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A comparison of the effects of three forms of dry needling and a conventional physiotherapy protocol on rotar cuff syndrome: a pilot study

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A COMPARISON OF THE EFFECTS OF THREE FORMS OF DRY NEEDLING AND A CONVENTIONAL PHYSIOTHERAPY PROTOCOL ON ROTATOR CUFF SYNDROME: A PILOT STUDY

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfillment of the requirements for the degree of Master of Science in Physiotherapy

Johannesburg
May 2012



Declaration

I, Bruce Bradley Barker declare that this research report is my own work. It is being submitted for the degree of Master of Science in Physiotherapy, in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

.....

Bruce Barker

.....day of May 2012

Dedicated to the Creator of Heaven and Earth.

“for You created my inmost being;
You knit me together in my mother’s womb.
I praise You because I am fearfully
and wonderfully made” Ps 139:13-14

Publications arising from this research

Some of the findings of this study were presented in poster format at the University of the Witwatersrand's School of Therapeutic Sciences Research day in August 2011. The poster was awarded First prize.

Abstract

Aim: This pilot study compared the efficacy of superficial dry needling (SDN), deep dry needling (DDN), placebo dry needling (PDN) and a common physiotherapy control group (CON) when used in the treatment of myofascial trigger points (MTrPs) in rotator cuff syndrome (RCS) patients.

Methodology: A randomised, single-blind, placebo-controlled pilot study (n=20) was conducted comparing the three needling groups to each other and to a common physiotherapy protocol. Participants were selected patients presenting for treatment in a private practice. The objectives of the study were to compare the groups on three levels: Pre trial-Post trial, within individual treatment session (Intra-treatment), and between treatment sessions (Inter-treatment). All groups were treated with the same basic common protocol but three of them had the addition of one each of the needling interventions. A modified Constant-Murley scale, range of motion and power were used as outcomes measures. Ethical permission was obtained from the University of the Witwatersrand.

Results: Results were analysed for the four groups using an ANCOVA. DDN had significant improvement over CON over the trial period *($p \leq 0.05$)* and *SDN ($p \leq 0.02$).* This was particularly due to highly significant intra-treatment effect on internal range of motion at session 3 ($p \leq 0.01$) and the highly significant inter-treament effect between session 3 and 4 ($p \leq 0.03$). DDN was significantly less effective than the other groups at session 3 ($p \leq 0.01$) and session 4 ($p \leq 0.03$). External rotation power was also significantly greater for DDN between sessions 2 and 3 (inter-treatment) ($p \leq 0.05$). 49% of the MTrPs identified were found within the infraspinatus muscles.

Discussion: Twitch-obtaining dry needling (DDN) appears to show greater clinical benefit on the effects of myofascial trigger points than SDN, CON or PDN. The effect appears to correlate with the greater incidence of MTrPs in the infrapinatus muscles whose functions directly relate to the improved parameters. The clinical effect may be related to the effects of the bleeding elicited by intramuscular needling (humoral effects). This is evidenced by the transiently poor effect of DDN immediate following treatment becoming significanly better by the following treatment.

Conclusion: The pilot study showed that DDN may be an effective treatment for RCS when used in conjunction with a conventional physiotherapy programme. The elicitation of a local twitch response and associated bleeding may be significant. In future studies, particular attention should be paid to both the infraspinatus muscle and the timing of the intervention and observation intervals.

Acknowledgements

My profound gratitude are due to my wife and family for their time and prayers.

I wish to thank my supervisors Dr. Linda Steyn and Dr. Wendy Wood for their patience and gracious advice, and Professor Piet Becker of the Medical Research Council of South Africa for his assistance with the statistical aspects of this work.

Table of abbreviations

ADL	**Activities of daily living**
ANCOVA	**Analysis of co-variance**
C-M	**Constant Murley**
CON	**Control group**
DDN	**Deep dry needling**
DN	**Dry Needling**
LTR	**Local twitch response**
Mod C-M	**Modified Constant-Murley**
MTrP	**Myofascial trigger point**
MTrPs	**Myofascial trigger points**
PDN	**Placebo dry needling**
PPT	**Pressure Pain Threshold**
RCS	**Rotator Cuff Syndrome**
ROM	**Range of motion**
SDN	**Superficial dry needling**
SFMPQ	**Short Form McGill Pain Questionnaire**
SRL	**Straight leg raise**
TOIMS	**Twitch Obtaining Intramuscular Stimulation**
TrP-DN	**Trigger point dry needling**
VAS	**Visual analogue scale**

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1. INTRODUCTION

1.1. BACKGROUND TO ROTATOR CUFF SYNDROME

One of the most common presentations of shoulder pain is that of a rotator cuff syndrome (RCS). The aetiology of RCS is enigmatic, but the syndrome classically presents with a combination of pain, loss of range of movement and decreased strength of the affected shoulder (Ferguson 2005). Bron et al (2007) reported the one-year prevalence of such pain to vary between 20% and 50%. In a United Kingdom community-based prevalence study, shoulder pain (mixed diagnoses) ranked as the third highest cause of musculoskeletal pain (Urwin et al 1998). There are no comparable figures for South Africa. The South African physiotherapist's scope of practice declares that physiotherapists are "primarily involved in the management of physical problems in particular those associated with neuromuscular, *musculoskeletal,* cardiovascular and respiratory systems" (Eales 2001:1). However, evidence for the success of physiotherapeutic intervention in this high prevalence musculoskeletal disorder is weak (Mitchell et al 2005*).*

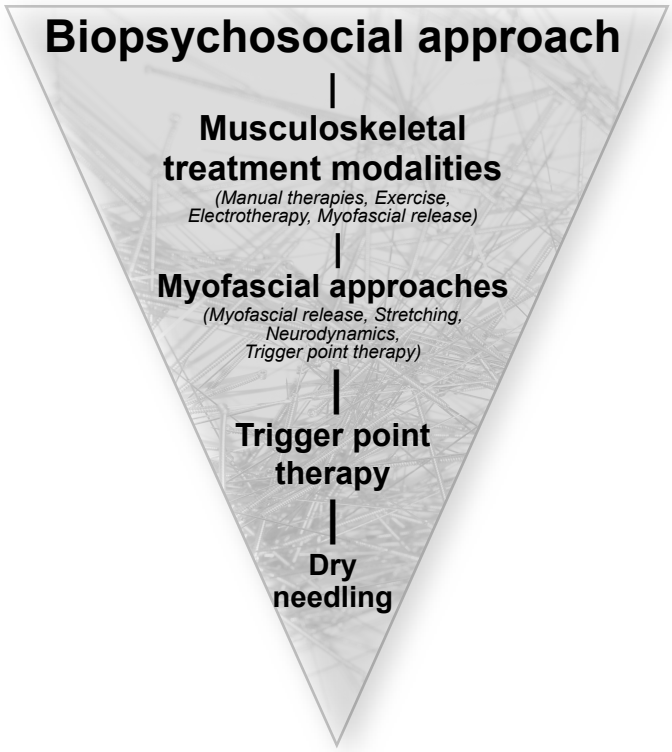

Fig 1.1 The place of dry needling therapy in Physiotherapy

Much of the published research on physiotherapeutic treatment of RCS concerns exercise, joint mobilisation and electrotherapy (Green et al 2003). Little is known about the contribution of myofascial sources for pain in RCS (Bron et al 2007). Travell and Simons held that myofascial dysfunction can exist in a painful joint with or *without structural abnormalities* (Travell & Simons 1999). The key element of such dysfunction is the phenomenon of the myofascial trigger point (MTrP) (Ingber 2003). MTrPs have characteristic symptoms which mimic those found in RCS, but the contribution of MTrPs to the RCS has not been fully addressed (Gerwin et al 1997).

Recommended Criteria for identification of MTrPs
Dommerholt & Huijbrechts 2010
Dommerholt et al 2006*

Essential Criteria	Confirmatory observations
Taught palpable band (if palpable)	Visual/tactile confirmation of local twitch response
Exquisite spot tenderness in a nodule of a taught band	Imaging of a Local Twitch Response (LTR) induced by needle penetration of a tender nodule
Patient pain recognition of current pain complaint by pressure on tender nodule	Pain or altered sensation in the distribution expected from a trigger point in the muscle on compression of the tender nodule
Painful limit to full stretch range of motion	Electromyographic demonstration of spontaneous electrical activity characteristic of the active loci in the tender nodule of a taught band
Muscle weakness as a result of muscle inhibition*	

Table 1.1: Recommended Criteria for identification of MTrPs

The presence of MTrP's alters the function of muscles (Perez-Palomares et al 2007). Table 1.1 shows the recommended criteria for MTrP identification based on Simons et al (1999), to which could be added an additional characteristic of reduced muscle power in the involved muscle/s (Dommerholt et al 2006). If the involved muscles are stabilising

muscles, then the neutral zone control of the relevant joint is negatively affected, either into “give” or “restriction," either of which may cause pain and movement dysfunction (Comerford & Mottram 2001). Lippitt & Matsen (1993) have argued for the importance of dynamic muscle contraction in the maintenance of stabilisation of the concavity compression forces around the glenohumeral joint. They point out that inherent structural instability of the glenohumeral joint means that ligamentous structures alone are incapable of preventing glenohumeral translation throughout the entire range of movement. This is particularly the case in the mid-range of movement. The implication is that the contractile elements around the joint are necessary for proper joint function, and that abnormal muscle function will result in abnormal arthrokinematics. It is therefore reasonable to investigate the effect of direct treatment of MTrPs on RCS.

