do not incur additional benefit with respect to pain and functional ability over cortisone injection or a home-based stretching and strengthening program in the short term. While these treatments may lead to small short term improvements in ROM in people with frozen shoulder, they do not appear to significantly alter the natural course of frozen shoulder.

*Chapter 3 – External Rotation Range of Motion in Healthy Subjects*

This study confirmed the findings of others that demonstrated that

- Active and passive shoulder external rotation ROM is greater when the arm is abducted at 90 degrees compared to lower positions of abduction, most likely as a result of the coracohumeral ligament not acting as a restraint to shoulder external rotation ROM above 60 degrees of shoulder abduction
• Passive external rotation ROM is significantly greater than active ROM in people with healthy shoulders.

This study investigated some issues that have not previously been investigated:

• Passive external rotation measured with the arm by the side or with the arm abducted to 45 degrees yields similar results, indicating that these positions may be used interchangeably in clinical practice.

Chapter 4 – Active Stiffness in Frozen Shoulder

Passive abduction and external rotation ROM was measured in participants with frozen shoulder pre and post anaesthesia. All five participants in this case series demonstrated an increase in passive shoulder abduction ROM following anaesthesia and four out of five shoulder demonstrated a significant increase in passive external rotation ROM. The large increases in ROM indicate that movement restriction cannot be attributed solely to contracture of the glenohumeral joint capsule. Active stiffness or muscle guarding appears to be a significant contributing factor to movement restriction in frozen shoulder. However, as these findings are from a small case series, further research is required to establish whether these findings can be generalised to a larger population with frozen shoulder.

CLINICAL IMPLICATIONS

• MUA, distension, and manual therapy, although commonly prescribed for people with frozen shoulder, do not significantly alter the natural history of frozen shoulder. However, the evidence in this area is limited as only a small number of RCTs have investigated the effectiveness of these treatments. Practitioners should be aware that these treatments may offer a small short term benefit but not a cure for frozen shoulder. Costs, risks and benefits of the treatments should be considered before recommending these interventions to patients. Further research is required in this area.
• Passive ROM measurements in patients with frozen shoulder are affected by pain and/or muscle guarding. Conclusions about the actual available ROM cannot be drawn from passive ROM assessment performed in a clinical setting with the patient conscious in patients with painful, restricted shoulder motion.

• Assessment of passive ROM under anaesthesia may be necessary to establish true available shoulder range of motion.

• If movement restriction in people with frozen shoulder is largely due to muscle guarding in response to pain, treatments aimed at stretching tight structures, which often causes pain, will be of limited benefit. Consideration should be given to treatments that help alleviate pain and restore pain-free shoulder function.

• The position of side lying with 45 degrees of shoulder abduction yields similar results to shoulder external rotation measured with the arm by the side and can be used if typical measurement position used clinically with the arm by the side is not possible or not desired.

• The effect of hand dominance on shoulder ROM is conflicting, therefore comparing ROM to the uninjured side in unilateral shoulder conditions is not recommended.

DIRECTIONS FOR FUTURE RESEARCH

This thesis demonstrates that capsular contracture is not solely responsible for ROM in people with frozen shoulder and it is hypothesised that ROM loss is due primarily to muscle activity of the rotator cuff, secondary to pain that leads to tightening of the shoulder capsule. Further research should focus on

1) whether findings from this case series are representative of people with frozen shoulder in general, and

2) undertaking specific measures of muscle activity to analyse whether this hypothesis is correct.
The review of the literature demonstrates that there is no universal agreement on diagnostic criteria for frozen shoulder. Several authors have expressed concern that frozen shoulder has become a catch-all term for all cases presenting with shoulder pain and stiffness (Lewis, 2015; R. J. Neviaser & Neviaser, 1987; Zuckerman & Rokito, 2011). Future research should be directed at developing reliable diagnostic criteria for frozen shoulder. However, since passive ROM measurements are affected by the presence of pain, passive ROM assessment may not be a reliable diagnostic test for frozen shoulder.

The review of the literature highlights that the understanding of the pathophysiology underlying frozen shoulder is poor. While the histological processes within the tissues of frozen shoulder and the arthroscopic appearance of the shoulder capsule are frequently described, the role of pain and inflammation and how this pathological process relates to symptoms is unclear. Recent literature in the area of chronic pain reported reorganisation within the primary motor cortex consistent with a guarding-type response at a motor planning level and an upregulation of defensive reflexes (Moseley & Butler, 2015; Wallwork, Grabherr, O’Connell, Catley, & Moseley, 2017). Further consideration should be given to changes within the primary sensorimotor cortex (central sensitisation) and resulting muscle function as a guarding or protective response in frozen shoulder.

