THE EFFECT OF CRYOTHERAPY ON POST DRY NEEDLING SORENESS

By

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A dissertation submitted to the faculty of health in partial compliance with the requirements for the Masters Degree in Technology: Chiropractic, at the Durban University of Technology.

I, Dheshini Chonan, do declare that this dissertation represents my own work in both conception and execution.

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DEDICATION

This dissertation is dedicated to my mom, dad and brother. You are the most important people in my life. Thank you for always being my support and anchor. You have been my strength when my steps have faltered. You have always seen hope through my despair. I look to you for guidance and comfort. Thank you for always believing in me and allowing me every opportunity to follow my dreams. I love you.
ACKNOWLEDGEMENTS

To **Dr Kretzmann**, thank you for your time, hard work and encouragement throughout my research study.

To **Hitesh**, thank you for keeping me sane the past six years. Thank you for always being there and making the time to help. You have been an incredible friend.

To my **friends**, thank you guys for making my days at DUT the best journey ever. We’ve had quite a ride. Never a dull moment. I will forever have fond memories of our time together. You guys are the greatest.

To **Natasha**, thank you for all your support and encouragement and for always being a phone call away. I’m blessed to call you my best friend.

To **Linda** and **Pat**, thank you all your patience, support and much needed guidance over the years.

To **Mrs Ireland**, thank you for always having a smile and hug ready. Thank you for making all the administrative aspects of my research run smoothly. You have been a godsend.

To **Tonya**, thank you for all your help with my statistical analysis.

To the **Staff of DUT Chiropractic** Department, thank you for moulding me into the best doctor I can be. The knowledge, advice and support you have given me over the years as been immeasurable. Thank you.

To all the **Patients** that participated in this study, without you this project would never have been possible. Thank you for your time and incredible support. It was an absolute pleasure having met each of you.
ABSTRACT

Dry needling is the most effective way of treating Myofascial Pain Syndrome and appears to be as effective as an injection of an anaesthetic into myofascial trigger points. However the side effect common to both dry needling and the injection of an anaesthetic, is the development of post-needling soreness. Post-needling soreness results from bleeding at the area of needle insertion. The immediate application of cold to a needled area may decrease the severity of the cellular damage by restricting local bleeding. Cryotherapy can also decrease both nerve excitability and histamine release, which may result in decreased pain experienced by patients. The purpose of this study was to determine the effectiveness of cryotherapy on post dry needling soreness.

Therefore a randomised, 2 group parallel controlled clinical trial was proposed to test this hypothesis. Sixty asymptomatic volunteer participants between 18 and 50 were randomly divided into two equal groups - group A (combination group) received dry needling in conjunction with a cold gel pack, and group B received dry needling only. Algometer readings, a Numerical Pain Rating Scale (NRS 101) and a 24 Hour Pain Diary were used as assessment tools.

SPSS version 15 was used for data analysis (SPSS Inc. Chicago, Ill, USA). Baseline demographics and outcome measurements (NRS 101, Algometer readings and 24 Hour Pain Diaries) were compared between the two groups using Pearson’s chi square tests or Independent Samples t-tests as appropriate

For the evaluation of the treatment effect for the NRS 101 and Algometer outcomes, repeated measures ANOVA procedure was used. Twenty four hour Pain Diaries by group interactions were reported for comparison of the treatment effect in the two treatment groups. The number of participants reporting pain at various time points post treatment were compared cross-sectionally by group with Pearson’s chi square tests. A Mann-Whitney U test was used to compare time points post treatment at which the worst pain was experienced between groups. The change in the presence of pain over time was recorded as either no change, an increase (from no pain to pain) or a decrease (from pain to no pain). This was
compared between treatment groups using the Pearson’s chi square test. Intra-group correlations between changes in outcome variables were achieved with Pearson’s correlation. P values of <0.05 were considered as statistically significant.

The results of the study showed no evidence of a beneficial effect of cryotherapy on objective or subjective findings. Thus it can be concluded that cryotherapy as used in this study had no significant effect on reducing post dry needling soreness.
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CHAPTER ONE

INTRODUCTION

1.1. Introduction

Myofascial Pain Syndrome (MPS) is a common muscular pain syndrome resulting from myofascial trigger points (MTrPs). Any skeletal muscle of the body is a potential trigger point site. These trigger points can refer intense and sometimes disabling pain to distant sites (Esenyel, 2000). It is reported that MPS is the condition most often seen in general practice (Schneider, 1995). It is responsible for loss of productivity, which costs billions of dollars in lost revenue every year (Fricton, 1990).

A wide range of treatment modalities exist, including massage, ischaemic compression, application of heat or cold, ultrasound, transcutaneous electrical nerve stimulation (TENS), spray-and-stretch technique, trigger points injection and dry needling (Cumming, 2003 and Wilks, 2003).

MTrP therapy has become an important primary technique in a chiropractic practice (Schnieder, 1995). Dry needling is a treatment commonly employed by chiropractors to treat MTrPs, however post-needling soreness is a common side effect. Post-needling soreness appears to be worse after dry needling, with respect to both intensity and duration, when compared to trigger point injections (Alvarez and Rockwell, 2002). This soreness can contribute to the delaying of further treatment and recovery in patients (Travell et al., 1999).

Post-needling soreness is related to hemorrhage caused by tissue damage at the needled site (Hong, 1994 and Travell et al., 1999). This tissue damage leads to the activation of an inflammatory process and the development of swelling and pain (Gatterman and Goe, 1990).

Cryotherapy is used to reduce tissue temperature and has various physiological effects i.e. vasoconstriction of blood vessels, decreased local metabolism,
decreased blood histamine release during inflammation and reduced nerve
excitability (Schafer and Faye, 1990). This makes cryotherapy first in line for
management of acute injuries concerning swelling, bleeding and pain relief
(MacAuley, 2001).

1.2. **Aims and Objectives of the study**

The aim of this study was to determine the effectiveness of cryotherapy on post-
needling soreness in muscle tissue of asymptomatic subjects receiving dry
needling and a cold gel pack versus subjects receiving dry needling only in terms
of subjective and objective findings.

1.2.1 **Objective 1**

To determine if the combination of dry needling and a cold gel pack versus dry
needling on its own to muscle tissue of asymptomatic subjects resulted in the
development of post-needling soreness in terms of subjective clinical findings.

1.2.2 **Objective 2**

To determine if the combination of dry needling and a cold gel pack versus dry
needling on its own to muscle tissue of asymptomatic subjects resulted in the
development of post-needling soreness in terms of objective clinical findings.

1.2.3 **Objective 3**

To determine, through analysing the data from the subjective and objective
findings, if cryotherapy had an effect on post-needling soreness.

1.3. **The Rationale**

Dry needling is an effective and commonly used treatment modality when treating
myofascial trigger points. However post-needling soreness is commonly
experienced and sometimes becomes a deterrent to patients with regards to
needling. Hemorrhaging and inflammation is thought to be responsible for the post-needling soreness. Cryotherapy is an easy to use treatment modality that is advised for the immediate management of acute soft tissue injuries. It is able to vasoconstrict the blood vessels, which helps curb the release of histamine and this may decrease nerve excitability. Together these properties may help diminish the patients experience of post-needling soreness.

The aim of this study was to clinically evaluate the practical value of the effectiveness of cryotherapy on post-needling soreness in asymptomatic patients that were treated using dry needling.
CHAPTER TWO

LITERATURE REVIEW

2.1. Introduction

Musculoskeletal pain is one of the leading reasons for visits to physicians and manual therapists (Rickards, 2006). Myofascial Pain Syndrome (MPS) is a common condition where hyperirritable foci develop in muscle and these foci are referred to as myofascial trigger points (MTrPs) (Bennett, 2007).

MPS has an excellent prognosis and utilizes many different approaches in its treatment (Auleceims, 1995). One of the most commonly used treatments is dry needling of the MTrP (Kamanli et al., 2004).

Trigger point dry needling is an invasive procedure in which an acupuncture needle is inserted through the skin and into the muscle (Dommerholt et al., 2006). Post-needling soreness is a common side effect to needling (Travell et al., 1999) and is thought to occur from bleeding at the area of needle insertion (Hong, 1994).

This chapter gives a review of the available literature on MPS, trigger points, dry needling, post-needling soreness and cryotherapy. The information reviewed will attempt to provide a clearer understanding of dry needling, post-needling soreness and how the properties of cryotherapy may help to decrease the soreness experienced by patients.

2.2. Incidence and prevalence of MPS

Specific figures regarding the incidence and prevalence of MPS in South Africa are not yet known. However it has been estimated that about 44 million Americans have myofascial pain problems (Bennett, 2007). MPS is the dominating cause of muscular disability in the shoulder girdle, neck, and lumbar regions (Kamanli et al., 2004).
Trigger points have been described in all age groups and in both sexes (Fomby and Mellion, 1997). These tender points have been found to be more frequent in women. Women also appear to have a lower tenderness threshold over tender points than men (Tunks and Crook, 1999). Sola et al. (1955) found trigger points in the shoulder muscles in 54% of females and 45% of males upon examination of 200 asymptomatic young adults. Although research has found that MPS occurs most often between the ages of 30 and 60 (Fomby and Mellion, 1997). It was noted that MPS occurred more frequently in 30% of women aged 20-40 and in both sexes between the ages of 30-49 (Han and Harrison, 1997). Tunks and Crook (1999) found that of 60 patients treated for myofascial pain, 52% were between the ages of 32-55 and 43% were between 20-31. Van Aardenne (2002) found that of 60 patients aged between 20-60 that were treated for myofascial pain in his study, 48.2% were between 31-50 while 36.6% were between 20-31. These studies suggest that the prevalence of MPS declines with advancing age (Fomby and Mellion, 1997) with the majority of sufferers being between the ages of 20-50 years.

2.3. **Predisposing and Perpetuating Factors**

A wide list of factors exist that are responsible for the development of MTrPs (Travell et al., 1999; Alvarez and Rockwell, 2002; Cummings and Baldry, 2007 and Eng-Ching, 2007):

- Trauma i.e. contusions, sprains, overuse and overloading of the muscle.
- Poor posture and environmental ergonomics.
- Sedentary lifestyles and lack of exercise.
- Structural degeneration of bones and joints.
- Muscle wasting and ischaemia
- Visceral pain referral
- Radiculopathic compression of motor nerves
- Emotional stress and anxiety
.m. Vitamin and mineral deficiencies
• Metabolic and endocrine deficiencies
• Climatic causes i.e. excessive cold, extreme heat, draughts and damp weather.

2.4. **Myofascial Trigger Points**

Travell *et al.* (1999), defines MTrPs as foci of hyperirritable spots found within a taut band of skeletal muscle or in its fascia. These trigger points result in intense pain and pain referral to distant sites (Esenyel, 2002). According to Eng-Ching (2007), approximately half of the body is made up of skeletal muscle which highly suggests trigger points are prone to occur anywhere in the body (Travell *et al.*, 1999).

Trigger points, can exist in either active or latent states. Active trigger points refer pain to secondary sites at rest, muscle activity and direct palpation, while latent trigger points remain non-painful and only refer pain when directly palpated (Travell *et al.*, 1999; Cummings and Baldry, 2007).

Direct palpation of the suspected muscle is a reliable and commonly used way of diagnosing MTrPs (Alvarez and Rockwell, 2002 and McPartland, 2004). Tenderness and referred pain, a transient muscle contraction ("local twitch sign") and lastly wincing and recoiling away from pain ("jump sign") are the three responses that usually occur when a trigger point is located (Travell *et al.*, 1999; Baldry, 2002 and Simons and Dommerholt, 2006).