1.2. THE PLACE OF DRY NEEDLING IN PHYSIOTHERAPY

One of the recommended techniques for treating MTrPs is dry needling (Dommerholt & Huijbregts 2010; Tough et al 2008). Dry needling is the name given to the use of medical grade needles in the treatment of myofascial pain and dysfunction. It is a therapeutically and theoretically distinct entity, not to be confused with the Traditional Chinese Medicine (TCM) technique of acupuncture (Travell and Simons 1999). It has been operationally defined by the Virginia Board of Physical Therapy’s Task force on Dry Needling as follows: *“Dry Needling is a technique used to treat myofascial pain that uses a dry needle, without medication, that is inserted into a trigger point with the goal of releasing/inactivating the trigger points and relieving pain”* (Virginia Board of Physical Therapy 2007: 2). This modality may thus be a potential tool for the treatment of RCS.

1.3. PROBLEM STATEMENT

There are various forms of dry needling described in the literature such as Superficial Dry Needling (SDN) (Baldry 2002; Edwards & Knowles 2003) and Deep Dry Needling (DDN) (Hong et al 1997a; Tsai et al 2010). There is debate as to the relative efficacies of each of these techniques (Ceccherelli et al 2001, Ceccherelli et al 2002).

Rotator cuff syndrome (See 2.3)	A common condition affecting the shoulder. Symptoms include a combination of pain, loss of range of movement and decreased strength of the affected shoulder (Ferguson 2005)
Dry needling (See 2.6)	"Dry Needling is a technique used to treat myofascial pain that uses a dry needle, without medication, that is inserted into a trigger point with the goal of releasing/inactivating the trigger points and relieving pain" (Virginia Board of Physical Therapy 2007: 2)

Table 1.2: Definitions of RCS and DN

1.4. Research question

What is the relative efficacy of each of three different forms of dry needing plus a conventional physiotherapy regime versus that physiotherapy regime alone when used in the treatment of RCS?

1.5. Research aim

This pilot study aimed to assess the relative efficacy of three forms of dry needling in RCS and compare these to a conventional physiotherapy intervention.

1.6. Research objectives

1.6.1. Compare the changes in Constant-Murley scale scores between patients treated with the four interventions on a pre-trial / follow up visit basis for each group.

1.6.2. Compare the changes in Constant-Murley scale scores, ROM, Power in patients on a pre-intervention / post-intervention (intra-treatment) basis at each treatment for each group.

1.6.3. Compare the changes in Constant-Murley scale scores in patients on a between intervention (inter-treatment) basis at each treatment for each group

1.7. SIGNIFICANCE OF THE STUDY

The study aimed to gain clarity as to the clinical efficacy of dry needling when used in combination with a common physiotherapeutic intervention in treating RCS. Specifically, the study intended to show there was a difference in both the effects, and the time needed to show the effects of the dry needling (DN) techniques. Implementation of this approach may have benefits to patients in terms of a more nuanced approach to the scheduling of DN treatments.

1.8. Conclusion

The general background to the study has been given, and the similarity of RCS symptoms to those of MTrPs shown. Three research objectives that follow from the specific research question generated from this similarity have been identified. In the chapters that follow, these objectives will be met by:

- Developing the general background given into greater specifics of the components used in the study by means of a literature review (Chapter 2)
- Defining the methodology used to investigate the research objectives (Chapter 3)
- Reporting on the findings of the investigations into the three research objectives (Chapter 4)
- Discussing the results of the study and making recommendations for further investigation (Chapter 5)

A comprehensive collection of Appendices relevant to the study is given at the end of this document including the Ethical Clearance certificate.

2. LITERATURE REVIEW

2.1. INTRODUCTION AND METHOD

This review of the published literature details the key problems which informed the design and thrust of this research report. Key terms used in the study are defined herein, and the chapter includes a brief historical review of the definition of dry needling and its place within musculoskeletal therapy. The key concept of the myofascial trigger point and its relevance to rotator cuff pathology is reviewed. It reviews the suitability of the Constant-Murley scale as the key outcome measure for the study.

Computerised searches of the Cochrane, PubMed and PEDro were conducted using the search terms “dry needling”, “rotator cuff syndome”,”trigger points” and “shoulder pain”. Additional papers were sourced using the reference lists of the results of the above searches, and from those listed in academic texts related to the issues under discussion.

2.2. THE PROBLEM OF SHOULDER PAIN IN PHYSIOTHERAPY

In a systematic review of physiotherapeutic interventions such as myofascial release, exercise and electrotherapy for “shoulder pain”, Green et al (2003) identified only 26 trials of sufficient data quality for a meta-analysis, and concluded that there was little evidence to guide existing physiotherapeutic treatment of conditions causing shoulder pain, stiffness or disability. Poor definition of the problem and methodological weaknesses in the studies hampered the conclusions. The diagnosis of rotator cuff syndrome was included in the study, but MTrPs were not specifically addressed.

2.3. DEFINING ROTATOR CUFF SYNDROME

Poor definition of the diagnosis hampered Green et al (2003) in their analysis. The diagnosis of RCS must be defined here to avoid a similar difficulty. However, a close definition of the term does not appear possible. Lewis (2008) considers RCS and the related subacromial bursa to be the most prevalent causes of shoulder pain in humans. The diagnosis is usually made on the basis of one or more described eponymous tests (Neer’s, O’Brien’s etc) and/or the findings of diagnostic imaging studies (MRI, Sonar).

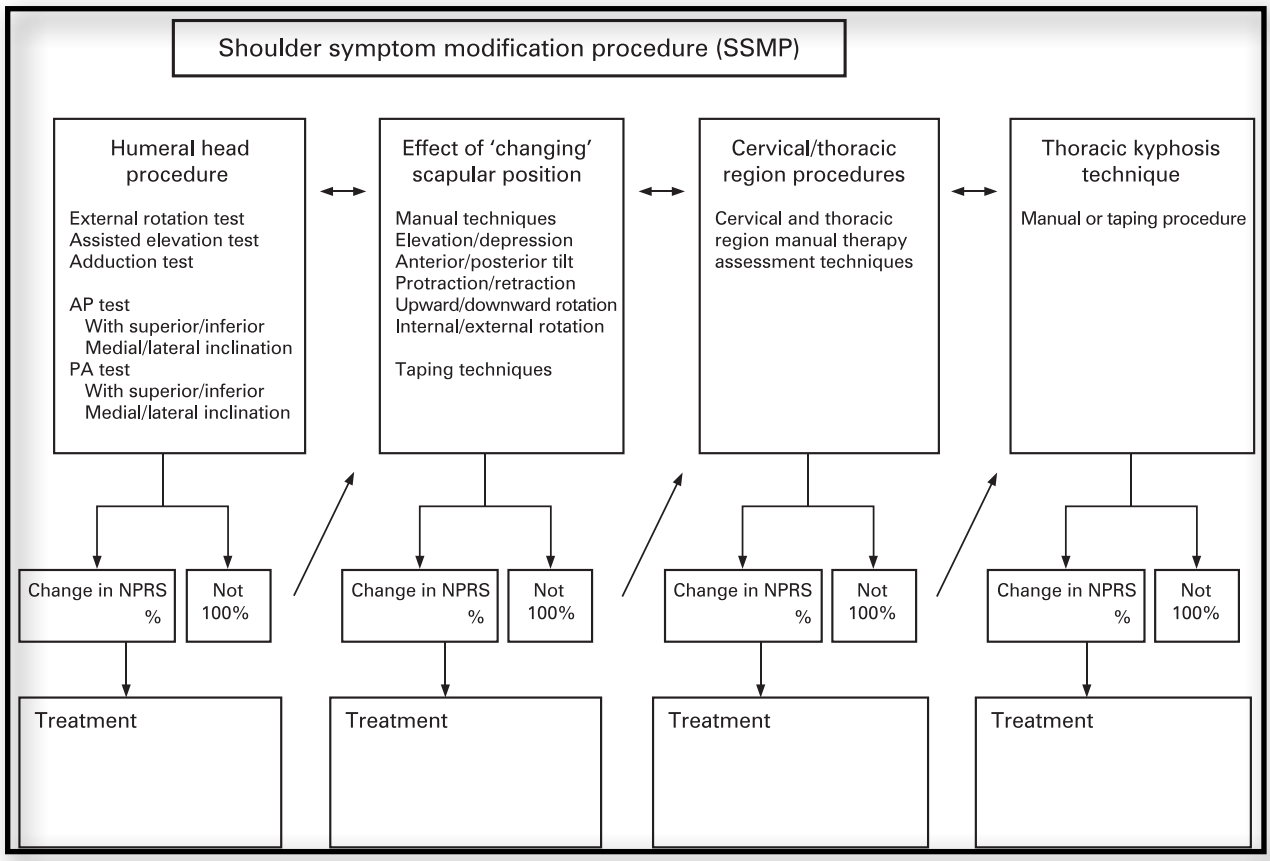

Figure 2.1: Lewis' SSMP approach to RCS

Lewis 2008 Br J Sports Med 43:250

Lewis (2008), citing Lewis (2007) and the Hegedus et al (2008) review has cogently argued against the use of such tests based on three factors.