Commonly used treatment targeting stiffness or capsular contracture result in only small short term benefits. An effective treatment for frozen shoulder remains elusive. Novel treatment approaches addressing pain and muscle function should be considered for patients with frozen shoulder.

Participants in all studies included in the systematic review showed improvements in ROM and pain from baseline to later follow-up periods, confirming that frozen shoulder has a tendency to improve over time. Therefore, it is essential to include a control group in all studies investigating treatments for frozen shoulder over time.

To assist clinicians in the assessment of shoulder conditions, further research should also focus on normative values of shoulder ROM in people with healthy shoulders. There is conflicting evidence on
the effect of handedness on ROM (Allander et al., 1974; Barnes et al., 2001; Kronberg et al., 1990; Riddle et al., 1987). Further evidence is needed to clarify the effect of handedness on range of motion.
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glenohumeral joint: ligament restraints and muscle effects in the neutral and abducted


Measures of Stiffness in the normal Shoulder

PARTICIPANT INFORMATION STATEMENT

(1) What is the study about?

You are invited to participate in a study to measure stiffness in normal shoulders. The aim of this study is to establish the amount of stiffness in normal, healthy shoulders.

(2) Who is carrying out the study?

The study is being conducted by Ms Luise Hollmann and will form the basis for the degree of Master of Philosophy at The University of Sydney under the supervision of Associate Professor Karen Ginn. Ms Luise Hollmann is a qualified Physiotherapist.

(3) What does the study involve?

If you agree to participate, you will be invited to attend a single session at the shoulder laboratory at the University of Sydney Cumberland Campus. We will perform a few simple shoulder tests to make sure your shoulder is completely pain free.

We will take some measurements to assess the movement of your shoulder. For all movements, you will be asked to relax your arm as much as possible while one of the researchers will assess how far they can move your arm passively (lifting the arm forward, lifting the arm out to the side and shoulder rotation). We will also place some markers onto your arm and take digital photographs. These photographs will be used to accurately measure the range of motion of your shoulder. During the tests, a device will be secured to your arm and shoulder to measure the load required to move your shoulder. These measurements will be performed in sitting, standing and side lying and each measurement will be repeated three times. This assessment should not cause any pain or discomfort and you will be able to tell the assessor to stop at any time.

(4) How much time will the study take?

The measurements on your shoulder will take about 45 minutes.

(5) Can I withdraw from the study?

Being in this study is completely voluntary - you are not under any obligation to consent and - if you do consent - you can withdraw at any time without affecting your relationship with The University of Sydney or any of the researchers.
(6) Will anyone else know the results?

All aspects of the study, including results, will be strictly confidential and only the researchers will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

(7) What will happen to the information collected about me?

All information will be safely stored on password protected laptops and locked cabinets at the University of Sydney for a period of 7 years. This is to comply with the National Ethical Conduct guidelines and Sydney University requirements. All data will be destroyed after this time.

(8) Will the study benefit me?

We cannot and do not guarantee or promise that you will receive any benefits from the study.

(9) Can I tell other people about the study?

Yes, you can openly discuss your participation in this study with others.

(10) What if I require further information about the study or my involvement in it?

When you have read this information, Ms Luise Hollmann will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Associate Professor Karen Ginn (Discipline of Biomedical Science) by email (Karen.Ginn@sydney.edu.au) or phone (02 9351 9552)

(11) What if I have a complaint or any concerns?

Any person with concerns or complaints about the conduct of a research study can contact The Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone), +61 2 8627 8177 (Facsimile) or humanethics@sydney.edu.au (Email).

This information sheet is for you to keep
PARTICIPANT CONSENT FORM

I, ..........................................................................................[PRINT NAME], give consent to my participation in the research project

TITLE: MEASURES OF STIFFNESS IN THE NORMAL SHOULDER

In giving my consent I acknowledge that:

1. The procedures required for the project and the time involved have been explained to me, including any inconvenience or discomfort and their implications, and any questions I have about the project have been answered to my satisfaction.

2. I have read the Participant Information Statement and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.

3. I understand that being in this study is completely voluntary – I am not under any obligation to consent.

4. I understand that my involvement is strictly confidential. I understand that any research data gathered from the results of the study may be published however no information about me will be used in any way that is identifiable.