**Histopathology**

To better understand and appreciate the nature of MTrPs, it is important to understand basic muscle structure and function. Skeletal muscle is a voluntary muscle that is made up of bundles of muscle fibres, each containing several hundreds to thousands of myofibrils (refer to Picture A) (Guyton, 1992). Each myofibril contains a chain of sarcomeres, which is the basic contractile unit of skeletal muscle. Sarcomeres are made up of interdigitating actin and myosin
filaments (Refer to Picture A). Together they interact and bring about muscle contractions. (Guyton, 1992 and Travell et al., 1999). The myofibrils exist within a matrix called the sarcoplasm. ATP producing mitochondria, potassium, magnesium, phosphate, protein enzymes and the sarcoplasmic reticulum are found in the sarcoplasmic fluid. The sarcoplasmic reticulum is important, as it contains large concentrations of calcium ions, which are necessary for muscle contraction (Tunks and Crook, 1999). When an action potential travels over the muscle fibre, large amounts of calcium ions are released into the sarcoplasmic fluid. These ions activate the actin and myosin filaments to interact and illicits the beginning of a contraction. ATP molecules supply the energy required for the contraction (Guyton, 1992).

![Picture A](image)

**PICTURE A**


Contraction knots are a very common histopathological finding during biopsies of trigger points. These contraction knots appear within longitudinal sections as darkly stained fibers with conspicuous bulges (Refer to picture B). Researchers
attribute these knots to contracted sarcomeres within individual muscle fibres (Travell et al., 1999 and Bennett, 2007).

Electromyography (EMG) of muscles that contain active trigger points rarely record any spontaneous electrical activity (SEA) at rest. However this activity was found to increase during contraction. Trauma causes excessive release in acetylcholine from dysfunctional motor endplates and this causes changes in SEA (Tunks and Crook, 1999, Hsu, 2003, Wheeler, 2004 and Bennett, 2007).

Several theories exist to explain the development of MTrPs. MTrPs present complex clinical findings. These clinical findings have no scientific theory that fully explains its pathophysiological nature (Rickards, 2006 and Bennett, 2007). There are several proposed theories that have been suggested, these include the Energy Crisis Theory, the Muscle Spindle Concept, the Motor Endplate Hypothesis and the Integrated Hypothesis. The Integrated Hypothesis is the most accepted and widely used hypothesis.
• **Energy Crisis Theory**
This theory tries to account for the presence of the taut band, MTrP pain, MTrP response to stretch therapy and the absence of any motor activity (Simons, 1996). According to this theory it is postulated that these taut bands resulted from injury or repetitive use (local energy crisis) that resulted in contractions of focal sarcomere units due to calcium release from the sarcoplasmic reticulum (Bennett, 2007).

• **Muscle Spindle Concept**
According to EMG studies, MTrPs where found to have highly localized electrical activity (Travell *et al.*, 1999). The source of this activity was from dysfunctional muscle spindles. The spikes recorded on an EMG were the result of mechanically induced release of acetylcholine at the neuromuscular junction of an extrafusal fibre. Therefore although muscle spindles sometimes contribute to the development of MTrPs, it is not thought to be the initial site of the development mechanism (Simons, 1996).

• **Motor Endplate Hypothesis**
This hypothesis highlights extrafusal motor endplates has being a major cause of MTrPs (Simons, 1996). It was found that dysfunctional endplates released large amounts of acetylcholine, which led to the formation of contraction knots. These knots are thought to be involved in the formation of triggers (Bennett, 2006).
The Intergrated Hypothesis
The integrated theory expands the previously mentioned hypotheses. It also includes local myofascial tissues, the central nervous system and biomechanical factors (Rickards, 2006). To better explain this hypothesis a flow diagram has been used (Diagram A).

![Diagram A](image)

The impaired circulation, combined with the increased metabolic demands generated by the sustained muscle contraction, results in a depleted ATP supply. This leads to an energy crisis. The energy crisis cascades into a local release of chemicals (i.e. bradykinins, somatostatins, leukotrienes, histamine, potassium, prostaglandins and cytokines) that sensitizes nociceptors and leads to tenderness in the area (McPartland, 2004).

Patient presentation

As trigger points form they cause other muscles in the region to compensate. This thereby creates additional trigger points. Trigger points create muscle spasms,
which lead to muscle fibre shortening (Travell et al., 1999). Patients who have these trigger points complain of persistent pain, decreased range of motion, headaches, tinnitus, torticollis and few even complain of systemic symptoms (Alvarez And Rockwell, 2002 and Rickards, 2006). The deltoid muscle was the muscle used for test purposes in this study, as it is a muscle that often develops MTrPs (Travell et al., 1999).

The following information and pictures on the deltoid regarding anatomical attachments, trigger point location, referral pain patterns and innervation are according to Travell et al. (1999).

**Attachments** - The proximal fibres of the anterior, middle and posterior parts attach to the clavicle, acromion and spine of the scapula, respectively. Distally, they all attach to the deltid prominence of the humerus (Refer Picture C).

**Trigger point location** - The deltoid is a superficial muscle. The relaxed muscle is examined by snapping palpation across the MTrPs with the arm positioned in 30 degrees of abduction. Trigger points in the middle deltoid can develop anywhere along the muscle.

**Referral Pain pattern** - Active trigger points in the deltoid muscle usually do not refer pain to a distance as in other muscles. Pain usually spreads locally in the region of the affected part. (Refer to Picture D)

Active MTrPs in the anterior deltoid refer pain to the anterior and middle regions. Active MTrPs in the middle deltoid refer pain in that region with some spillover pain to adjacent areas.

Active MTrPs in the posterior deltoid refers pain that concentrates over the posterior shoulder while sometimes spilling into adjacent areas of the arm.

**Innervation** - This muscle is supplied by the axillary nerve.
In this study the deltoid muscle used was not specified to a particular side. Participants were excluded from the study if they were found to have either active or latent trigger points in the muscle as this study did not permit dry needling of trigger points.

**PICTURE C**

2.5. Management of MPS

MPS is a condition that can be successfully treated by eliminating the trigger points that are the cause of pain (Molina, 2000). When effectively managed MPS has an excellent prognosis (Auleciems, 1995). The goal of MTrP therapy is to relieve pain and tightness of the involved muscles (Esenyel, 2000).

The management of MPS must take into account the chronic nature of the disease process as well as the physiologic and psychosocial stressors that are involved (Han and Harrison, 1997). The location of the trigger point in the muscle is very important in deciding how it is treated. There are two types of trigger point locations, central and attachment trigger points. Central trigger points are located in the endplate region of a muscle while attachment trigger points are located near the region where the muscle attaches to its tendon, bone or aponeurosis. Central trigger points respond better to the application of warmth and stretching whereas attachment trigger points respond better to cold. Stretching is avoided as it could aggravate attachment trigger points. Attachment trigger points also respond well
to the application of manual therapy, especially when it is directed toward the central trigger point (Travell et al., 1999).

The chiropractic profession has long utilized the manual treatment approach to MPS (Molina, 2000). These various forms of manual treatment for MPS including the spray and stretch technique, ischaemic compression, massage, osteopathic manual medicine techniques, application of heat or cryotherapy, ultrasound, diathermy, transcutaneous electrical nerve stimulation (TENS), exercise, acupressure, acupuncture, trigger point injection and dry needling (Alvarez and Rockwell, 2002).

- **Spray and Stretch**
  This uses a vapocoolant spray to block reflex spasm and pain, this allows for gradual and passive stretching of the muscle and inactivation of the trigger point (Auleciems, 1995). By restoring muscle length and reducing muscle tension, the consequent muscle spasms, sensitive points and referred pain are eliminated (Raj and Paradise, 2004).

- **Tens**
  Tens is a popular modality as the low intensity stimulation of TENS selectively activates the large diameter fibres to close the pain gate in the dorsal horn of the spinal cord or at a higher level and thus eliminating pain (Melsack and Wall, 1985).

- **Ultrasound**
  Ultrasound treatment involves the use of high-frequency acoustic energy that is generated using the reverse piezoelectric effect It is known for both its thermal and non thermal effects on tissue (Esenyel., 2000). These effects are able to reduce joint stiffness, muscle pain and spasm, increase blood flow and even stimulate soft tissue repair and regeneration (Rickards, 2006).

- **Massage, Ischaemic compression, Acupressure**
  Massage, ischaemic compression and acupressure mechanically helps to break up fibrous bands in muscle, improves circulation, reduce the muscle spasm and deactivate the trigger point (Travell et al., 1999).
• **Exercise**

Myofascial stretching exercises are an important part of any pain management regime. Cardiovascular fitness and low impact aerobic exercises are highly recommended (Nicolakis et al., 2002 and Hsu, 2003).

• **Heat**

Moist heat helps increases bloodflow and relaxes underlying muscles (Travell et al., 1999) this decreases tension on the trigger point and decreases referred pain and local tenderness (Auleciems, 1995).

• **Cold**

Cold helps to depress nerve endings and increase pain threshold. This enables muscles to decrease their contractility and decreases tension in the trigger point (Prentice, 1994).

• **Dry needling**

Dry needling can deactivate active foci within the muscle fibres with rapid needle insertion into multiple sites within the trigger points. This helps relieve pain, muscle spasm and referred pain (Travell et al., 1999).

**2.6. Dry needling**

Trigger point dry needling is an invasive procedure in which an acupuncture needle is inserted into the skin and muscle. Dry needling is used by over 75% of South African physical therapists at least once daily and in combination with other physical therapy interventions (Dommerholt et al., 2006). No studies were found to say that dry needling was more effective than other types of therapies. According to Travell et al. (1999), dry needling is an effective way of treating myofascial pain syndrome and appears to be as effective as an injection of medication in the treatment of myofascial trigger points (Speed, 2007). Benefits of other forms of treatment take longer to show results when compared to injection type treatments (Alvarez and Rockwell, 2002). As trigger point injections are
associated with unwanted side effects of medicinal injections i.e. allergic reactions, muscle necrosis (Travell et al., 1999 and Baldry, 2002), skin de-pigmentation and tendon atrophy, as well as syncope, apnoea and palpitations (Ruane, 2001), dry needling is recommended as a safer option for the patient (Rickards, 2006).

Trigger points are located by digital palpation and the needle is inserted 1-2 cms away and directed towards the trigger point such that the needle approaches at an angle of 30 degrees to the skin (Travell et al., 1999). Various techniques can be used to stimulate the needle once it has been inserted into a trigger point. These include rotation, vibration, twirling and twisting, lifting and thrusting and snapping (Baldry, 1988). Although all these techniques exist, the fanning dry needling technique was selected for this research. This technique involves partially withdrawing the needle from the skin and redirecting it in a fan-like manner, in order to inactivate all active foci (Travell et al., 1999). According to literature, to inactivate active foci it is necessary to illicit a local twitch response (LTR) when needling. In Hong’s (1994) study he found that this response could be obtained anywhere from 10-60 needle insertions.

According to Travell et al. (1999), some of the postulated mechanisms in which dry needling is effective in the deactivation of trigger points are:

1) Its ability to mechanically disrupt the muscle/ or nerve fibres within the pain-spasm cycle.
2) Mechanical disruption of muscle fibres causes increased levels of extracellular potassium, which in turn leads to the depolarisation of nerve fibres.
3) The removal of nerve sensitizing substances by local hemorrhage.
4) The interruption of the central feedback mechanism.