- The impossibility of clinically isolating individual components of the cuff. The described tests are not specific enough to be valid
- The anatomical location and features of the subacromial bursa. The bursa appears to have a large and underreported role in shoulder pain
- The lack of correlation between imaging findings and clinical findings.

In the absence of a single valid test, Lewis (2008) has proposed a new diagnostic procedure based on symptom provocation and finding a mechanical alteration which alleviates the provoked symptom. This Shoulder Symptom Modification Procedure (SSMP) is a series of four sequential mechanical techniques which are applied by the therapist to the patient while the patient performs a pain provoking movement. These are employed sequentially on a needs basis - if the patient does not obtain full relief on the first battery of

interventions, the therapist moves on to the next battery until full relief is obtained (see Figure 2.1).

This approach has the benefit of solid clinical reasoning, but the method does not yet have widespread adoption and required further empirical research and refinement before it can be clinically adopted as an alternative to the currently used, but flawed, common tests.

For clarity, and the above discussion notwithstanding, in this research report, the term RCS will be taken to mean a positive result on the tests given on in the Inclusion Criteria (Table 3.1) i.e. positive Neer's or Hawkins-Kennedy impingement signs (Magee 1997:219).

Myofascial trigger points (MTrP's) have characteristic symptoms which mimic those found in rotator cuff pathology (see Table 1.2), but the contribution of MTrP's to the pathology has not been fully addressed (Gerwin et al 1997).

Comparison of the similarity in symptoms of RCS and MTrPs in muscles of the rotator cuff

RCS	MTrPs
Local pain over shoulder joint	Active MTrPs cause local joint pain
Referred pain into the arm	Rotator cuff muscle MTrPs refer pain in a predictable pattern in to the arm
Reduced range of glenohumeral movement	Knotted myofibrils cause functional shortening of muscle and consequent reduction of range of movement in the glenohumeral joint
Reduced power in arm movements	Knotted myofibrils reduce recruitment of muscle fibres with consequent loss of power in the rotator cuff muscles
Reduction in ADL performed by the arm	Pain and loss of range cause muscle guarding and kinesiophobia
Pain is aggravated by sleeping on shoulder	Lowered pressure point threshold of MTrPs results in pain when the muscles are compressed between the body and the mattress

Table 2.1: Comparison of the similarity in symptoms of RCS and MTrPs in muscles of the rotator cuff

2.1. THE EFFECT OF MTRPS ON MUSCLES

The presence of MTrP's alters the function of muscles (see Table 1.1) The therapeutic effects of dry needling are ascribed to the "deactivation" of MTrP's (Travell & Simons 1992; Chen et al 2001; Hsieh et al 2007). The mechanisms will be elucidated later.

Indeed, the 1983 publication of the first volume of the Manual of Myofascial pain and Dysfunction (Travell and Simons 1999) represented a radical departure in medical circles precisely because it challenged the dominant orthopaedic surgical paradigm which holds that – with regard to musculoskeletal injuries - only structural problems can cause pain. This seminal publication, referenced in this report in its second edition (1993), has been largely responsible for establishing the scientific basis for the consideration of myofascial sources for pain as evidenced by the increasing numbers of studies which reference the work (Bron et al 2010, Hidalgo-Lozano et al 2011).

This study focussed on the myofascial aspects of RCS, specifically the phenomenon of the MTrP. The significance of the symptomatic correlation between RCS and MTrPs is that it suggests that at least a part of the presenting signs and symptoms of rotator cuff syndrome could be explained by the presence of MTrP's. The relative contributions of neural dynamics, motor control, postural alignment and other known contributory factors falls outside of the scope of the study.
It is not possible to conclusively state the extent to which this *prima facie* case may be true, for as Bialowsky et al (2009) have pointed out, it is not possible to isolate the specific effects of manual therapies. The interaction of the neuromusculoskeletal components is often too close to be clinically separated.

MTrPs have previously been implicated in myofascial dysfunction. In a single case study, Cummings (2003) reported relief of pain and neurological symptoms relating to a MTrP in the Pectoralis Major muscle (caused by an intercostal drain) using dry needling.
Ingber (2000) showed that a combination of dry needling and therapeutic stretching was clinically effective in treating shoulder impingement problems in three case reports of refractory pain in racquetball sufferers; the improvements were in joint range, power and pain sensitivity. A similar approach to treatment of the Psoas major muscle also yielded

encouraging results in a series of six patient with “failed lower back syndrome” regarding lumbar spine and hip range of movement (Ingber 1989). Huguenin et al (2004) assessed the effect of dry needling MTrPs in the gluteal region on the straight leg raise test but found no significant correlation. Chen et al (1998) have shown in a two patient case report that relief from chronic chest wall pain caused by *herpes zoster* infection of intercostal nerves may be alleviated by treatment of MTrPs in the intercostal muscles. Wheeler et al (1998) assessed the effectiveness of treating chronic refractory neck pain using Botulinum toxin infiltrations of MTrPs, but found no significant differences between the injection of normal saline and Botulinum toxin, although both groups did improve significantly. Botulinum toxin was selected as it is a potent acetylcholine antagonist, active at the neuromuscular junction. MTrPs are a pathological phenomenon specific to the neuromuscular junction, and are thought to involve the abnormal release of acetylcholine at this junction (see 2.5).

There are electromyographic indications that the muscle dysfunction seen in myofascial pain syndromes may also have a neural component. Hubbard and Berkoff (1993) showed abnormal EMG activity in muscles at rest when the electrical potential difference was measured between MTrPs and the taught band compared to uninvolved parts of the muscle, signalling abnormal autonomic stimulation of the muscle spindles, increasing resting tone in the muscle. Chu (1997) noted that EMG needling of the cervical muscles in patients arm and neck pain was positively correlated with clinical reduction in pain when the sites needled were MTrPs but not when the sites were randomly selected. Similarly, Fricton et al (1985) have shown motor unit activity to MTrPs to be significantly higher to that of normal muscle and this is related to “progressive abnormal muscle change from a functional neuro-dystrophic stage to an organic musculo-dystrophic stage” (*ibid* 1985: 316*).* Bialowsky et al’s (2009) clinical caveat regarding the interaction of muscle and nerve alluded to above find resonance in the MTrP.

2.2. THE MYOFASCIAL TRIGGER POINT

A myofascial trigger point (MTrP) is a hyperirritable locus in a skeletal muscle associated with hypersensitive palpable nodules within a taught intramuscular band (Fricton et al 1985; Travell and Simons 1999). Previously, the MTrP was also not consistently shown by electron or light microscopy (Hubbard and Berkhoff 1993). However, the hypersensitive nodule is now biochemically (Travell and Simons 1999), histologically (Shah et al 2004)

and electromyographically (Hubbard and Berkhoff 1993; Simons et al 2002) distinguishable, and is readily palpable (Chu 2000). It is distinct from a *tender point*, but the two may be coincident (Jimbo et al 2008*).*

The key clinical features of MTrP's are *patient recognised* pain, loss of range of motion in the associated joint, decreased muscle power without atrophy, a local twitch response (LTR), autonomic symptoms and reproduction of the patient's familiar symptoms (functional deficits) (Gerwin et al 1997; Hong & Simons 1998)(see Table 1.1).

MTrPs were previously thought to be secondary to primary joint disease (Reynolds 1981). However, in the current conception, the cause of these phenomena is ascribed to the affected area being in a state of energy crisis due to a lack of oxygen supply according to the "Integrated Hypothesis" (Hong & Simons 1998). This central idea of an oxygenation supply problem is hinted at by Jimbo et al (2008) who have identified (in a small population sample of patients with *tender points*) that the time taken for a muscle to exhibit recovery from a hypoxic state is reduced by the application of a non-stimulated needle a day before. Gerwin et al (2004) concurred with this hypothesis and have proposed an expansion to it to account for new experimental data and established muscle pathophysiology. They emphasised the importance of the balance between the release of, and the breakdown of, acetylcholine (ACh) in the injured muscle. ACh is the major neurotransmitter involved in motor end plate function (Gerwin et al 2004, Niddam 2009*).* McPartland and Simons (2010) state that the MTrP phenomenon centres upon dysregulated motor end plates, and that this phenomenon is sustained by a neural loop of sensory afferents and autonomic afferents.