5. I understand that I can withdraw from the study at any time, without affecting my relationship with the researchers or the University of Sydney now or in the future.
6. I consent to:
   - Receiving Feedback  YES  ☐  NO  ☐

   If you answered YES to the “Receiving Feedback” question, please provide your details i.e. mailing address, email address.

   **Feedback Option**

   **Address:**
   
   ______________________________________________________
   ______________________________________________________

   **Email:**
   ______________________________________________________

   ..............................................................

   Signature

   ..............................................................

   Please PRINT name

   ..............................................................

   Date
Active Stiffness is Frozen Shoulder

PARTICIPANT INFORMATION STATEMENT

(1) What is the study about?

You are invited to participate in a study on active stiffness in frozen shoulder. The aim of this study is to establish to what extent 'active stiffness' or muscle guarding contributes to movement restriction in people with frozen shoulder.

(2) Who is carrying out the study?

The study is being conducted by Ms Luise Hollmann and will form the basis for the degree of Master of Philosophy at The University of Sydney under the supervision of Associate Professor Karen Ginn. Ms Luise Hollmann is a qualified Physiotherapist.

(3) What does the study involve?

If you agree to participate, you will be invited to attend a pre-operative appointment at Wollongong/Macquarie Hospital no more than two weeks prior to your operation. At this appointment, one of the researchers will take a detailed history of your shoulder problem to establish whether you are suitable to participate in this study. If you are eligible, you will be asked to complete two questionnaires. These questionnaires are used to assess the level of pain, disability and atrophy you experience as a result of your frozen shoulder.

At this pre-operative appointment, we will take some measurements to assess the movement of your shoulder. Firstly, you will be asked to move your arm yourself as far as possible into three different positions (lifting the arm out to the side, rotation, and putting your hand behind your back). Secondly, you will be asked to relax your arm as much as possible while one of the researchers will assess how far it can move your arm passively into the same positions (lifting the arm out to the side, rotation, and putting your hand behind your back). We will also take some markers onto your arm and take digital photographs. These photographs will be used to accurately measure the range of motion of your shoulder. During the rotation tests, a device will be secured to your arm and shoulder to measure the load required to move your shoulder. This assessment may cause some pain and discomfort but you will be able to tell the assessor to stop at any time.

To help us determine assess muscular and joint stiffness in your shoulder, we will perform some gentle movements (mobilisations) at your shoulder for about two minutes. These mobilisations will not be painful but you may feel uncomfortable. Your shoulder will then be re-assessed the same way as mentioned above to see whether the mobilisation techniques have had any effect on your shoulder movement.
On the day of your operation, while you are under general anaesthetic and just prior to your surgery, we will repeat two of the passive movements performed while you were awake (lifting the arm to the side and rotation) and these measurements will be recorded in the same way as pre-operatively. No further testing is required after your operation.

(4) How much time will the study take?

Discussing the history of shoulder at your pre-operative appointment will take 10 minutes. The two questionnaires you will be asked to complete will take approximately 5-10 minutes each. Measurements and testing of your shoulder taken while you are awake will take no longer than 15 minutes. The measurements repeated under general anaesthetic and will also take approximately 10 minutes.

(5) Can I withdraw from the study?

Being in this study is completely voluntary - you are not under any obligation to consent and - if you do consent - you can withdraw at any time without affecting your relationship with The University of Sydney, Wollongong Hospital or Macquarie University Hospital.

(6) Will anyone else know the results?

All aspects of the study, including results, will be strictly confidential and only the researchers will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

(7) What will happen to the information collected about me?

All information will be safely stored on password protected laptops and locked cabinets at the University of Sydney for a period of 7 years. This is to comply with the National Ethical Conduct guidelines and Sydney University requirements. All data will be destroyed after this time.

(8) Will the study benefit me?

We cannot and do not guarantee or promise that you will receive any benefits from the study.

(9) Can I tell other people about the study?

Yes, you can openly discuss your participation in this study with others.

(10) What if I require further information about the study or my involvement in it?

When you have read this information, Ms Luise Hollmann will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Associate Professor Karen Ginn (Head of Discipline, Discipline of Biomedical Science) by email (Karen.Ginn@sydney.edu.au) or phone (02 9351 9352).

(11) What if I have a complaint or any concerns?