The needling process however mechanically disrupts the muscle tissue and can damage surrounding structures i.e. nerves and blood vessels (Baldry, 2002). This initiates a series of responses, one of them being inflammation. Inflammation is characterized by swelling, redness, heat and pain (Michlovitz, 1996). This pain is frequently perceived as post-needling soreness (Travell et al., 1999).
2.7. Post-needling soreness

Post-needling soreness is an entity that has been mentioned by many authors (Lewit, 1979; Travell et al., 1999; Alvarez and Rockwell, 2002). According to Hong (1994) post-needling soreness is related to hemorrhage caused by tissue damage at the needled site and therefore is a common side effect to both dry needling and the injection of medication (Alvarez and Rockwell, 2002).

Post-needling soreness is described as a constant pressure or a dull aching sensation. It is distinguishable from the sharp and tight aching feeling that is experienced prior to needling (Hong, 1994). Post-needling soreness can contribute to the delaying of treatment and recovery as it prevents any further needling of the same region for 3-4 days after treatment (Travell et al., 1999). Both single insertion and fanning dry needling techniques have been found to produce post-needling soreness (Rowley, 2000; Ferreira, 2006).

Research has found that the change in the amount of creatine kinase (CK) is used as a reflection of the amount of tissue damage incurred (Kumar et al., 1997). In a controlled clinical trial Nosaka and Sakamoto (1999) found that following an intramuscular injection into the biceps brachii muscle, blood results revealed CK levels started to increase 2 hours post-needling and peaked at 12 hours. The results of this study however was based on a limited sample group of five male subjects.

In previous dry needling studies it was unclear whether post-needling soreness arose from the trigger point itself or whether the tissue damage caused by the needle insertion was responsible. Ferriera (2006) conducted a study to investigate whether dry needling muscle tissue in asymptomatic subjects resulted in post-needling soreness. His study was a randomised, placebo controlled experimental investigation consisting of 60 subjects between the ages of 18 and 50 that were asymptomatic of lower back pain. These subjects were randomly allocated into three equal groups. Group one received the single needle insertion technique, the second group received the fanning dry needling technique and the last group formed the control group. Those subjects were treated using placebo
needles. His findings according to the NRS 101 and 24-hour pain diaries revealed that asymptomatic subjects did experience post-needling soreness. His study was hampered by the small sample size. He also found that the gender distribution hampered the results somewhat as male subjects failed to report mild levels of discomfort.

In a double-blinded and controlled study designed to investigate the effects of lidocaine injections versus dry needling of upper trapezius MTrPs in 58 patients, Hong (1994) reported that 2-8 hours after receiving needling, all patients within the dry needling group developed post-needling soreness. These patients had post-needling soreness of greater intensity and longer duration than those treated with lidocaine injection. Post–needling soreness appears to be at its most severe at 22-24 hours after injection (Hugenin, 2004).

To help curb the development of post-needling soreness, moist heat, stretching and application of pressure to the needled area has been previously recommended (Travell et al., 1999) However some patients still find the pain intolerable (Huguenin, 2004) so a need still exists to find better treatments when dealing with post-needling soreness.

2.8. Cryotherapy

Cryotherapy, is the local and systemic application of cold for therapeutic purposes (Olsen and Stravino, 1972). It is one of the oldest and simplest therapies used to treat soft tissue injuries (MacMasters, 1982 and Bleakly et al., 2006). Cold is used as the initial treatment for most injuries in the musculoskeletal system (Prentice, 1994, Jutte et al., 2001). In a survey of the National Board of Chiropractic Examiners, 92.6 percent of all chiropractors polled reported using cryotherapy as a non-adjustive technique (Christensen, 1996).
Cryotherapy is used for a wide list of indications (Michlovitz, 1996 and Cameron, 1999):

- to control inflammation
- to decrease edema
- to reduce pain
- to decrease metabolism
- to reduce spasticity

When a cooling technique is applied, the patient experiences a series of varying sensations. First there is a sensation of cold followed by aching or burning and finally skin analgesia or numbness (Prentice, 1994).

According to Michlovitz (1996) and Nadler et al. (2004), cryotherapy should not be used when treating patients with:

- cold hypersensitivity,
- cold intolerance,
- cryoglobulinemia,
- paroxysmal cold cryoglobulinuris,
- Raynaud’s phenomenon and
- cold induced urticaria.
- Cold should not be applied over regenerating peripheral nerves or areas with circulatory compromise or peripheral vascular disease (Cameron, 1999).

When an injury occurs, inflammatory and metabolic reactions begin to increase causing oxygen to be used up at a faster rate. When the oxygen supply is depleted the cells begin to die and structures begin to breakdown. Extravascated blood cells and fluid cause swelling and bruising. When cold is applied it reduces the tissue temperature, thus slowing down the rate of chemical reactions and hence the demand for ATP. A decrease in the amount of cellular ATP decreases the demand for oxygen, which leads to longer tissue survival during hypoxia (Hubbard et al., 2004). Thus the physiological effects of cryotherapy to vasoconstrict blood vessels, decrease local metabolism, decrease blood histamine
release and reduce nerve excitability (Schafer and Faye, 1990) makes it very effective in controlling edema, inflammation and pain (Michlovitz, 1996 and Cameron, 1999).

Schaser et al. (2007) used male rats with a closed soft tissue injury in a controlled study to investigate the effects of prolonged cold on inflammation. His results showed a reduction in vascular dysfunction, inflammation and tissue damage. Superficial cold activates the cutaneous cold receptors, which stimulates smooth muscle contractions in the walls of blood vessels thus causing vasoconstriction. This mechanism is responsible for the reduction in swelling (MacAuley, 2001). Bleakley et al. (2004) found after their evaluation of cryotherapy clinical trials that the vasoconstriction of blood vessels was effective in limiting swelling and decreasing pain immediately after application to one week post-injury. Twenty one subjects between the ages of 29 and 63 years of age were studied by Ho et al. (1994) in an attempt to determine the effect of an ice wrap on blood flow and bone metabolism. He applied an ice wrap to one knee and applied an identical wrap left at room temperature to the other knee. This served as a control. Both wraps were left on for 20 minutes. Ho et al. (1994) measured blood flow using triple phase technetium bone scan. His study found that an ice wrap applied for 20 minutes to a knee resulted in decreased arterial and soft tissue blood flow and bone metabolism thus providing a scientific rationale for the use of ice in limiting hemorrhage and cellular injury in acute musculoskeletal injuries. These clinical trials show that cold is effective in limiting swelling and decreasing pain immediately post-injury.

The analgesic effect of cryotherapy is one of the primary reasons clinicians use it in the management of acute injuries. Cold can increase pain threshold and decrease the sensation of pain by reducing nerve conduction velocity (Hubbard et al., 2004). Myelinated, pain-transmitting A-delta fibres are most affected by cooling. These fibres transmit a fast, acute, pricking type of pain that is felt when a needle is stuck into the skin (Guyton, 1992). Hayward et al. (2006) found in their randomised clinical trial that 16 of the 20 participants reported that the soreness caused by 2 lignocaine injections into the hallux was significantly reduced with a six minute application of ice prior to injection. This study however lacked a large
sample size and the ability to blind participants to the effects of cold. A more precise effect of ice might also have been ascertained if the study was done using real patients undergoing a digital nerve block. Saito et al. (2004) reported that a cold compressive device was effective for pain reduction during the postoperative recovery phase in patients undergoing Total Hip Arthroplasty (THA). This was the first controlled study to evaluate whether continous cryotherapy could relieve pain soon after THA. Forty six patients were randomly divided into 2 groups. The cryotherapy group was fitted with a computer-controlled cooling device for 4 days while the control group was not fitted with this cooling device. The cryotherapy group reported pain disappearance in a shorter time and required a significantly lower amount of analgesic medication than the control group. The reliability of this research was reduced because the control group was aware they where not in the therapeutic group. This knowledge may have affected the way patients rated their pain.

In the past clinicians have found that for the relief of MTrP distress, many patients preferred application of heat to cold (Travell et al., 1999). However some patients preferred application of cold to MTrPs (Travell et al., 1999). The degree and effectiveness of cooling seems to be largely dependant on the method and duration of cooling, temperature of the ice and the depth of subcutaneous fat (Bleakley et al., 2004).

There are numerous techniques for applying cold to the body. These include cold packs, ice bags, ice cubes, iced towels, vapocoolant sprays, cold baths and cold-compression units (Michlovitz, 1996 and Cameron, 1999). Different cooling methods have differing degrees of cooling. To maximize the therapeutic effects of cryotherapy, an optimal tissue temperature reduction of 10 to 15 degrees celsius is necessary (MacAuley, 2001). Ethyl chloride spray causes the greatest reduction in skin temperature, up to 28 degrees celsius, while ice massage causes the least reduction, approximately 18 degrees celsius (Olsen and Stravino, 1972). When using ice, Lavelle and Synder (1985) have shown little difference in using ice over an area with no barrier, damp barrier or dry barrier. Janwantanakul (2004) found that the application of an ice bag directly to the skin was a more effective
cryotherapy technique than that of an ice bag over a damp towel barrier. Quillen and Underwood (1995) and Michlovitz (1996) suggested a damp towel be used when using cold therapy. This is advised for various reasons i.e. hygiene, to facilitate energy transfer from cold-pack to skin and to prevent damage to the skin i.e. frostbite and burns. In approximately 15-30 minutes ice packs where found to decrease intramuscular tissue temperature by 3-7 degrees celsius while gel packs decreased tissue temperature by 2-4 degrees celsius (Christensen, 1996). According to Fiscus et al. (2005) all studies examining blood-flow during cold pack and ice bag treatments showed a decreased blood-flow after application. As the literature is unclear as to the therapeutic difference between an ice pack and a cold gel pack, this study used cold gel packs as the treatment modality. This was done because they are inexpensive and are available in a variety of shapes and sizes which allows it to be moulded to the area being treated (Michlovitz, 1996 and Cameron, 1999). They are also less messy to work with as ice packs melt.

In a paper by Bleakley et al. (2004) reviewing cryotherapy treatments, he found that the duration and frequency of cryotherapy treatments are not consistent. Most clinical cryotherapy treatments are typically applied for 20-30 minutes as this is the time needed to reach tissue that is 20mm or less deep (McMaster, 1982 and Otte et al., 2002). If cold is applied for longer than 15 minutes a reflex vasodilation occurs (Olsen and Stravino, 1972 and Michlovitz, 1996) which is known as the Huntington response. However cold-induced vasodilation occurs in distal extremities such as fingers and toes when cold is applied for more than 15 minutes at temperatures below 1 degree celsius. (Cameron, 1999). However longer treatment durations may be used for areas other than the distal extremities (Taber et al., 1992 and Weston et al., 1994).