The focus on understanding the pathological features of the MTrP has revolutionised treatment approaches to myofascial pain (Dommerholt & Huijbreghts 2010). The apparently diverse approaches involving myofascial tissues, local and systemic biochemical factors and the neural components has found expression in the "Integrated Hypothesis" relating to the motor end plate (Travel & Simons 1999). More recently, this model has been modified to account for the increasing amount of molecular and genetic evidence supporting the model (Dommerholt & Huijbreghts 2010). The nidus of MTrP is chemically distinct, and is typical of a painful area. There are also features of antidromal production of Substance P and CGRP, which point to centralised pain generation (Shah et al 2005). It appears as if MTrPs may have pathological features in the presynaptic, intrasynaptic and postsynaptic parts of the motor end plate. An in depth examination of

these features is beyond the scope of this pilot study, but it important to note that the core element is a relative hypoxia in the muscle tissue which primarily results in peripheral symptoms, and that it is reasonable to expect a local intervention which targets the hypoxia (i.e. one that improves local blood oxygen delivery) to show more clinical benefit than a non-humoral mechanism.

This study was designed to assess the effect of treating the MTrPs on the typical symptoms of a RCS. The specific modality of treatment chosen was DN. By definition, DDN causes local intramuscular bleeding, whereas SDN does not.

2.3. Defining Dry Needling

The term ”dry needling” is not a globally recognised term. It is used in South Africa, Spain, Australia, and in selected states within the United States of America among other countries, but the terms “Medical acupuncture” and Western acupuncture” are used in the United kingdom. The subgroup of the World Confederation for Physical Therapy (WCPT) dealing with needling therapy is International Acupuncture Association of Physical Therapists (IAAPT). However In Australia - a founding member of the IAAPT, the member group dealing with needling therapy is called the “Acupuncture *and* dry needling group” (italics mine). Confusion between dry needing and acupuncture has lead to lack of clarity regarding the indications for dry needling treatment. However, a commonly accepted definition of dry needling would include the elements of:

- the use of a filamentous needle
- which is inserted into the skin and/or muscle
- particularly targeting the MTrP
- to treat musculoskeletal pain and dysfunction (See Dommerholt et al 2006; Virginia Board of Physical Therapy 2007: 2)

Green et al (2005) published a systematic review of *acupuncture* interventions for shoulder pain in which they concluded that there is insufficient evidence to determine the efficacy of *acupuncture* for “shoulder problems”. There was no specific focus on the MTrP in this study as would have been the case if the needling technique was of the dry needling variety. However, an internet search of the PEDro, Medline, Cochrane and PubMed

databases did not reveal a randomised control trial which addresses the *myofascial trigger point component* of rotator cuff pathology with regard to *dry needling* specifically.

The most recent and comprehensive needling study identified in the Cochrane database was published in 2005 by Furlan et al (2005). This is a systematic review of acupuncture and dry needling therapies as used in treating “low back pain” pathologies. The findings indicate that a difference exists between the modalities. The authors concluded that dry needling, but not acupuncture, appears to show clinical benefits when used for treating low back pain.

A further discussion of the differences can be found in Dommerholt et al *(*2011). The authors developed the abbreviation TrP-DN to indicate Trigger Point Dry Needling, and differentiate this from any suggestion of similarity to acupuncture.

“From a physical therapy perspective, TrP-DN has no similarities with traditional acupuncture other than the tool” (*ibid* 2011:179).

Despite the continued use of dry needling in the clinical setting, there is no clarity on the best clinical practice regarding the technical use of dry needling. This study attempted to identify which of the two main forms of dry needling showed the greater therapeutic benefit by defining them clearly and then comparing each of them to both a control and a placebo group (see 1.3)

A major distinction between acupuncture and dry needling lies in the importance of the MTrP. The most recent and comprehensive needling meta analysis identified was published in 2001 by Cummings & White. The objective of the Cummings and White review was to “establish whether there is evidence for or against the efficacy of needling as a treatment approach for *myofascial trigger point pain*” (italics mine), and included both acupuncture and dry needling randomised control trials which treated myofascial pain. They made four conclusions as follows:

1. Direct needling of myofascial trigger points (MTrP’s) appears to be an effective treatment for the symptoms of myofascial pain.
2. The nature of the effect is due either to the needle itself or to placebo, rather than the injected substance.
3. There was no clinical trial evidence to either support or refute the hypothesis that needling has an effect beyond that of placebo.

4. Controlled trials are needed to investigate whether needling does indeed have an effect beyond that of placebo.

This review also highlighted the lack of consistency in interventions. Although the studies all claimed to be studying myofascial pain, only eight of the twenty-three included trials include strict minimum diagnostic criteria for myofascial trigger points as formulated by Gerwin (1997). Of these, only a single study reported on the phenomenon of a local twitch response, which is clinically considered an essential indicator of therapeutic success (Hong 1994b; Travell and Simons 1999; Chen et al 2001; Chu et al 2002; Irnich et al 2002; Shah et al 2004; Shah et al 2005). The Ceccherelli et al (2001) study was not included in the review, but it too does not mention the local twitch response. It is not therefore surprising that a consistent comparison with placebo could not be established, as the interventions themselves are only nominally comparable.

This pilot study sought to elucidate this problem by defining the modalities used and then comparing them (see 1.3).

Hong et al (1997a) cogently and scientifically argued for a dry needling technique used in treating MTrP's which seeks the elicitation of a LTR. In this they are supported by Alencar (2008). A LTR is a brisk transient contraction of a portion of any given muscle, and is distinct from a more general "jump sign" which is demonstrated when an entire limb or body segment is moved away from a noxious stimulus. It is a primarily a centrally mediated, spinal reflex phenomenon (Hong 1994a) and is a valuable objective sign that confirms the presence of a MTrP (Hong 1994c). The elicitation of a LTR has been described as "a necessary sign that must be obtained to ensure penetration of the myofascial trigger point" (Gerwin & Dommerholt 1995:8). Dry needling the MTrP is an easier way of eliciting a LTR than can be achieved by digital palpation (Hong et al 1997a). Chu (2000) has reported that the clinically similar TOIMS (Twitch Obtaining Intramuscular Stimulation) technique was significantly more clinically effective than standard treatments for MTrP's. In a study comparing the injection of different concentrations of local anaesthetic into myofascial trigger points, Alencar et al (2008) described the importance of eliciting this LTR even when infiltrating a muscle with either a local anaesthetic like Procaine (registered as Novocaine in South Africa) or a corticosteroid. This method of dry needling (DDN) is beginning to gain currency as a standard technique, as demonstrated

by its use in recent publications (Gallego & del Moral 2007, Fernández-Carnero et al 2009, Tsai et al 2010, Ay et al 2010).

DDN is the first form of DN included in this study.
The second form of dry needling to be included in this study is SDN, which involved the placing of a dry needle into the skin superficially to a MTrP. This technique is detailed in the next section, which also explains the reasoning behind including both techniques in the study (see 1.3)

2.4. A DISCUSSION OF SUPERFICIAL VERSUS DEEP NEEDLING

Several attempts to evaluate the relative efficacy of the techniques of deep, or intramuscular dry needling, versus the more superficial, or intradermal technique have been made. A discussion of some of these papers follows below.

One of the most influential clinicians in the field is Peter E.Baldry, Emeritus Consultant physician and is generally held as the authority on the superficial needling technique. In his contribution to a debate held at the ICMART 10th World Conference in 2002, he laid out his position on the matter, and indicated that fully 90% of his patients were treated with the superficial technique alone (Baldry 2002). A description of the technique he proposed in that paper serves as a basis for this discussion.

Baldry (2005) typically used a 0.3x30mm long needle, but only inserted the needle 5-10mm. In this he employed a technique similar to the acupuncture approach. (It is the depth of the point of the needle rather than the length of the needle that defines the technique). The needle was inserted shallowly into the skin and left in place for a period of time (usually 30 seconds) in which the needle was stimulated such that both the “jump sign” and the “shout sign” are abolished. These were defined as effects of the palpation of the exquisitely tender trigger points. If these were not abolished, the needle was reinserted and left for a number of minutes, with the option of further stimulation. Baldry emphasised the need for muscle stretches and the use of postural advice post needling. He also identified 5 main reasons for choosing the superficial technique over the deeper one when the primary complaint is of uncomplicated, nociceptive myofascial trigger point pain:

1. Personal experience of effectiveness over many years of practice
2. Ease of performing the technique
3. Relatively painless compared to deep needling (barring the “prick”)
4. Minimal risk to nerves, blood vessels and other structures
5. Minimal bleeding and therefore low incidence of post-treatment soreness

Baldry (2005) identified the neural mechanism of operation posited by Bowsher (1988) as the mechanism of action used by superficial needles to treat the uncomplicated, nocioceptive myofascial trigger point pain. In this theoretical mechanism, stimulation of A-δ fibres on the dorsal horn cell (whereby an inhibitory endogenous enkephalinergic response is generated), caused both pre-and–post synaptic blocking of nocioceptive Group IV afferent transmissions at a central, or spinal cord level. This is a neural, rather than a humoral mechanism, and was thought to have an effective analgesic effect in the acute phase, as well as in down-regulating the effect of central sensitisation in more chronic states. The effect of the stimulation of A-δ fibres at a central level may have an effect at a peripheral level via the phenomenon of antidromic stimulation of both Substance P (SP) and Calcitonin-Gene-related-polypeptide (CGRP) (Shah & Gilliams 2008).