Any person with concerns or complaints about the conduct of a research study can contact The Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone); +61 2 8627 8177 (Facsimile) or nhumanethics@sydney.edu.au (Email).

This information sheet is for you to keep
APPENDIX A

Karen Ginn’s Office
Discipline of Biomedical Science
Sydney Medical School
Faculty of Medicine

ABN 15 211 513 454

KAREN GINN
Associate Professor
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The University of Sydney
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Lidcombe NSW 1825 AUSTRALIA
Telephone: +61 2 9351 9352
Facsimile: +61 2 9351 9520
Email: karen.ginn@sydney.edu.au
Web: http://www.sydney.edu.au

PARTICIPANT CONSENT FORM

I, ..............................................................................................[PRINT NAME], give consent to my participation in the research project.

TITLE: ACTIVE STIFFNESS IN FROZEN SHOULDER

In giving my consent I acknowledge that:

1. The procedures required for the project and the time involved have been explained to me, including any inconvenience or discomfort and their implications, and any questions I have about the project have been answered to my satisfaction.

2. I have read the Participant Information Statement and have been given the opportunity to discuss the information and my involvement in the project with the researchers.

3. I understand that being in this study is completely voluntary – I am not under any obligation to consent.

4. I understand that my involvement is strictly confidential. I understand that any research data gathered from the results of the study may be published however no information about me will be used in any way that is identifiable.

5. I understand that I can withdraw from the study at any time, without affecting my relationship with the researchers, the University of Sydney, Macquarie University Hospital or Wollongong Hospital now or in the future.
APPENDIX A

6. I consent to:
   • Receiving Feedback  YES □  NO □

If you answered YES to the “Receiving Feedback” question, please provide your details i.e. mailing address, email address.

Feedback Option

Address: ____________________________________________
           ____________________________________________
           ____________________________________________

Email: ____________________________________________

---------------------------------------------------------------------
Signature

---------------------------------------------------------------------
Please PRINT name

---------------------------------------------------------------------
Date
APPENDIX A

UNIVERSITY OF WOLLONGONG

APPRAVAL – ISLHD AUTHORIZATION
In reply please quote: HE12/434
Further Enquiries Ph: 4221 3386

26 November 2012

A/Professor Karen Ginn
The University of Sydney
Discipline of Biomedical Science, Sydney Medical School
Head, Discipline of Biomedical Science
Sydney Medical School
University of Sydney

Dear Associate Professor Ginn

Your response dated 23 November 2012 has been reviewed and I am pleased to advise that the application has been approved.

Ethics Number: HE12/434
All RED Number: HREC/12/WS/GON/131
Project Title: In there a component of “active stiffness” to deficits in range of motion in patients with frozen shoulder

Name of Researchers: A/Professor Karen Ginn, Dr Mark Halaki, Dr Mark Haber, Dr Seamus Dalton, Ms Luise Hoffmann, Professor Robert Herbert

Sites/CIs approved:

<table>
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<tr>
<th>Site</th>
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</thead>
<tbody>
<tr>
<td>The Wollongong Hospital</td>
<td>A/Professor Karen Ginn</td>
</tr>
<tr>
<td>The University of Sydney</td>
<td>A/Professor Karen Ginn</td>
</tr>
<tr>
<td>Macquarie Hospital</td>
<td>A/Professor Karen Ginn</td>
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Documents Reviewed/Approved:
- LNR Application (submission code AL/1C700112)
- Participant Information Sheet Version 2, November 23, 2012
- Participant Consent Form Version 2, November 23, 2012
- Shoulder Pain and Disability Index (SPADI)
- Patient Questionnaire

Approval Date: 20 November 2012
Expiry Date: 19 November 2013

The University of Wollongong/ISLHD Health and Medical HREC is constituted and functions in accordance with the NHMRC National Statement on Ethical Conduct in Human Research. The HREC has reviewed the research proposal for compliance with the National Statement and approval of this project is conditional upon your continuing compliance with this document.
A condition of approval by the HREC is the submission of a progress report annually and a final report on completion of your project. The progress report template is available at http://www.uow.edu.au/research/rso/ethics/UOW009385.html. This report must be completed, signed by the appropriate Head of School and returned to the Research Services Office prior to the expiry date.

As evidence of continuing compliance, the Human Research Ethics Committee also requires that researchers immediately report:

- proposed changes to the protocol including changes to investigators involved
- serious or unexpected adverse effects on participants
- unforeseen events that might affect continued ethical acceptability of the project.