Cryotherapy treatment durations rarely take into account subcutaneous fat thickness. Otte et al. (2002) found that there was a direct relationship between adipose thickness and required cooling time. A 25 minute treatment time was found to be sufficient in patients with a skin-fold thickness of 20mm or less while 40 minutes was required in patients with a skin-fold thickness between 21-30mm and 60 minutes was needed for those with a thickness between 30-40 mm.
3.9. **Conclusion**

The use of cryotherapy is not a new concept and its physiological effects have been well documented. However despite the general acceptance of the use of cold, many of the studies found have been old. Even recent articles cite these older articles. Clinical trials involving cryotherapy are riddled with insufficiencies. In the literature the duration and frequency of cryotherapy treatments are not consistent. These treatment durations rarely take into account subcutaneous fat thickness. Most studies do not report on the temperature of the cold modality being used. Most cryotherapy research studies are of poor methodological quality, have small sample sizes and many lack the ability to blind subjects to the cold. Despite these shortcomings in research studies, cryotherapy still remains one of the oldest and simplest therapies used to treat soft tissue injuries because of its ability to control edema, inflammation and pain. It has already been established that post-needling soreness is due to the tissue damage as a result of dry needling. Thus cold should be applied as soon as possible after this acute trauma to limit bleeding, edema, inflammation and soreness. The aim of this study was to consider the effectiveness of cryotherapy as an adjunct to dry needling thereby providing the manual therapy professions a greater understanding when treating myofascial pain syndrome.
CHAPTER 3
METHODOLOGY

3.1. Study design

The study was a randomised, 2 group parallel controlled trial. A sample group of 60 asymptomatic participants was used. This study has been approved by the ethics clearance committee (Appendix J).

3.2. Subject recruitment

Participants were selected from those who responded to advertisements (Appendix A) placed in public places, pamphlet distribution and newspaper advertisements. This study was conducted using asymptomatic participants only and all volunteers were screened prior to their acceptance into the study based on the inclusion and exclusion criteria. There was no restriction on ethnicity, cultural or socioeconomic background.

3.3. Sample size and group allocation

A sample size of 60 was used for this study and participants were randomly divided into two groups of 30. This was done by placing 30 A’s and 30 B’s in an envelope, the participants were asked to remove a piece of paper from the envelope and without looking at it, hand it to the researcher. The paper removed from the envelope therefore determined which group the participant was allocated to. Group A received dry needling in conjunction with ice, and group B received dry needling only.

3.4. Clinical procedure

3.4.1. Patient procedure

Participants were given an information sheet outlining the research details (Letter of Information) (Appendix B), which were personally explained by the researcher.
Each participant signed an Informed Consent Form (Appendix C). Each participant’s case history (Appendix D) was taken and a general physical examination (Appendix E) was performed. The shoulder regional examination (Appendix F) was performed in detail. The skin-fold thickness measurement over the deltoid region was taken using a caliper and was recorded on the physical examination form. Thereafter the inclusion and exclusion criteria, set forth for this study was used for assessing if participants were suitable for the study.

3.4.2. Inclusion criteria

1. Past epidemiological studies suggested that the greatest prevalence of MPS were between the ages 20-50 (Sola *et al.* 1955; Fomby and Mellion, 1997; Han and Harrison, 1997 and Van Aardenne, 2002) thus participants between the ages of 18 and 50 were selected for this study.

2. Otte *et al.* (2002) found in his study that a 20-25 minute treatment time was sufficient to reach deep tissue in subjects with a skin-fold thickness of 20mm or less. In this study a 20 minute cold application was used hence participants with a skin-fold thickness of 20mm and less only were included.

3. Participants were only accepted once they had read and signed the Informed Consent form and had undergone a complete case history, a revised physical examination and a shoulder regional examination.

3.4.3. Exclusion criteria

1. Participants with contra-indications to dry needling and cryotherapy were excluded. These are:
   
   a. Participants under the influence of alcohol or those suffering from systemic illness, fever, bleeding disorders, anxiety or syncopial reactions (Travell *et al.*, 1999). Participants who report initially being adverse to the thought of dry needling were excluded. All smokers were excluded as tobacco causes low vitamin C levels which can
lead to increased fragility of capillaries, possibly resulting in unsightly ecchymoses and altered development of post-needling soreness. (Travell et al., 1999).

b. Skin diseases, cardiac disease, cold urticuria, Raynaud’s disease and arterial deficiencies, after local injection of hydrocortisone, on anaesthetized skin, over regenerating peripheral nerves, on people who become emotionally upset to the local application of cold. (Cameron, 1999; McMasters, 1982).

2. Participants taking, or those who have taken, analgesic or anti-coagulant medication during the three days prior to the initial consultation were excluded from the study (Travell et al., 1999).

3. Participants receiving or those who had received dry needling in the three months prior to the initial consultation were excluded, as maximal naivety regarding the onset of post-needling soreness was desired (Mouton, 1996).

4. Participants suffering from Primary Fibromyalgia Syndrome were not allowed to participate in the study (Han and Harrison, 1997).

5. Participants found to have either active or latent myofascial trigger points in the middle deltoid muscle.

6. Participants that were unable to commit to the 24 hour follow up appointment.

3.4.4. Intervention

Once the participant had undergone the full medical case history, revised physical, shoulder regional examinations and had read and signed the Informed Consent Form, participants were positioned in a lateral recumbent position on the side opposite to the one being tested for the duration of the treatment. The arm was placed in 30 degrees of flexion. Participants were tested for their ability to feel hot
and cold, by placing hot and cold water filled glasses on the deltoid area. An Algometer reading was taken from the spot to be needled prior to the commencement of dry needling.

The area to be needled was located in the mid-belly of the middle deltoid muscle. Both groups, A and B received the fanning technique as bleeding worsens post-needling soreness (Travell et al., 1999; Rowley, 2000) and thus leads to the assumption that the fanning dry needling technique would result in the development of greater post-needling soreness.

All acupuncture needles were used only once. The needles were opened in front of the participants. The area that was needled was cleaned with alcohol before and after treatment. Once used, the needles were discarded in the medical waste bins provided in accordance with normal clinical procedure. The examiner wore surgical gloves throughout the entire procedure.

GROUP A – Combination group (Dry Needling and Cold Gel Pack)
Visit 1

The area was exposed. An Algometer (Appendix H) reading was taken. The participant was asked to fill out a NRS 101 form (Appendix G) prior to needling. The area was then cleansed with alcohol. The needle was inserted into the muscle. Caution was taken to ensure that the needle was not inserted to its hub as this is where it is most likely to break. The needle was then withdrawn to the subcutaneous tissue layer and then redirected to another position ten times, without completely withdrawing the needle from the skin (Hong, 1994; Travell et al., 1999, Ferriera. 2006). According to literature it is necessary to illicit a local twitch response (LTR) when needling a MTrP. In Hong’s (1994) study he found that this response could be obtained anywhere from 10-60 needle insertions. For the purpose of this study we have adapted the technique of ten needle insertions as used in Ferriera’s study (2006).

Immediately after the needle had been removed the area was cleaned with alcohol. The needled spot was marked with a body pencil.
Thereafter a cold gel pack wrapped in a damp towel was placed over the needled area for 20 minutes. A damp towel was used for various reasons i.e. hygiene, to facilitate energy transfer from cold gel pack to tissue and to prevent damage to the skin (Lavelle and Snyder, 1984, Quillen and Underwood, 1995 and Michlovitz, 1996). The participant’s response was verbally checked after the first 2 minutes for discomfort, then after every 5 minutes. If the participant experienced discomfort a visual check was to be performed. A visual check for wheals, welts, blisters and skin colour changes was done after the first 4 minutes and at 20 minutes after the treatment was completed. If wheals, welts or blisters appeared, or if the skin colour changed to absolute white, bluish-purple or grey, treatment was stopped. (Quillen and Underwood, 1995).

Ten minutes after the cold gel pack was removed, participants were asked to complete an NRS 101 form and an Algometer reading was taken of the needled spot. This ten minute period was used to allow the numbness experienced by the skin to fade so that the NRS 101 and Algometer readings could be taken.

All participants were asked to keep a 24 hour pain diary (Appendix B) in order to monitor the development of post-needle soreness following treatment. The needled area was marked with henna and then covered with a plaster. The henna was used to mark the area in order to ensure that all measurements were obtained from the exact spot that was needled and that consistency occurred.

The cold gel packs used in this study where kept in the clinic freezer in a separate freezer tray so as not to be used by other students. These packs where kept at a temperature of 0 degrees celsius. When needed, three cold gel packs where removed from the fridge and placed in a cooler bag. The cold gel packs were stacked one above the other. This was done to keep the middle cold gel pack cool as this was the pack used in the treatment. After the treatment the cold gel packs were once again placed in the freezer and another three cold gel packs were used.
**GROUP B- Dry Needling Only**

Visit 1

The area was exposed. An Algometer reading was taken. The participant was asked to fill out a NRS 101 form prior to needling. The skin was cleansed using alcohol. The needle was inserted into the muscle. Caution was taken to ensure that the needle was not inserted to its hub as this is where it is most likely to break. The needle was then withdrawn to the subcutaneous tissue layer and then redirected to another position ten times, without completely withdrawing the needle from the skin (Hong, 1994; Travell et al., 1999, Ferriera. 2006). According to literature it is necessary to illicit a local twitch response (LTR) when needling a MrTP. In Hong’s (1994) study he found that this response could be obtained anywhere from 10-60 needle insertions. For the purpose of this study we have adapted the technique of ten needle insertions as used in Ferriera’s study (2006).

Immediately after the needle has been removed the area was cleaned with alcohol. The needled spot was marked with a body pencil. Ten minutes after needling participants were asked to complete a NRS 101 form and an Algometer reading was taken of the needled spot. All participants were asked to keep a 24 Hour Pain Diary in order to monitor the development of post-needle soreness following treatment.

The needled area was marked with henna and then covered with a plaster. The henna was used to mark the area in order to ensure that all measurements were obtained from the exact spot that was needled and that consistency occurred.

**GROUPS A & B**

Visit 2

This occurred 24 hours after the first treatment. Participants once again completed a NRS 101 form and an Algometer reading of the needled area was taken. The Pain Diaries were collected.
3.5. Outcome measures

3.5.1. Subjective data

3.5.1.1. Numerical Pain Rating Scale 101 (NRS 101)

The NRS 101 is used in order to monitor the development of post-needling soreness as perceived by the participant. The NRS 101 involves asking the participant to rate his or her pain intensity on a numerical scale from a score of 0 to 100, with 0 representing the participant experiencing no pain and 100 representing the participant experiencing the pain at its worst.

In a study conducted by Jensen et al. (1986) using 75 participants, all suffering from chronic pain, the NRS 101 proved to be the most precise, replicable, predictive and valid measurement.

Participants in this study were required to complete the NRS 101 at three different time intervals: 1.] prior to needling, 2.] ten minutes post-needling and 3.] twenty four hours post-needling.

3.5.1.2. Pain Diary

Owing to the uncertainty regarding the time period pertaining to the onset of post-needling soreness, all participants were required to complete a 24 Hour Pain Diary (Appendix B) in order to monitor its onset and duration following the treatment. The Pain Diary had 5 time points (3 hrs, 6 hrs, 9 hrs, 12 hrs and 24 hrs), commencing immediately after the treatment, and participants were required to either tick ‘yes’ or ‘no’ to whether or not they were experiencing pain at that point. The Pain Diary required participants to record at which time, in hours, they experienced the most pain.
3.5.2. **Objective data**

3.5.2.1. **Pressure Threshold Algometry**

The Algometer was used in this study in order to measure the participants’ pressure pain threshold (ppt), defined as “the minimum pressure (force) that induces pain or discomfort” (Fischer, 1987). In a study performed by Nussbaum and Downes (1998) it was concluded that the non-electronic Algometer is a reliable way of measuring pressure pain threshold over three consecutive days. In this study, the Algometer reading was taken once the area of needle insertion was marked. Pressure was gradually applied until the participant indicated the point they first felt pain. A reading was then taken and recorded. This procedure was performed three times and the average reading was calculated. In this study, readings were taken at three different time intervals: 1.] prior to needling, 2.] ten minutes post-needling and 3.] twenty four hours post-needling. A general decrease in measurements indicates an increase in pain.