The effect of this central neural mechanism on peripheral neural sensitivity raises a methodological problem. Bialowsky et al (2009) have noted that current literature fails to acknowledge the combined effect of neurological and biomechanical effects of manual therapies. They suggest that a mechanistic stimulus may give rise to a number of potential neurological effects, and that the clinical outcomes seen by manual therapists in treating musculoskeletal pain may best be described as the cumulative effect of neural and mechanical factors. This cautionary observation is not limited to a discussion around dry needling alone, but to all physical therapy

Physiotherapists Edwards and Knowles have published an assessment of the effect of superficial needling on myofascial pain (Edwards & Knowles 2003). In this pragmatic single-blind randomised control trial, the use of superficial needling combined with an active stretching programme was shown to be more effective than the use of an active stretching programme alone (with respect to both pain as measured on the Short Form McGill Pain Questionnaire (SFMPQ) and Pressure Pain Threshold (PPT) after 6 weeks of

treatment). This was especially true of the reduction in pain scores (SFMPQ), and less so of pressure pain threshold (PPT). (The authors identified a similar list of advantages of SDN, but did not cite the Baldry (2005) paper above.
The point to note from this study is the nature of the improvement in the patient's pain – it is in the perception (SFMPQ score), rather than the objective reality (PPT), again reflecting the *neural* rather than humoral effect. This self reported variable could be ascribed to the placebo effect.

Ceccherelli et al (2001) utilised a randomised control group to assess the relative efficacy of superficial acupuncture versus deep acupuncture in a group of patients 40-65 years of age with shoulder pain. This study was unusually explicit in detailing the depths to which the needles were inserted in each group. In the superficial group, the needles were 0.3x15mm in size, and inserted to a depth of just 4mm into the skin. In the deep group, the needles were 0.3x25mm in size and inserted to a depth of 25mm into a muscle. All the insertion points chosen were classical acupuncture points rather than MTrPs, and were rotationally stimulated. The outcome measure was the MGPQ, specifically the pain rating index and the number of words chosen. Both parameters were shown to have a statistically significant improvement in both groups ($p<0.05$) for a "before and after" analysis, and this was maintained at a 3 month follow up. However, the magnitude of the change was markedly different. For the superficial group, an improvement of 38.49% was found, while the deep group showed an 86.38% reduction in pain. The magnitude of change in the superficial group is again close to that which can be expected from a placebo effect (33%). It is not clear if there was any attempt to address myofascial trigger points or elicit local twitch responses in this study, despite the title's reference to "myofascial pain".

Similarly, Ceccherelli et al (2002) previously attempted a comparison of deep and superficial acupuncture in a double-blind randomised control study group of lumbar myofascial pain. Again, the MGPQ was used and the same two parameters chosen. Again, classical acupuncture points of insertion were chosen, but in this study, four "trigger points", or the four most painful muscular tender points, were also needled. The depth of insertion of the superficial group was 2mm into the skin of both the acupuncture points and superficially over the trigger point areas. The deep group were similarly uniformly needled to 15mm, despite differences in subcutaneous tissue thickness. The study design appears

to accommodate different tissue thicknesses as it discusses various lengths of needles, but the depth of insertion of the deep group (group B in the study) was uniform:
"In group B patients, the needle was inserted to a depth of approximately 1.5cm in the muscle or in the trigger points"(Ceccherelli et al 2002:151)

Again, all needles were rotationally stimulated. It is not clear how the participants were blinded as to the group they were randomly assigned. As noted above, one of the appealing aspects of superficial needling is that it is less painful than deep needling. Such a condition cannot be said to be proper blinding, and as such this study is best regarded as a single-blind study. The insufficient depth of insertion of the deep group should also be regarded as a significant methodological weakness, as is the statistical weakness of the study, which was powered at <80%.

Notwithstanding these weaknesses, the study demonstrated no significant difference between the groups at the end of the 8 treatment cycle, but did show a better result for the deep group at a three-month follow up. It is difficult to interpret these findings given the methodological weaknesses, but it is instructive to note the similarity of result from techniques which were both relatively superficial given the areas used. Both techniques are essentially the same "superficial needling" in nature. It appears as if the two groups could have been defined too narrowly, leading to the incorrect labeling of a technique as "deep" when a true deep technique should rather have been inserted more deeply, and actually penetrate the muscle. Hong (1994b) has pointed out that it is imperative to penetrate the myofascial trigger point for deep needling to occur (and to elicit a local twitch response). In Ceccherelli's (2001) study of the previous year, the deep needles were inserted to a depth of 25mm (*contra* the 2002 study where 15mm was used) into a body region commonly far less prone to subcutaneous variation than the lumbar spine and buttock areas. This inconsistent methodology reflects the common inattention to definition and standardisation that has plagued the field (see introduction).

In one of the better described studies, Huguenin et al (2005) similarly used a 25mm long needle to investigate the effect of dry needling on gluteal trigger points. They pointed out that local twitch responses were obtained, and that the myofascial trigger points were needled until the local twitch responses were no longer observed. This would seem contradictory given the above discussion where the needle length of 25mm was held as insufficiently long to adequately reach the deeper lying gluteal muscles. The difficulty is

somewhat resolved when it is noted that the Huguenin study specifically recruited male athletes as participants, whereas Ceccherelli (2002) used a mixed sample taken from among the low back patients at a Pain Therapy unit. Although Ceccherelli excluded patients for “obesity that does not allow the muscular insertion and stimulation of needles” (Ceccherelli 2002:150), it is possible that the average thickness of gluteal adipose tissue in trained athletes is significantly different to that of the average chronic pain patient. Certainly, the typical adipose deposition pattern between males (android pattern) and females (gynoid pattern) is phenotypically different, and these two factors can be considered confounding variables which make direct comparison difficult.

In the Huguenin (2005) study above, an attempt was made to assess the effect of the dry needling release of trigger points in the gluteal region by assessing the change in range of a straight leg raise and the change of range of hip internal rotation. A Visual Analogue Scale was also used to rate the pain on running. A single-intervention design (see 2.7), with measures taken immediately-before, immediately-after, 24-hours, and finally 72-hours after was employed. No significant changes in VAS scores after running were observed, but resting variables were significantly improved immediately after intervention; they were however stable thereafter. No significant differences between placebo and “real” needling in terms of range of motion for either the straight leg raise or for hip internal rotation were observed. This lead the investigators to declare that these outcomes were of no value as reassessment measure after the treatment of gluteal trigger points. The investigators noted that the findings of subjective improvement but objectively negative results (no better than placebo) is reflected in 2 other dry needling studies, neither of which is reflected in the systematic review by Cummings (Cummings 2001). Karakurum et al (2001) Used a sample of 30 people to compare the effects of an intramuscular needling technique with a placebo technique in the treatment of tension-type headaches. The intramuscular technique used was not of a twitch-obtaining type; the needles were left *in situ* for 30 minutes. The “placebo” technique used was essentially superficial needling as the needles were inserted only subcutaneously. This is not a placebo, but another form of needling (superficial needling). This study thus compared a (sub-optimal) “deep” dry needling technique with superficial needling. Indeed, both groups showed significant improvement ($p<0.05$) improvement in headache pain scores, with similarly matched scores for change in range of movement), beyond what would be expected from a mere placebo (+/-30%). There was also a significant improvement in tenderness scores in the treatment group ($p<0.001$), and the difference in this score between groups was also

significant ($p<0.001$). The conclusion drawn by Huguenin et al (2005) concerning the results of dry needling being no better than placebo cannot be supported from this study because of methodological difficulties.

As indicated above, there are two distinct effects occurring with any dry needle intervention, these being the effect of penetrating the skin (which both superficial and deep needles do) and the penetration of the myofascial trigger point, which is classically reserved for deep needles. Superficial needles generate a neurally mediated effect; deep needles generate this *as well as* a humorally mediated effect (bleeding and the consequences of activating an inflammatory response), which will be elucidated below. Huguenin et al (2005) made mention of the humoral effects (citing Travell & Simons 1998 but herein referenced as 1999), describing this as an "early theory" but did not distinguish between the deep and superficial effects. The authors - while stating that the mechanism of pain relief associated with trigger point relief was unknown - ascribed the effects of the needle not to local muscle factors but to a centrally mediated analgesic effect, and in their discussion favoured neural processing explanations for the subjective relief rather than actual physical changes in the gluteal muscles (Huguenin et al 2005). Several other papers dealing with the reduction in symptoms of myofascial trigger points have identified a spinal cord mechanism alone for this phenomenon (Audette et al 2004, Hsieh et al 2007). However, these papers did not consider the paper by Shah et al (2005) which provides powerful evidence in favour of the local biochemical factor model as discussed below.