Please note that approvals are granted for a twelve month period. Further extension will be considered on receipt of a progress report prior to expiry date.

Please note that Governance approval is required for research within NSW Ministry of Health. Before you can proceed with this research project you must complete a Site Specific Assessment (SSA) for each Local Health District included in your project. Refer to: https://ethicsform.org/Au/SigIn.aspx

For further information regarding the SSA in the ISLHD, contact:

Research Governance Officer
Illawarra Shoalhaven Local Health District
Research Directorate
Wollongong Hospital
Block C, Level 8
P: 02 4253 4876
E: Kristy.Pierce@SIAHS.HEALTH.NSW.GOV.AU

A copy of this letter has been forwarded to the ISLHD Research Governance Officer.

If you have any queries regarding the HREC review process, please contact the Ethics Unit on phone 4221 3386 or email rso-ethics@uow.edu.au.

Yours sincerely

Associate Professor Sarah Ferber
Chair, UOW & ISLHD Health and Medical
Human Research Ethics Committee

cc: Governance Officer, Research Directorate, ISLHD
Shoulder Pain and Disability Index (SPADI)


The Shoulder Pain and Disability Index (SPADI) is a self-administered questionnaire that consists of two dimensions, one for pain and the other for functional activities. The pain dimension consists of five questions regarding the severity of an individual’s pain. Functional activities are assessed with eight questions designed to measure the degree of difficulty an individual has with various activities of daily living that require upper-extremity use. The SPADI takes 5 to 10 minutes for a patient to complete and is the only reliable and valid region-specific measure for the shoulder.

Scoring instructions
To answer the questions, patients place a mark on a 10cm visual analogue scale for each question. Verbal anchors for the pain dimension are 'no pain at all' and 'worst pain imaginable', and those for the functional activities are 'no difficulty' and 'so difficult it required help'. The scores from both dimensions are averaged to derive a total score.

Interpretation of scores
Total pain score: _______ / 50 x 100 = %
(Note: If a person does not answer all questions divide by the total possible score, eg, if 1 question missed divide by 40)

Total disability score: _______ / 80 x 100 = %
(Note: If a person does not answer all questions divide by the total possible score, eg, if 1 question missed divide by 70)

Total Spadi score: _______ / 130 x 100 = %
(Note: If a person does not answer all questions divide by the total possible score, eg, if 1 question missed divide by 120)

The means of the two subscales are averaged to produce a total score ranging from 0 (best) to 100 (worst). Minimum Detectable Change (90% confidence) = 13 points
(Change less than this may be attributable to measurement error)
APPENDIX B

Shoulder Pain and Disability Index (SPADI)

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

Pain scale

How severe is your pain?
Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable.

<table>
<thead>
<tr>
<th>At its worst?</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>When lying on the involved side?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Reaching for something on a high shelf?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Touching the back of your neck?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Pushing with the involved arm?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>

Disability scale

How much difficulty do you have?
Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help.

<table>
<thead>
<tr>
<th>Washing your hair?</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washing your back?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Putting on an undershirt or jumper?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Putting on a shirt that buttons down the front?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Putting on your pants?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Placing an object on a high shelf?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Carrying a heavy object of 10 pounds (4.5 kilograms)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Removing something from your back pocket?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>
Pain Catastrophizing Scale

<table>
<thead>
<tr>
<th>Name:</th>
<th>Age:</th>
<th>Gender:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>□ Male □ Female</td>
<td></td>
</tr>
</tbody>
</table>

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

*Instructions:*
We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

<table>
<thead>
<tr>
<th>RATING</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEANING</td>
<td>Not at all</td>
<td>To a slight degree</td>
<td>To a moderate degree</td>
<td>To a great degree</td>
<td>All the time</td>
</tr>
</tbody>
</table>

*When I'm in pain …*

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I worry all the time about whether the pain will end.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>I feel I can’t go on.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>It’s terrible and I think it’s never going to get any better</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>It’s awful and I feel that it overwhelms me.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>I feel I can’t stand it anymore.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>I become afraid that the pain will get worse.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>I keep thinking of other painful events</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>I anxiously want the pain to go away</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>I can’t seem to keep it out of my mind</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>I keep thinking about how much it hurts.</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>I keep thinking about how badly I want the pain to stop</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>There’s nothing I can do to reduce the intensity of the pain</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>I wonder whether something serious may happen.</td>
<td></td>
</tr>
</tbody>
</table>