3.6. **Statistical analysis**

All participants had a data sheet (Appendix I) on which all their data was recorded. This was done for the convenience of the statistician.

SPSS version 15 was used for data analysis (SPSS Inc. Chicago, Ill, USA). Baseline demographics and outcome measurements were compared between the two groups using Pearson’s chi square tests or Independent Samples t-tests as appropriate.

For the evaluation of the treatment effect for the outcomes of the NRS 101 and Algometer readings, repeated measures ANOVA procedure was used. Time by group interactions were reported as treatment effects. Profile plots were generated to visually compare treatment effects by treatment group. The number of participants reporting pain at various time points post treatment, as well as duration of pain were compared cross-sectionally between groups with chi square tests. A Mann-Whitney U test was used to compare time since treatment at which
the most severe pain was experienced between groups. P values of <0.05 was considered as statistically significant.

3.7 Definitions of tests used

3.7.1. Analysis of variance (ANOVA): This is a statistical technique for analysing data that tests for a difference between two or more means by comparing the variances within and between groups. ANOVA determines an overall p value, but does not determine differences between specific groups (www.isixsigma.com, 2007).

3.7.2 Pearson’s chi square tests: Pearson's correlation reflects the degree of linear relationship between two variables. Pearson's correlation coefficient for continuous data ranges from -1 to +1. Positive correlation indicates that both variables increase or decrease together, whereas negative correlation indicates that as one variable increases, so the other decreases, and vice versa (www.isixsigma.com, 2007).

3.7.3 Mann-Whitney U test: Mann-Whitney performs a hypothesis test of the equality of two population medians and calculates the corresponding point estimate and confidence interval. This test is used as a nonparametric alternative to the two-sample t-test (www.isixsigma.com, 2007)

3.8 Abbreviations

N = Number
% = Percentage
CI = Confidence interval
SD = Standard Deviation
P = Probability value
df = Degrees of freedom
Std = Standard
CHAPTER FOUR

RESULTS

4.1. Demographics by groups

4.1.1. Demographics by age

Table 1: Comparison of mean age in the two treatment groups

<table>
<thead>
<tr>
<th>Age in years</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dry needling and cold gel pack (combination group)</td>
<td>30</td>
<td>25.73</td>
<td>8.115</td>
<td>1.482</td>
<td>0.953</td>
</tr>
<tr>
<td></td>
<td>dry needling only</td>
<td>30</td>
<td>25.87</td>
<td>9.442</td>
<td>1.724</td>
<td></td>
</tr>
</tbody>
</table>

Table 1 shows that the mean age was very similar in the two treatment groups. There was no statistically significant difference in age between the groups (p=0.953). The mean age of participants overall was 25.8 years with a standard deviation of 8.7 years and a range from 18 to 47 years.
4.1.2. Demographics by gender

Table 2: Cross tabulation of gender by treatment group

<table>
<thead>
<tr>
<th>Group</th>
<th>gender</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>combination group</td>
<td>Count</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>% within group</td>
<td>33.3%</td>
</tr>
<tr>
<td>dry needling only</td>
<td>Count</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>% within group</td>
<td>26.7%</td>
</tr>
<tr>
<td>Total</td>
<td>Count</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>% within group</td>
<td>30.0%</td>
</tr>
</tbody>
</table>

Pearson's chi square = 0.317, p = 0.573

The majority of participants were female (70%). Table 2 shows that the percentage distribution of females and males were similar in the two groups. Gender did not significantly differ when comparing the two treatment groups (p = 0.573).

4.1.3. Demographics by age and skin-fold thickness

Table 3: Comparison of mean skin-fold thickness in the two treatment groups

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin-fold thickness in cms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>combination group</td>
<td>30</td>
<td>1.477</td>
<td>.3411</td>
<td>.0623</td>
<td>0.480</td>
</tr>
<tr>
<td>dry needling only</td>
<td>30</td>
<td>1.537</td>
<td>.3113</td>
<td>.0568</td>
<td></td>
</tr>
</tbody>
</table>

To be included in this study, participants needed to have a skin-fold thickness of 2cms and less. Table 3 shows there were no statistical difference in mean skin-fold thickness between the two groups (p = 0.480).
4.1.4. Demographics by occupation

Table 4: Occupations of study participants (n=60)

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student</td>
<td>42</td>
<td>70.0</td>
</tr>
<tr>
<td>Housewife</td>
<td>3</td>
<td>5.0</td>
</tr>
<tr>
<td>Manager</td>
<td>3</td>
<td>5.0</td>
</tr>
<tr>
<td>Admin assistant</td>
<td>2</td>
<td>3.3</td>
</tr>
<tr>
<td>Caterer</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Catering manager</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Clerk</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Consultant</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Food scientist</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Instrumentation mechanic</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>LAN engineer</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Policeman</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Receptionist</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Teacher</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Participant occupations are shown in Table 4. The majority (70%) of participants were students.
4.2. Baseline outcomes

**Table 5: Comparison of mean baseline outcomes in the two treatment groups**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS 1 Pain rating from 0-100</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination group</td>
<td>30</td>
<td>.000</td>
<td>.0000*</td>
<td>.0000</td>
<td>*</td>
</tr>
<tr>
<td>dry needling only</td>
<td>30</td>
<td>.000</td>
<td>.0000*</td>
<td>.0000</td>
<td></td>
</tr>
<tr>
<td>Algometer 1 in kgs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination group</td>
<td>30</td>
<td>6.795</td>
<td>2.1358</td>
<td>.3899</td>
<td>0.729</td>
</tr>
<tr>
<td>dry needling only</td>
<td>30</td>
<td>6.610</td>
<td>1.9792</td>
<td>.3614</td>
<td></td>
</tr>
</tbody>
</table>

* t cannot be computed because the standard deviations of both groups are 0.

Table 5 shows no significant difference between the two groups in terms of the baseline outcome measurements. As asymptomatic participants where used the NRS 101 readings in all participants at baseline (before any treatment) was 0. Thus no comparison could be made between the groups.

4.3. Assessment of the treatment effect

4.3.1. Objective outcome: Algometer

**Table 6: Inter and Intragroup effects for algometer readings**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Statistic</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>Wilk’s lambda=0.653</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time*group</td>
<td>Wilk’s lambda=0.961</td>
<td>0.319</td>
</tr>
<tr>
<td>Group</td>
<td>F=0.857</td>
<td>0.358</td>
</tr>
</tbody>
</table>
Table 6 shows that both groups changed significantly over time for Algometer readings (p=<0.001). However there was no evidence of a differential time effect with treatment (p=0.319). Figure 1 illustrates the marginal means for the Algometer readings. These readings were taken at three different periods. Time 1 – measurements taken prior to needling, Time 2 – measurements taken ten minutes post-needling and Time 3 – measurement taken 24 hours post-needling. Figure 1 shows that there was a general decrease in Algometer measurements over the three time points, which indicates an increase in pain. However, the rate of decrease is slightly slower in the combination group (blue line) compared with the needling only group (green line). Thus there was a trend that began to show the efficacy of cryotherapy however the sample size was not high enough to show this statistically.
4.3.2. Subjective outcome- NRS 101

Table 7: Inter and Intragroup effects for NRS 101

<table>
<thead>
<tr>
<th>Effect</th>
<th>Statistic</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>Wilk’s lambda=0.515</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time*group</td>
<td>Wilk’s lambda=0.999</td>
<td>0.971</td>
</tr>
<tr>
<td>Group</td>
<td>F=0.001</td>
<td>0.980</td>
</tr>
</tbody>
</table>

Table 7 shows that both groups changed significantly over time for NRS 101 readings (p<0.001). However, this rate of change was the same in both groups over time and there was no evidence of a differential time effect with treatment (p=0.971). Figure 2 illustrates the marginal means for the NRS readings. These readings were taken at three different periods. Time 1 – measurements taken...
prior to needling, Time 2 – measurements taken ten minutes post needling and Time 3 – measurement taken 24 hours post needling. Figure 2 shows that initially both group lines increased sharply in terms of pain but this was followed by a decrease between time 2 (measurements taken post needling) and 3 (measurements taken 24 hours post needling). The rate of decrease in pain was found to be almost the same in both groups.

4.3.3. Subjective outcome: Post-needling soreness as reported in the 24-hour pain diaries

Table 8: Cross sectional analysis of presence of post-needling soreness by group

<table>
<thead>
<tr>
<th>Group</th>
<th>Combination group</th>
<th>dry needling only</th>
<th>Count</th>
<th>Column %</th>
<th>Count</th>
<th>Column %</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain 3hrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>9</td>
<td>30.0%</td>
<td>13</td>
<td>43.3%</td>
<td></td>
<td></td>
<td>0.284</td>
</tr>
<tr>
<td>no</td>
<td>21</td>
<td>70.0%</td>
<td>17</td>
<td>56.7%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain 6hrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>7</td>
<td>23.3%</td>
<td>8</td>
<td>26.7%</td>
<td></td>
<td></td>
<td>0.766</td>
</tr>
<tr>
<td>no</td>
<td>23</td>
<td>76.7%</td>
<td>22</td>
<td>73.3%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain 9hrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>5</td>
<td>16.7%</td>
<td>8</td>
<td>26.7%</td>
<td></td>
<td></td>
<td>0.347</td>
</tr>
<tr>
<td>no</td>
<td>25</td>
<td>83.3%</td>
<td>22</td>
<td>73.3%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain 12hrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>3</td>
<td>10.0%</td>
<td>9</td>
<td>30.0%</td>
<td></td>
<td></td>
<td>0.053</td>
</tr>
<tr>
<td>no</td>
<td>27</td>
<td>90.0%</td>
<td>21</td>
<td>70.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain 24hrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>6</td>
<td>20.0%</td>
<td>9</td>
<td>30.0%</td>
<td></td>
<td></td>
<td>0.371</td>
</tr>
<tr>
<td>no</td>
<td>24</td>
<td>80.0%</td>
<td>21</td>
<td>70.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Pearson’s chi square test
The pain diary had 5 time points at which pain was recorded (3hrs, 6hrs, 9 hrs, 12 hrs and 24 hrs post-needling). These recordings commenced immediately after treatment. The presence and absence of pain was recorded as a binary variable at each time point in the Pain Diary. Figure 3 and Table 8, shows the percentage of participants that had any pain at each time point by group. At all time points the percentage of participants with pain was lower in the combination group than in the dry needling only group. However, at no point was there a statistically significant difference except for the 12 hours post treatment period. At this period there was a borderline non-significant difference in favour of the combination group with 10% of them having pain, while 30% of the dry needling only group reported pain (p=0.053, Table 7). The percentage of participants with post-treatment soreness started to decrease in both groups from 3 hours but elevations in pain percentage was noted at 12 hours post needling in the dry needling only group and at 24 hours post needling in both groups.
Table 9: Change in presence of pain by treatment group

<table>
<thead>
<tr>
<th>Group</th>
<th>Change in the presence of pain</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>decrease</td>
<td>no change</td>
</tr>
<tr>
<td>combination group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td>% within group</td>
<td>16.7%</td>
<td>76.7%</td>
</tr>
<tr>
<td>dry needling only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>7</td>
<td>20</td>
</tr>
<tr>
<td>% within group</td>
<td>23.3%</td>
<td>66.7%</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>43</td>
</tr>
<tr>
<td>% within group</td>
<td>20.0%</td>
<td>71.7%</td>
</tr>
</tbody>
</table>

Pearson’s chi square =0.743, p=0.690

The change in the presence of post-needling soreness was calculated from the 24 Hour Pain Diary assessments for each participant. Table 9 shows that 16.7% of the combination group experienced a decrease in pain from 3 hours to 24 hours post needling, while 23.3% in the dry needling only group showed an overall decrease in presence of pain. The combination group reported 76.7% had no change in pain while the needling only group reported 66.7% experienced no change in pain. No change in pain was found to be the highest in the combination group by 10% while an increase in pain was slightly more frequent in the needling only group. There was, however no significant difference overall between the groups changes for pain (p=0.690).
4.3.4. Subjective outcome: Time point at which post-needling soreness was worst

The 24 Hour Pain Diary required the participants to record at which point in time they had experienced their worst pain, if any, following the treatment.