There may be different mechanisms in play for each of these types of dry needling. However, the studies cited above seemed to indicate that a greater therapeutic effect could be expected from the DDN group as opposed the either of needing groups (SDN and PDN) or the control group when the MTrP is targeted with an LTR obtaining technique. It was not known how long it would take for the effects to manifest, but it was thought that the neural mechanism (SDN) would have an immediate effect, and the humoral mechanism (DDN) would demonstrate a delayed response.

2.5. THE PHYSIOLOGICAL EFFECTS OF DRY NEEDLING

Alencar et al (2008:2) citing Han & Harrison (1997) identified five possible mechanisms for the success of trigger point injection therapy. These apply principally to the injections of substances that can be injected ("wet needling"), and are as follows:

1. Mechanical disruption of muscle fibres and nerve endings
2. Mechanical disruption of muscle fibres, causing increased extracellular potassium, which leads to depolarisation of nerve fibres
3. Interruption of the positive feedback mechanism that perpetuates pain
4. Local dilution of nocioceptive substances by the infiltrated local anaesthetic or saline that is infiltrated
5. Vasodilatory effect of local anaesthetics, increasing the removal of metabolites

Alencar et al (2008) conducted a study comparing two such wet needling techniques (Group 2= lidocaine 0.25% without vasoconstrictor, Group 3= lidocaine 0.25% without vasoconstrictor, but with added Decadron 4mg/ml) with each other, and used a dry needling technique (the same needles, but no injectable substance in the syringe) in the control group (Group 1). The major finding of this study concurs with findings of Hong (1994b) in that it was of little consequence which substance was injected as all groups improved significantly ($p<0.05$) with respect to pain intensity, frequency and duration, use of rescue medication, time and duration of relief. The only parameter which showed a significant difference was that of post-needling soreness, which was less in group 3. The same gauge needle was used in all groups. This major finding was repeated in a study comparing the effects of Botulinum toxin A and physiological saline (Ojala et al 2006) and again in comparing Botulinum Toxin A with bipuvicaine (Graboski et al 2005). These findings also correlate with those of Ay et al (2010) who used a randomised control study to examine the relative effects of dry needling and wet needling with 2ml of 1% lidocaine on cervical range of movement, psychological depression and pain (Ay et al 2009). In this study of 80 patients (but with limited statistical powering), the effects for both groups was found to be significant and matched at both 4 weeks and 12 weeks.

Significantly, the groups in Ay et al (2009) did not show a difference in post-needling soreness, and this was ascribed to the use of the thinner, solid needles typically employed in the dry needling approach. Clearly the common element is that of the needle itself, or

"dry needling", and the common effects of the various interventions can be ascribed to the mechanistic effects of the needle rather than the chemical effects of injected substances. This implies that, of the options given by Alencar et al (2008) citing Han & Harrison (1997) above, the better candidates for explaining the effect of dry needling were the first three possible mechanisms.[1] The first two effects did not occur in the superficial DN (SDN) group in this study, while all three occurred in the deep DN (DDN) group. This again seemed to favour the DDN group as the group which would show the greatest clinical effects[2].

2.6. THE TIMING OF THE TREATMENT EFFECT

Srbely et al (2010) identified very short term reductions in pressure point sensitivity (<10 minutes) after single episodes of intramuscular needling of MTrP-like entities which they refer to as "secondary loci of hyperalgesia". They hypothesised that a greater effect would be seen if mutiple loci were needled at repeated interventions[3]. Srbely et al (2010) strongly advocated a neurogenic model, and did not address local biomechanical issues. This use of acupuncture-like needling was similar to Osborne and Gatt (2010) in interpreting the immediate change seen in acupuncture-type DN. Osborne and Gatt (2010) published a case report in which acupuncture-like needling of MTrPs was used in the treatment of the shoulders of elite volleyball players during competition. The needles were inserted and then twisted to achieve what is purported to be a local stretch effect. The needle was twisted until the typical referral pattern of the muscle was reported by the patient. This represents the specific targetting of the cardinal signs of a MTrP, as did Srbely et al (2010). In contrast, Osborne and Gatt (2010) favour a biochemical

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[1] Hameroff et al (1981) found evidence for preferring Bupivocaine and Etidocaine injections over saline ones, but did not employ either a twitch obtaining technique nor a control. Similarly, Graboski et al 2005 compared the infiltration of trigger points using Botulinum A and bipuvicaine without looking at twitches, and found no significant difference between the two. A home exercise programme was however employed in this study. In a recent study, Ay et al (2009) employed a twitch obtaining technique, an appropriate size needle and an exercise programme, and found no difference between lidocaine (2ml of 1%) and dry needling.

[2] Srbely et al (2010) proposed that the needling of a MTrP has a segmental inhibitory modulation effect which was predominantly neural in nature. They used the novel term "secondary hyperalgesic locus" in referring to the MTrP, calling them discrete secondary peripheral manifestations of a primary neural pathology within the common neuromeric field

[3] In the Srbely et al (2010) study, the primary parameters measured was Pressure Point Threshold (PPT). There was a highly significant difference between the needled group (accurate deep needling of the MTrP) and the control group (deep needling into the same muscle, but not into the MTrP) in this study at three minutes post intervention ($p=0.0002$) and at five minutes ($p=0.015$), but the groups were not significantly different by ten minutes post intervention

explanation for the changes seen in their elite athletes, which included changes to ROM, power and pain rather than PPT. These parameters were noted to be improved by 24-hours after therapy, barring one subject who required a second treatment (on day 2) of TOIMS, accompanied by a greater level of pain than the less aggressive "insert and twist" method. This lead to a great improvement on all parameters[4]. Further treatments in the same competition did not yield greater functional gains; two sessions appeared to be enough in that elite athlete setting.

Huguenin et al (2005) discussed above used a single-intervention method to investigate the effect of needling on MTrP's in the gluteal muscles, but did not find evidence that needling affected the range of hip flexion even after a 72-hour follow up.

2.7. The Constant-Murley scale

Numerous outcomes scales have been used to assess the efficacy of dry needling (Hong et al 1997b; Ceccherelli et al 1998; Ceccherelli et al 2002; DiLorenzo et al 2004). Ingber studied the use of dry needling in the treatment of subscapularis MTrP's in isolated cases (Ingber 2000). Hsieh et al (2007) used a single blind study design with contralateral controls to show the effects on *range of motion* and on *satellite MTrP sensitivity*. Edwards and Knowles (2003) studied the effects of superficial needling and active stretching on *myofascial pain* (Edwards 2005). Both major forms of dry needling (SDN and DDN) are purported to address the MTrP (Kostopoulos and Rizopoulos 2001; Baldry 2002). However, a search of the databases mentioned above did not reveal any human studies which compare the deep and superficial dry needling techniques using validated outcome measures more suited to assessing the *full spectrum* of symptoms related to myofascial trigger points (MTrP's). An example of such a scale is the widely used Constant-Murley (C-M) scale (Constant & Murley 1985).

2.7.1. Validity and reliability of the C-M Scale

The C-M scale reduces the combined therapeutic effect on pain, range of movement, activities of daily living, and strength to a single score an a 100 point scale. Ramzjou et al (2008) have shown that this scale has moderate correlation (0.56 to 0.75) with other scales measuring individual aspects of shoulder function, and that is appears to reflect a component of shoulder compromise which is not captured by an analysis of the individual

[4] There were only 4 participants in this case report. No statistical significance figures were available.

components (range of motion, power). They concluded that the use of the C-M scale was supported by their study in terms of construct validity, but recognised the need for specifically described methodology to facilitate study comparisons.

Roy et al (2012) conducted a systematic review of the psychometric validity and reliability of the C-M scale. They found the C-M score correlated strongly (>0.7) with other shoulder specific outcome measures like the Western Ontario Rotator Cuff index and the Simple Shoulder Test. They found acceptable benchmark reliability coefficient scores ($r > 0.80$), and that the responsiveness of the scale in detecting an effect was in excess of ($r>0.80$) across a range of shoulder pathologies. They cautioned that lack of methodological standardisation limited the external validity of their findings.

This is confirmed by Blonna et al (2012) who demonstrated improved reliability scores for both inter- and intra- rater reliability when conditions were standardised for both experienced and inexperienced observers.

The C-M scale was used by Kleinhenz et al (1999) in a study of the effect of *acupunctur*e on rotator cuff problems using this measure but did not directly address the MTrP in their study). This was an appropriate outcome measure to use in examining the full spectrum of the effects of MTrPs on RCS. The Kleinhenz et al (1999) study was thus used as a methodologic and statistical base for the current study. However, in view of the methodological limitations of the C-M scale, slight variations from the less rigorous original technique were used (see 3.2).