**Table 10: At how many hours after needling was pain worst?**

<table>
<thead>
<tr>
<th>Group</th>
<th>Median (Hours)</th>
<th>Minimum (Hours)</th>
<th>Maximum (Hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combination group</td>
<td>.0</td>
<td>.0</td>
<td>24</td>
</tr>
<tr>
<td>Dry needling only</td>
<td>1.5</td>
<td>.0</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>.0</td>
<td>.0</td>
<td>24</td>
</tr>
</tbody>
</table>

![Boxplot of time of worst pain by group](image)

**Figure 4: Boxplot of time of worst pain by group**

Table 10 and Figure 4 shows that the median time of worst pain in the combination group was reported at 0 hours (immediately after needling) while
The median time of worst pain in the dry needling only group was reported 1.5 hours post needling. Figure 4 shows that there was one outlier in the combination group and two outliers in the dry needling only group. This is indicated by circles in the plot. This means that the values were between 1.5 and 3 box lengths from the top end of the boxes. There was an extreme point in the dry needling only group (shown with an asterisk – more than 3 box lengths from the top end of the box). The box length is the interquartile range, while the dark line in the box is the median. The whiskers are the minimum and maximum values (excluding outliers and extreme points).

**Table 11: Mann Whitney U test comparing median time of worst pain between the two groups.**

<table>
<thead>
<tr>
<th>Ranks</th>
<th>Group</th>
<th>N</th>
<th>Mean Rank</th>
<th>Sum of Ranks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worst pain</td>
<td>combination group</td>
<td>30</td>
<td>30.67</td>
<td>920.00</td>
</tr>
<tr>
<td></td>
<td>dry needling only</td>
<td>30</td>
<td>30.33</td>
<td>910.00</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>60</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Test Statistics(a)**

<table>
<thead>
<tr>
<th>Worst pain</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mann-Whitney U</td>
<td>445.000</td>
</tr>
<tr>
<td>Wilcoxon W</td>
<td>910.000</td>
</tr>
<tr>
<td>Z</td>
<td>-.080</td>
</tr>
<tr>
<td>Asymp. Sig. (2-tailed)/ (p value)</td>
<td>.936</td>
</tr>
</tbody>
</table>

a Grouping Variable: group

The Mann Whitney U test is a non-parametric test that uses the ranks of the data rather than the actual values. The ranks are found by ranking (ordering) the values from smallest to largest. The p value is generated by the computer package from the Mann Whitney U test statistic value (445.000). Table.11 shows that there was no significant difference in time of worst pain between the two treatment groups (p=0.936).
4.4. Intra-group correlations between changes in outcome variables

4.4.1. Combination group: Dry needling and cold gel pack

**Table 12: Correlation between changes in outcomes in the combination group**

<table>
<thead>
<tr>
<th></th>
<th>Change in algometer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in NRS 101</td>
<td>Pearson Correlation</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)/(p value)</td>
</tr>
<tr>
<td></td>
<td>N-group sample size</td>
</tr>
</tbody>
</table>

Table 12 shows that the changes in NRS 101 and Algometer measurements over the time was not correlated in the combination group (r = -0.130).

4.4.2. Dry needling only group

**Table 13: Correlation between changes in outcomes in the needling only group**

<table>
<thead>
<tr>
<th></th>
<th>Change in algometer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in NRS 101</td>
<td>Pearson Correlation</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)/(p value)</td>
</tr>
<tr>
<td></td>
<td>N-group sample size</td>
</tr>
</tbody>
</table>

Table 13 shows that the change in NRS 101 and Algometer measurements over time was not correlated in the dry needling only group (r = -0.325).
CHAPTER FIVE

DISCUSSION OF RESULTS

5.1 Introduction

This chapter includes the discussion of the results from the statistical analysis of both the subjective (NRS 101 and 24 Hour Pain Diary) and objective (Algometer readings) data.

5.2 Subjective data

5.2.1 Numerical Pain Rating Scale 101 (NRS-101):

The results from the NRS 101 found that both groups experienced similar trends of increase in pain from the baseline. Both groups showed a sharp increase in pain between NRS 101 reading Time 1 (measurement prior to needling) and Time 2 (measurement 10 minutes post-needling) [Figure 2]. The increase in pain readings between these two time periods could be due to the development of post-needling soreness. As stated in chapter 2, very little detail is available regarding post-needling soreness and its exact cause. The development of post-needling soreness has been attributed to the hemorrhage caused by tissue damage as a result of needling (Hong, 1994). Hong (1994) and Rowley (2000) found that those participants who had received the fanning dry needling experienced greater post-needling soreness than those who had received single needle insertion. So for the purpose of bringing about post-needling soreness, the fanning technique was used in this study. In order to prevent confusion of determining whether soreness resulted from the needling process or the MTrP itself, asymptomatic patients where used in this study. Ferriera (2006) found when investigating the effect of dry needling of asymptomatic participants with respect to post-needling soreness that both intervention groups experienced some degree of soreness according to the findings from the NRS 101. As previously mentioned, cold is used to control edema, inflammation and pain (Mennel, 1975, Michlotivz, 1996 and Cameron, 1999) and according to MacMaster (1982) and Otte et al.
(2002) a 20 minute application of cold is therapeutically sufficient to reach tissue 20mm and less deep. Ho (1994) found that a 20 minute ice application decreased blood flow and pain. The application of the cold gel pack in this study however appeared to make little difference in the pain experienced by the combination group when compared to those in the dry needling only group. Pain readings did show a decline when taken 24 hours post-needling (time 3)[Figure 2]. The decrease in rate of pain was found to be similar in both the groups. Thus these readings have shown no evidence of a beneficial effect of cryotherapy as used in this study on subjective pain. This lack of benefit of cryotherapy could be due to differences in pain perception that exists between genders.

5.2.2 Pain diary

The majority of subjects in both groups in this study reported pain in the initial 3 hour post-needling period [Figure 3]. Hong (1994) found that in his study, which investigated the effects of lidocaine against dry needling of trigger points that all patients in the dry needling group reported pain within the first 2-8 hours after needling. Hugenin (2004) reported that post-injection soreness appeared to be at its most severe at 22-24 hours after injection. Ferriera (2006), when investigating the effect of dry needling of asymptomatic participants with respect to post-needling soreness, found no participants reported pain between 12-24 hours. In this study however, at 12 hours, 10% of the combination group reported pain while 30% of the needling only group experienced pain. By 24 hours the percentage that experienced pain increased in both groups [Figure 3]. Ferriera (2006) reported that, his single needle insertion group experienced their worst pain 7.5 minutes after the treatment, too few subjects reported pain in the fanning dry needling group and the placebo group to be statistically computed by the statistical package. This study revealed that the dry needling only group on average experienced their worst pain 1.5 hours post needling while the combination group reported their worst pain immediately after needling [Table 10 and Figure 4]. The deltoid muscle is a superficial muscle and the 20 minute application of the cold pack may have been too long because studies have shown that if cold is applied for longer than 15 minutes a reflex vasodilation (Huntington response) occurs (Olsen and Stravino, 1972). Although it has been suggested
that longer time periods could be used in areas other than distal extremities (Taber et al., 1992 and Weston et al., 1994), we are unable to be completely certain that a Huntington response did not take place in the combination group in this study. This means that instead of alleviating the bleeding caused by needling, the cold application itself could be responsible for added vasodilation in the area thus worsening the initial experience of post-needling soreness, this could be the reason why those in the combination group reported worst pain earlier than those in the needling only group. The 24 hour pain diaries showed that at all points of the diary, pain experienced by the combination group was lower. However at no point was there a difference between the groups that was significant enough to indicate the efficacy of cryotherapy.

5.3 Objective data

5.3.1 Algometer readings:

Both groups in this study showed a decrease in Algometer readings over the three time points [Figure 1]. This indicates that in both groups the needling process did cause increased tenderness in the area that was needled. Hong (1994), Rowley (2000) and Ferriera (2006) also experienced similar findings in the algometer readings within their studies. As stated earlier in chapter 2, needling does cause tissue damage (Travell et al., 1999). The change in the amount of creatine kinase (CK) is used as a reflection of the amount of tissue damage incurred (Kumar et al., 1997). Nosaka and Sakamoto (1999) found that following an intramuscular injection into the biceps brachii muscle CK levels started to increase 2 hours post-needling and peaked at 12 hours. Cold reduces metabolic demands of cells and this helps reduce tissue damage (Schaser et al., 2007) and this could be the reason why the cryotherapy group in this study showed a slower rate of decrease in their readings which indicates a trend of efficacy. This however could not be shown statistically as the sample size was too small.
CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1. Conclusion

The aim of this study was to investigate if cryotherapy had an effect on post-needling soreness.

In this study objective and subjective data from both groups reported post-needling soreness. However this study has shown no statistical evidence of a beneficial effect of cryotherapy on post needling soreness when used following dry needling of asymptomatic deltoid muscles. There was a slight non significant trend towards cryotherapy reducing the rate of increase in post needling soreness in terms of the objective measure of pain (Algometer) but the effect was very slight compared with the needling only group and was not verified by NRS 101 readings. The presence of post needling soreness was not significantly different up to 24 hours post needling between the groups and the overall increase or decrease in soreness was also not different between the groups. Similarly the time period at which soreness was worst was similar between the groups. So it can be concluded that cryotherapy has no significant effect on reducing post-needling soreness.

Travell et al. (1999) found that central trigger points were more responsive to heat than cold. The heat applied causes a dilation of blood vessels thereby increasing circulation in the area of the MTrP. This increase in blood flow help promotes muscles relaxation and a reduction in muscle tension. However this vasodilatory property of heat would not be advised as a post-needling soreness treatment modality because post-needling soreness is caused by bleeding. An increase in blood flow would only serve to exacerbate the soreness. According to literature in acute injury, cold should be used. This failure of cryotherapy to have an effect on post–needling soreness in this study may be attributed to various reasons. Studies have shown that if cold is applied for longer than 15 minutes a reflex vasodilation (Huntington response) occurs (Olsen and Stravino, 1972). Although it
has been suggested that longer time periods could be used in areas other than
distal extremities (Taber et al., 1992 and Weston et al., 1994). In this study a 20
minute application of cold was used thus we are unable to be completely certain
that a Huntington response did not take place in the combination group of this
study. This response may have worsened the participants initial experience of
post-needling soreness, this could be the reason why those in the combination
group reported worst pain earlier than those in the dry needling only. Travell et al.
(1999) state that there are vast differences in the response of patients in the
application of heat versus cold in the treatment of MTrPs and recommends that
more critical investigations be carried out.

6.2. Recommendations

Sample sizes should be larger than the one in this study, this will allow for more
statistically significant results.

The researcher should consider limiting the study to one gender and age group to
limit differences in pain perception.

Follow-up interviews should be conducted at different intervals over a time period
longer than 24 hours. This will allow the researcher to obtain a time period for the
duration of post-needling soreness as the exact duration of this experience is still
unknown and will help determine if the use of cold has an effect on the duration of
post-needling soreness.

Future studies should consider the effects that post-needling soreness could have
on muscle stiffness and range of motion measurements.

To obtain a more clinically relevant study, future studies could use symptomatic
patients.

Follow up studies of this nature should consider using different periods and
degrees of cooling as the literature suggests many varied treatment times. And
most cryotherapy studies fail to note the temperature of the cooling modality.
Future studies of a similar nature should compare the effect of moist heat versus cryotherapy on post-injection soreness as Travell et al. (1999) recommends both.

A study could be done to investigate the occurrence of post-needling soreness in 1.) different muscle groups or 2) in superficial versus deep muscles to determine if particular muscles are more prone to developing post-injection soreness.

Studies comparing the effects of different types of cold therapy modalities on post-needling soreness should be considered. Using an ice massage as opposed to using a cold pack would be an interesting study as an ice massage may produce a greater degree of cooling and the pressure applied may help with homeostasis.
References


Ferreira, E. 2006. A clinically controlled study investigating the effect of dry needling muscle tissue in asymptomatic subjects with respect to post-needling soreness: Masters degree in technology: Chiropractic Dissertation, Durban Institute of Technology, Durban, South Africa.


APPENDIX A:

ARE YOU BETWEEN THE AGES OF 18 TO 50?

A NON-SMOKER?

Have NO SHOULDER PAIN?

INTERESTED IN PARTICIPATING IN RESEARCH?

At THE DURBAN UNIVERSITY OF TECHNOLOGY CHIROPRACTIC DAY CLINIC

One FREE treatment (if you fit the research criteria)

CONTACT: DHESHINI
(031) 3732205 / 0844722340
APPENDIX B:

LETTER OF INFORMATION

Title of Research
The effect of cryotherapy on post-needling soreness.

RESEARCH SUPERVISORS: Dr H. Kretzmann  Mdip Chiropractic (SA), CCFC (SA) (031 2055520)

RESEARCH STUDENT: Dheshini Chonan (031 3732205) / 0844722340

INSTITUTION: Durban University of Technology.

Dear Patient.
Welcome and Thank you for participating in my research.
Dry needling is a commonly used modality in the chiropractic profession however post needling soreness is a common side effect of dry needling. Due to convience of ice and its many therapeutic properties, this study aims to find out if using ice after dry needling can decrease the occurrence of post-needling soreness.

Procedure:
At the initial consultation you will undergo a History, Physical, and a regional examination, after which you will be selected providing you fit the necessary criteria for the research. This consultation will last for approximately 11/2 – 2 hours. Once accepted into the study you will receive one treatment, after which you will be required to complete the 24-hour diary, which will be provided. A follow-up assessment will take place 24 hour after the initial treatment. This consultation will last for approximately 45 minutes-1 hour. You will remain in the study as long as you commit to the appointment schedule.

Risks or Discomforts:
You may experience soreness in the area that the needle was inserted.

Conditions you need to follow:
- Please refrain from having any other form of treatment to your neck or upper back during course of the study.
- Please refrain from using analgesics and anti-inflammatory drugs.
- Please refrain from strenuous activity during the course of the treatment.
- Please attend your follow-up appointment as failure to do so will lead to you being removed from the study.

Benefits:
This will benefit you as a patient in the long run, as we will be able to provide you with more effective health care in the future. You are entitled to one free treatment following your participation.

AS A VOLUNTARY PARTICIPANT IN THIS RESEARCH STUDY, YOU ARE FREE TO WITHDRAW FROM THE STUDY AT ANY TIME, WITHOUT GIVING A REASON.
**Remuneration:**
None

**Costs of study:**
None

**Confidentiality:**

All patient information is confidential. The results from this study will be used for research purposes only. Only individuals that are directly involved in this study (Dr. H. Kretzmann and myself) will be allowed access to these records.

Persons to contact should you have any problems or questions:
Should you have any problems or questions that you would prefer being answered by an independent individual, feel free to contact my supervisor on the above number. If you are not satisfied with a particular area of this study, please feel free to forward any concerns to the Durban University of Technology Research and Ethics Committee.

Thank you for participating in my research study.

---

Dheshini Chonan  
(Researcher)  

Dr. H. Kretzmann  
(Supervisor)

**PAIN DIARY**

Dear patient.

Kindly complete this pain diary documenting any soreness you may experience, in the area that was needled, during the 24 hours following your treatment.

Did you experienced pain in the area that was needled at:  YES  NO

<table>
<thead>
<tr>
<th>Time</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 hours</td>
<td>I</td>
<td></td>
</tr>
<tr>
<td>6 hours</td>
<td>I</td>
<td></td>
</tr>
<tr>
<td>9 hours</td>
<td>I</td>
<td></td>
</tr>
<tr>
<td>12 hours</td>
<td>I</td>
<td></td>
</tr>
<tr>
<td>24 hours</td>
<td>I</td>
<td></td>
</tr>
</tbody>
</table>

My pain was worst at _____ hours after receiving dry needling therapy. If you have any questions regarding the research, kindly contact Dheshini Chonan on (031) 3732205 or 0844722430 or you can contact my research supervisor Dr. Kretzmann on (031) 2055520

Patient Name: ____________________  Signature: ________________

Research Student Name: ____________  Signature: ________________
APPENDIX C:

INFORMED CONSENT FORM

TITLE:
The effect of cryotherapy on post-needling soreness.

Date: __________

Supervisor:                Dr. H. Kretzmann Mdip Chiropractic (SA),CCFC(SA)
                        (031- 2055520)
Student researcher:  Dheshini Chonan
                        (031 3732205/ 0844722340)

Please circle the appropriate answer

- Have you read the research information sheet?    Yes    No
- Have you had an opportunity to ask questions regarding this study? Yes    No
- Have you received satisfactory answers to your questions? Yes    No
- Have you has an opportunity to discuss this study? Yes    No
- Have you received enough information about this study? Yes    No
- Who have you spoken to? __________________________.
- Do you understand the implications of your involvement in this study? Yes    No
- Do you understand that you are free to withdraw from this study
  - at any time
  - without having to give any reason for withdrawing, and
  - without affecting your future health care. Yes    No
- Do you agree to voluntarily participate in this study? Yes    No

If you have answered no to any of the above, please obtain the information
before signing.

Please print in block letters:

Patient/subject Name: _______________________________________________

Signature: _________________________________________________________

Witness Name: ____________________________________________________

Signature: _________________________________________________________

Research Student Name: ____________________________________________

Signature: _________________________________________________________
APPENDIX D:

DURBAN UNIVERSITY OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient: ____________________________ Date: ________

File #: ______________ Age: ________

Sex : __________ Occupation: ____________________________

Intern : __________________ Signature __________________

FOR CLINICIANS USE ONLY:
Initial visit
Clinician: __________________ Signature : ______________

Case History:

<table>
<thead>
<tr>
<th>Examination:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous:</td>
<td>Current:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>X-Ray Studies:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous:</td>
<td>Current:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Path. lab:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous:</td>
<td>Current:</td>
</tr>
</tbody>
</table>

CASE STATUS:

<table>
<thead>
<tr>
<th>PTT:</th>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
</table>

CONDITIONAL:
Reason for Conditional:

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

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

Signature: __________________ Date: __________

<table>
<thead>
<tr>
<th>Conditions met in Visit No:</th>
<th>Signed into PTT:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Summary signed off:</td>
<td></td>
<td>Date:</td>
</tr>
</tbody>
</table>
**Intern’s Case History:**

1. **Source of History:**

2. **Chief Complaint : (patient’s own words):**

3. **Present Illness:**

<table>
<thead>
<tr>
<th>Complaint 1</th>
<th>Complaint 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; Location</td>
<td></td>
</tr>
<tr>
<td>&lt; Onset : Initial:</td>
<td></td>
</tr>
<tr>
<td>&lt; Recent:</td>
<td></td>
</tr>
<tr>
<td>&lt; Cause:</td>
<td></td>
</tr>
<tr>
<td>&lt; Duration</td>
<td></td>
</tr>
<tr>
<td>&lt; Frequency</td>
<td></td>
</tr>
<tr>
<td>&lt; Pain (Character)</td>
<td></td>
</tr>
<tr>
<td>&lt; Progression</td>
<td></td>
</tr>
<tr>
<td>&lt; Aggravating Factors</td>
<td></td>
</tr>
<tr>
<td>&lt; Relieving Factors</td>
<td></td>
</tr>
<tr>
<td>&lt; Associated S &amp; S</td>
<td></td>
</tr>
<tr>
<td>&lt; Previous Occurrences</td>
<td></td>
</tr>
<tr>
<td>&lt; Past Treatment</td>
<td></td>
</tr>
<tr>
<td>&lt; Outcome:</td>
<td></td>
</tr>
</tbody>
</table>

4. **Other Complaints:**

5. **Past Medical History:**

   | < General Health Status |             |
   | < Childhood Illnesses |             |
   | < Adult Illnesses |             |
   | < Psychiatric Illnesses |             |
   | < Accidents/Injuries |             |
   | < Surgery |             |
   | < Hospitalization |             |
6. **Current health status and life-style:**

- Allergies
- Immunizations
- Screening Tests incl. x-rays
- Environmental Hazards (Home, School, Work)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
  Analgesics/week:
  - Tobacco
  - Alcohol
  - Social Drugs

7. **Immediate Family Medical History:**

- Age
- Health
- Cause of Death
- DM
- Heart Disease
- TB
- Stroke
- Kidney Disease
- CA
- Arthritis
- Anaemia
- Headaches
- Thyroid Disease
- Epilepsy
- Mental Illness
- Alcoholism
- Drug Addiction
- Other
8. **Psychosocial history:**
   - Home Situation and daily life
   - Important experiences
   - Religious Beliefs

9. **Review of Systems:**
   - General
   - Skin
   - Head
   - Eyes
   - Ears
   - Nose/Sinuses
   - Mouth/Throat
   - Neck
   - Breasts
   - Respiratory
   - Cardiac
   - Gastro-intestinal
   - Urinary
   - Genital
   - Vascular
   - Musculoskeletal
   - Neurologic
   - Haematologic
   - Endocrine
   - Psychiatric
Durban University of Technology
PHYSICAL EXAMINATION: SENIOR

<table>
<thead>
<tr>
<th>Patient Name :</th>
<th>File no :</th>
<th>Date :</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student :</td>
<td>Signature :</td>
<td></td>
</tr>
</tbody>
</table>

### VITALS:

<table>
<thead>
<tr>
<th>Pulse rate:</th>
<th>Respiratory rate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure: R L</td>
<td>Medication if hypertensive:</td>
</tr>
<tr>
<td>Temperature:</td>
<td>Height:</td>
</tr>
<tr>
<td>Weight:</td>
<td>Any recent change? Y / N</td>
</tr>
</tbody>
</table>

### GENERAL EXAMINATION:

- General Impression
- Skin
- Jaundice
- Pallor
- Clubbing
- Cyanosis (Central/Peripheral)
- Oedema
- Lymph nodes
  - Head and neck
    - Axillary
    - Epitrochlear
    - Inguinal
- Pulses
- Urinalysis

### SYSTEM SPECIFIC EXAMINATION:

- CARDIOVASCULAR EXAMINATION
- RESPIRATORY EXAMINATION
- ABDOMINAL EXAMINATION
- NEUROLOGICAL EXAMINATION

### COMMENTS

<table>
<thead>
<tr>
<th>Clinician:</th>
<th>Signature :</th>
</tr>
</thead>
</table>
# APPENDIX F: SHOULDER REGIONAL EXAMINATION

Patient: ................................. File No: ......................... Date: ..............
Intern: .................................Signature: ........................................
Clinician: .................................Signature: ........................................