This pilot study proposes to compare the effects of twitch obtaining intra-muscular dry needling (DDN), non-twitch obtaining superficial needling (SDN) and placebo needling (PDN) on myofascial trigger points associated with rotator cuff syndromes using the Constant Murley (C-M) scale to holistically assess the change in shoulder function and disability (see 1.6).

2.8. Conventional physiotherapy interventions

There is little evidence to support traditional physiotherapeutic interventions (see 2.2). Bron et al (2011) found that in the treatment of shoulder pain where MTrPs was a feature of the pathology, a combination of myofascial therapies including stretching, postural advice, cryotherapy and ischaemic compression was significantly more effective than no

treatment (wait-and-see) (p<0.05) when using the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire. At the end of the study, the reduction in the number of active MTrPs was positively correlated with DASH improvements seen. This result of the effectiveness of hands on myofascial treatment of MTrPs in the shoulder is supported by Hains et al (2010) using the Shoulder Pain and Disability index. In this single blind, randomised crossover-control study, 41 patients with chronic shoulder pain were treated using ischaemic compression therapy, and showed a significant SPADI improvement (p=0.003) for the initial study. A similar result was obtained when the control group received the active intervention in the crossover phase (p=0.001). These recent studies indicate that the use of ischemic compression therapy may be useful in the treating MTrPs when used in combination with therapeutic exercise.

2.9. The role of the Infraspinatus muscle

The rotator cuff is the name given to the grouping of the muscles controlling the rotation of the glenohumeral joint. The cuff consists of the Subscapularis, Supraspinatus, Infraspinatus and Teres Minor muscles. Of these, Infraspinatus pathology is a known co-factor in shoulder problems (Oyama et al 2011). Bron et al 2007b found that the palpation of the Infraspinatus muscle showed the highest inter-rater reliability of all the shoulder muscles[5] assessed (Pair-wise agreement of 69-80%). On the basis of their findings, Bron et al 2007b proposed that MTrP palpation may potentially be a useful tool in the diagnosis of myofascial pain in patients with non-traumatic mixed pathology shoulder pain.

In this pilot study (See 4.1.2), incidence of MTrPs in the Infraspinatus muscle alone was almost equal to the incidence of the other three muscles combined. A full examination of the relative contributions of each of the four cuff muscles is outisde of the scope of this pilot study, but the particularly skewed incidence of Infraspinatus MTrPs bears investigation of this muscle.

The anatomical functions of the Infraspinatus muscle are to *isometrically* help maintain the head of the humerus within the glenoid, *concentrically* to laterally rotate the humerus at the glenohumeral joint, and *eccentrically* to check-rein the glenohumeral joint as it moves into medial rotation (Moore & Dalley 2006; Oyama et al 2011). Clinically, classic findings of patients with rotator cuff pathology include reduced lateral rotation power of the

[5] The muscles assessed were the Biceps Brachii and the anterior deltoid

glenohumeral joint, reduced internal rotation of the glenohumeral joint, and an anteriorally translated humeral head within the glenoid. Oyama et al (2001) studied the effect of eccentric overloading of the infraspinatus muscle with respect to cross sectional area and shoulder range of motion. They found a significant correlation between eccentric overload of the infraspiantus and the development of reduced internal rotation range of the shoulder. This was correlated with ultrasonically identified increased cross sectional area of the muscles, and ascribed the effects to a combination of muscle damage and oedema accumulation but no accouting was made for the presence of MTrPs. MTrPs are activated by *eccentric overload*, particularly in the inner and outer ranges of movement and can subsequently alter the functional activation of muscles (Mense & Simons 2001). Ge et al (2008) noted that MTrPs in patients with unilateral shoulder pain (not more specifically diagnosed) tended to occur multiply ie not as single MTrPs within the Infraspinatus muscle.

SUMMARY OF CHAPTER 2

Rotator cuff syndrome symptoms may be caused in part by MTrPs. Dry needling is a modality of therapy for MTrPs, but has two distinct forms. It is not known which form of dry needling may be clinically more effective in RCS patients, but evidence seems to favour DDN over SDN or placebo. The C-M scale is well suited to assessing the full spectrum of the effects of MTrPs in shoulder patients, and has been used previously in a needling study of patients with RCS, but without focussing on MTrPs specifically. There does not appear to be consensus as to the appropriate time to measure outcomes post needling, or how many sessions of needling are required to show maximal clinical benefit. The infraspinatus muscle may play a key role in RCS.

The aim of this study was to assess the relative of dry needling in RCS when added to a common physiotherapy regime compared to a common regime alone.

3.METHODOLOGY

3.1. INTRODUCTION

In Chapter 3, the methodology for a pilot study assessing the relative effects of DDN, SDN, PDN and a physiotherapy regime CON on RCS patients will be laid out.

3.2.DESIGN

The study was designed to be a single-blinded, randomised control study, with a validated placebo intervention as well as two other needling interventions, and a non-needling group, (4 groups). The invasive nature of the technique precludes the use of a double-blind design.

3.3. POPULATION

Participants were drawn from the referrals from 2 local orthopaedic surgeons, drawing on a population of the geographic area of the Gauteng West Rand towns (Krugersdorp, Randfontein, Mohlakeng, Bekkersdal, Simunye, Westonaria, Glenharvie and Hillshaven).

3.4. SAMPLE

Each of the referred patients was asked to either participate in the study or not. Patients that agreed were screened according to inclusion and exclusion criteria (*Table 3.1*). All participants included in the study had a primary positive diagnosis of RCS based on the Hawkins-Kennedy or Neer's tests. The sample size was 5 per group, giving a total sample size of 20 participants.

Details of the statistical considerations is given in 3.11

3.5. ETHICS

Ethical clearance for the pilot study has been obtained through the University of the Witwatersrand (Appendix K).

The concerns over possible side effects and the anticipated patient discomfort were addressed in the patient information sheet (Appendix B). The most important side effect concerns the chance of causing a pneumothorax. The accurate palpation of the MTrP,

correct selection of needle length and appropriate patient positioning reduce the risk of such an event to a very safe level.

3.6. RESEARCH SETTING

The study was carried out in the private practice rooms of Luke & Barker Inc Physiotherapy, located in the Medical Centre of Life Robinson Hospital, Randfontein, South Africa.

3.7. PROCEDURE

All prospective candidates were greeted by the researcher and given the explanatory document (Appendix B) to read and asked to sign consent (Appendix C) to participate in this study based on this information. Those signing consent were regarded as participants, and were randomly allocated to one of the treatment groups by means of a random number allocator administered by research assistants 1or 2[6]. Both assistants had been trained by the researcher in DN and MTrPs prior to the study, and received additional specific training on the procedures used in this study. The randomly allocated number (RAN) was recorded on the patient's demographic information sheet (Appendix A) and on all subsequent documentation. No other link between identifying information and clinical

Inclusion and Exclusion criteria

Inclusion criteria	Exclusion Criteria
Limitation of shoulder range	Currently being treated for shoulder problems by a physiotherapist, chiropractor or biokinetician
Between 18-55 years of age	Positive test for shoulder instability (Magee 1997:219)
Pain in the shoulder region for more than 1 week	Any previous needle therapy
Presence of discrete MTrPs which reproduce the patient's familiar pain	Haemophilia
Positive Neer's or Hawkins-Kennedy impingement signs (Magee 1997:219)	Known C5-C6 pathology
	Previous shoulder surgery
	Pregnancy
	Needle phobia
	Sportspeople currently competing at elite level
	Lack of signed informed consent

Table 3.1: Inclusion and Exclusion criteria

[6] Both assistants had been trained in the appropriate techniques by the principal investigator

data was made possible. The initial assessment was the only document with uncodified identifying information on it and was physically stored separately from the trial data.

The initial assessment and Pre-Treatment assessment were conducted by the researcher in room 1, and recorded on the Shoulder Assessment Tool (Appendix F) (visit 1), or Pre-Treatment assessment form (Appendix D) (visits 2-5) as appropriate. The participant then proceeded to room 2 where the appropriate intervention was carried out by research assistant 1 or 2. After treatment, the participant returned to room 1 for a Post-Treatment assessment which was recorded on Data collection sheet 2 (Appendix E). Interventions were carried out every three days for four sessions in Randfontein. A follow up fifth session (assessment only) was conducted in room 1 and recorded on Data Collection sheet 2 (Appendix E). Patients were invited to this follow up assessment (session 5) one month after the fourth session[7] (See figure 3.4).

[7] The interval between sessions was based on the Kleinhenz, et al. (1999) study. Only half of the number of sessions performed in that study were performed in this one for logistical and financial reasons. However, a physical follow up was conducted after one month rather than a postal follow up as in the Kleinhenz study.