## Observation

<table>
<thead>
<tr>
<th>Observation</th>
<th>S-C Joints</th>
<th>Clavicles</th>
<th>A-C Joints</th>
<th>Scapulae</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posture</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swelling</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder levels</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Palpation

<table>
<thead>
<tr>
<th>Palpation</th>
<th>SCM:</th>
<th>Scalenes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C Joint:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sternum:</td>
<td>Ribs and costal cartridge:</td>
<td></td>
</tr>
<tr>
<td>Clavicle:</td>
<td>Coracoid process:</td>
<td></td>
</tr>
<tr>
<td>A-C Joint:</td>
<td>Acromion:</td>
<td></td>
</tr>
<tr>
<td>Greater Tuberosity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesser Tuberosity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intertubercular (bicipital groove):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trapezius:</td>
<td>Deltoid:</td>
<td></td>
</tr>
<tr>
<td>Biceps:</td>
<td>Triceps:</td>
<td></td>
</tr>
<tr>
<td>Supraspinatus insertion:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculotendinous portion of supraspinatus:</td>
<td>Lymph nodes:</td>
<td></td>
</tr>
<tr>
<td>Axilla:</td>
<td>Brachial artery:</td>
<td></td>
</tr>
<tr>
<td>Serratus anterior (medial wall):</td>
<td>Pectoralis major (anterior wall):</td>
<td></td>
</tr>
<tr>
<td>Lattissimus dorsi (posterior wall):</td>
<td>Spine:</td>
<td></td>
</tr>
<tr>
<td>Scapula:</td>
<td>Borders:</td>
<td></td>
</tr>
<tr>
<td>Supraspinous fossa:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infraspinous fossa:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervico-thoracic spine:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Active Movements (note ROM and pain)

<table>
<thead>
<tr>
<th>Movement</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevation through abduction</td>
<td>170-180°</td>
</tr>
<tr>
<td>Painful arc with abduction</td>
<td></td>
</tr>
<tr>
<td>Elevation through forward flexion</td>
<td>160-180°</td>
</tr>
<tr>
<td>Elevation through scapula plane</td>
<td>170-180°</td>
</tr>
<tr>
<td>Lateral rotation</td>
<td>80-90°</td>
</tr>
<tr>
<td>Medial rotation</td>
<td>60-100°</td>
</tr>
<tr>
<td>Extension</td>
<td>50-60°</td>
</tr>
<tr>
<td>Adduction</td>
<td>50-75°</td>
</tr>
<tr>
<td>Horizontal adduction/abduction</td>
<td>130°</td>
</tr>
<tr>
<td>Circumduction</td>
<td>200°</td>
</tr>
</tbody>
</table>

### Passive movements (note end-feel, ROM and pain)

<table>
<thead>
<tr>
<th>Movement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevation through abduction</td>
<td>Bone to bone or tissue stretch</td>
</tr>
<tr>
<td>Elevation through forward flexion</td>
<td>Tissue stretch</td>
</tr>
<tr>
<td>Lateral rotation</td>
<td>Tissue stretch</td>
</tr>
<tr>
<td>Medial rotation</td>
<td>Tissue stretch</td>
</tr>
<tr>
<td>Extension</td>
<td>Tissue stretch</td>
</tr>
<tr>
<td>Adduction</td>
<td>Tissue approximation</td>
</tr>
<tr>
<td>Horizontal adduction</td>
<td>Tissue stretch or approximation</td>
</tr>
<tr>
<td>Horizontal abduction</td>
<td>Tissue stretch</td>
</tr>
</tbody>
</table>

### Resisted Isometric Movements (note strength and pain)

<table>
<thead>
<tr>
<th>Movement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>Medial rotation</td>
</tr>
<tr>
<td>Extension</td>
<td>Lateral Rotation</td>
</tr>
<tr>
<td>Adduction</td>
<td>Elbow flexion</td>
</tr>
<tr>
<td>Abduction</td>
<td>Elbow extension</td>
</tr>
</tbody>
</table>

### Joint Play Movements (and motion palpation)

<table>
<thead>
<tr>
<th>Joint</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SC Joint</td>
<td>Supero-inferior (shrug shoulder with arm at side):</td>
</tr>
<tr>
<td></td>
<td>Horizontal add/abduction (arm abducted 90°):</td>
</tr>
<tr>
<td>AC Joint</td>
<td>A-P Shear:</td>
</tr>
<tr>
<td></td>
<td>Supero-inferior shear:</td>
</tr>
<tr>
<td>Scapula</td>
<td>Normal scapulo-humeral rhythm?:</td>
</tr>
<tr>
<td></td>
<td>General mobility of scapula:</td>
</tr>
</tbody>
</table>

### Glenohumeral Joint

<table>
<thead>
<tr>
<th>Movement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral movement of humeral head</td>
<td></td>
</tr>
<tr>
<td>Inferior movement of humeral head</td>
<td>(Caudalglide)(50°)</td>
</tr>
<tr>
<td>Anterior movement of humeral head</td>
<td>(P-A glide)(25°)</td>
</tr>
<tr>
<td>Posterior shear of humeral head</td>
<td>(A-Pglide)&gt;50%</td>
</tr>
<tr>
<td>Backward glide of humeral head in abduction</td>
<td>At 10° flexion &gt;50%</td>
</tr>
<tr>
<td>Long-axis distraction of humeral head in abduction</td>
<td>At 90° flexion</td>
</tr>
<tr>
<td>Downward and backward (S-I → A-P)</td>
<td></td>
</tr>
<tr>
<td>Outward and backward (med-lat → A-P)</td>
<td></td>
</tr>
<tr>
<td>External rotation of humeral head</td>
<td></td>
</tr>
<tr>
<td>Internal rotation of humeral head</td>
<td></td>
</tr>
</tbody>
</table>
## Instability Tests

### 1. Anterior Instability Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>R</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior drawer Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Rowe Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Fulcrum Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Apprehension (crank) Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Clunk Test (tear of labrum)</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Rockwood Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
</tbody>
</table>

### 2. Posterior Instability Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>R</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior Apprehension Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Norwood Stress Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Push-pull Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Jerk Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
</tbody>
</table>

### 3. Inferior and Multi-directional instability tests

<table>
<thead>
<tr>
<th>Test</th>
<th>R</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inferior Shoulder Instability Test</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Feagin Test (antero-inferior instability)</td>
<td>Pos</td>
<td>Neg</td>
</tr>
</tbody>
</table>

### Tests for Muscle or Tendon Pathology

1. Speed’s Test (bicipital tendonitis)
2. Gilchrest Sign (bicipital tendonitis)
3. Supraspinatus Test (supraspinatus tendonitis)
4. Hawkins-Kennedy Impingement Test (supraspinatus tendonitis)
5. Drop-‐arm Test (rotator cuff tear)
6. Impingement Test
7. Pectoralis Major Contracture Test
8. Ludington’s Test (rupture of long head of biceps)

### Tests for neurological function

<table>
<thead>
<tr>
<th>Test</th>
<th>C4</th>
<th>C5</th>
<th>C6</th>
<th>C7</th>
<th>C8</th>
<th>T1</th>
<th>T2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brachial Plexus Tension Test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radial Nerve</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median Nerve</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tinel’s Sign (Scalene triangle)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermatones</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biceps(C5/6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triceps (C7/8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Thoracic Outlet Syndrome Tests

<table>
<thead>
<tr>
<th>Test</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Adson’s Test</td>
<td>Halstead’s Test</td>
</tr>
<tr>
<td>Costoclavicular Test</td>
<td>Eden’s Test(cervicalrib)</td>
</tr>
<tr>
<td>Hyperabduction Test</td>
<td>Roos Test</td>
</tr>
<tr>
<td>Allen’s Test</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX G:
Numerical Pain Rating Scale – 101

Date:_________________        File number:_________________        Visit number:

Patient name:___________________________________________________________________________

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience when it is at its worst. A zero (0) would mean “no pain at all”, and one hundred (100) would mean, “pain as bad as it could be”.

Please write only one number.

0_________________________________________________100

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience when it is at its least. A zero (0) would mean “no pain at all”, and one hundred (100) would mean “pain as bad as it could be”.

Please write only one number.

0_________________________________________________100
**APPENDIX H:**

**Algometer readings:**

<table>
<thead>
<tr>
<th>PATIENT NAME: ___________________</th>
<th>GROUP: ____________________________</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ALGOMETER READING</th>
<th>PRIOR TO NEEDLING</th>
<th>10 MINUTES AFTER INTERVENTIONS</th>
<th>24HOURS AFTER NEEDLING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# APPENDIX I:

## Data collection sheet

Patient name: ________________________________

File number: ________________________________

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NRS</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Algometer</td>
<td></td>
<td></td>
<td>Ave.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Pain diary | 0-3 | Y | N |
|            | >3 <6 | Y | N |
|            | >6 < 9 | Y | N |
|            | >9 < 12 | Y | N |
|            | >12 < 24 | Y | N |
|            | >24 | Y | N |

Worst pain (hours)
**ETHICS CLEARANCE CERTIFICATE**

<table>
<thead>
<tr>
<th>Student Name</th>
<th>D. Chonan</th>
<th>Student No</th>
<th>20200709</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethics</td>
<td>FHSEC 018/07</td>
<td>Date of FRC Approval</td>
<td>16/07/2007</td>
</tr>
<tr>
<td>Reference Number</td>
<td>The effect of cryotherapy on post dry needling soreness.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In terms of the ethical considerations for the conduct of research in the Faculty of Health Sciences, Durban University of Technology, this proposal meets with institutional requirements and confirms the following ethical obligations:

1. The researcher has read and understood the research ethics policy and procedures as endorsed by the Durban University of Technology, has sufficiently answered all questions pertaining to ethics in the DUT 186 and agrees to comply with them.
2. The researcher will report any serious adverse events pertaining to the research to the Faculty of Health Sciences Research Ethics Committee.
3. The researcher will submit any major additions or changes to the research proposal after approval has been granted to the Faculty of Health Sciences Research Committee for consideration.
4. The researcher, with the supervisor and co-researchers will take full responsibility in ensuring that the protocol is adhered to.
5. The following section must be completed if the research involves human participants:

<table>
<thead>
<tr>
<th>Provision has been made to obtain informed consent of the participants</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential psychological and physical risks have been considered and minimised</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provision has been made to avoid undue intrusion with regard to participants and community</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rights of participants will be safeguarded in relation to: Measures for the protection of anonymity and the maintenance of Confidentiality</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Access to research information and findings.</td>
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</tr>
<tr>
<td>Termination of involvement without compromise</td>
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<td></td>
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</tr>
<tr>
<td>Misleading promises regarding benefit of the research</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Signature of Student/Researcher:**

**Signature of Supervisor(s):**

**Signature of Head of Department:**

**Signature Chairperson of Research Ethics Committee:**

**Date:**

15/10/2007

29-10-07

11/07

7/02/08