Fig 3.2 Tip of needles: Placebo needle (left). Normal needle (right)

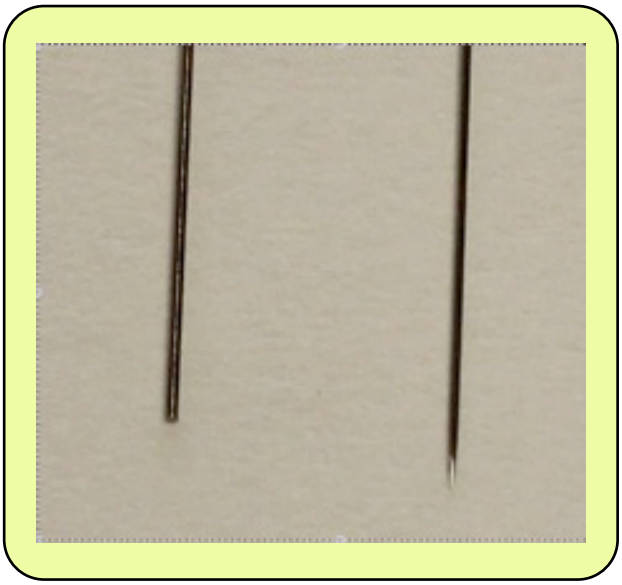

Fig 3.3: Placebo needle showing the shaft telescoping into the handle. All the needles shown are the same "length"



3.8. TREATMENT PROCEDURES

The treatment regimes are summarised in table 3.3. All participants had the Supraspinatus, Infraspinatus, Teres minor and Subscapularis muscles gently palpated (less than 4kg.cm², determined as just enough pressure to cause slight blanching of the researcher/therapist's finger) to locate active trigger points which were then physically marked on the both the skin and the assessment sheet by the researcher (Wolf et al 1900). The use of precise pressure measurement instruments (dolorimeters) in the palpation phase does not appear to carry any clinically significant advantage over simple digital palpation as long as the patient's familiar pain is elicited (Lavelle et al 2007). The

participants were then taken to the treatment room where they were treated by the research assistant using the randomly allocated group protocols as detailed in Table 3.3.

Table 3.2: Needle lengths & Participant positioning

Muscle	Deep Needle	Superficial needle	Needling position
Supraspinatus	0.35x75mm	0.22x13mm	Contralateral side lying, affected shoulder in neutral
Infraspinatus	0.3x30mm	0.22x13mm	Contralateral side lying, affected shoulder in neutral
Teres Minor	0.3x30mm	0.22x13mm	Contralateral side lying, affected shoulder in neutral
Subscapularis	0.35x75mm	0.22x13mm	Supine, with affected arm abducted as far as possible

Table 3.2 Needle lengths and patient positioning

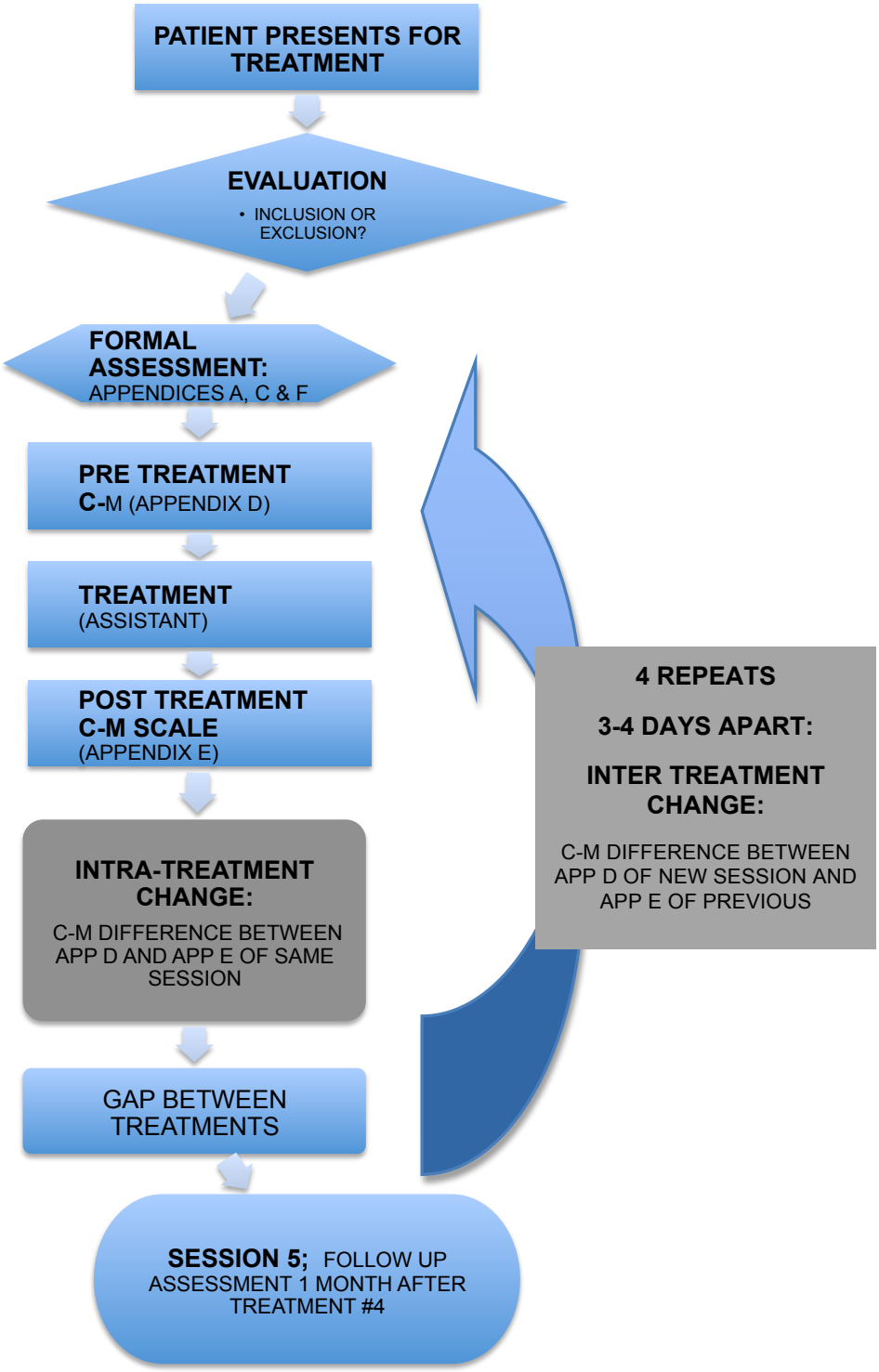

Figure 3.4: Flow diagram showing at which stage the Inter- and Intra- treatment changes were measured

Table 3.3 : Treatments given to the intervention groups			
CON	**DDN**	**SDN**	**PDN**
Control group	Deep dry needling	Superficial dry needling	Placebo dry needling
Hot pack (60C) applied for 5 minutes prior to treatment Digital ischemic pressure with pressure varied according to patient's pain tolerance, applied to MTrPs identified by palpation by researcher. (Manheim 2001) Passive stretches of internal and external rotators, shoulder flexors and extensors (Appendix G).	CON plus the use of verum needles of appropriate length (see table 3.2) which were repeatedly inserted into the palpated MTrPs using a partial withdrawel and re-insertion technique, causing maximal LTR elicitation in 30 seconds. The therapists respected the patient's feedback using the question "how are you doing?", and ceasing to move the needle if the needle grasp occurred or if the patient felt unusually uncomfortable.	CON plus the use of verum 0.25x13mm needles inserted intradermally superficial to the palpated trigger points. The needles were manually twirled to elicit maximal pin prick sensation in 30 seconds.	CON plus use of validated non-insertional placebo needle (Streitberger and Kleinhenz 1998) over areas of the RC muscles where MTrPs were palpated. Technique of repeated insertion was mimicked for 30 seconds. Note: Placebo needle has a blunted tip and telescopes into the handle rather than being inserted into skin (see figs. 3.1 and 3.2).

Table 3.3: Treatments given to intervention groups

3.9. OUTCOME MEASURES

All measurements were conducted under standardised conditions in room 1.

The Constant-Murley scale was used as an outcome measure, mimicking that of the Kleinhenz study (Constant & Murley 1985; Kleinhenz et al 1999). This scale was developed as an easy to use measure of shoulder function with broad application across shoulder pathologies. It is a weighted scaling of the relative contributions of pain, effect on activities of daily living (ADL), effect on range of movement (ROM), and effect on strength. It gives a composite score out 100 possible points. The pain and ADL parameters were assessed subjectively by the patient prior to the objective testing of ROM and strength (*see* Appendix D and E).

A *physical* follow up assessment using the C-M scale was conducted at one month after the fourth session. This represents a difference to the Kleinhenz et al(1999) study in which follow up was conducted by means of a postal questionnaire four months after the final session.

Strength measurements were taken as isometric mid range maximum exertions using a hand held dynamometer (Nicholas Manual Muscle tester (Lafayette Instruments 3700 Sagamore Parkaway North, Lafayette Indiana, USA)) at either 90 degrees of glenohumeral abduction or the maximum glenohumeral abduction the patient can achieve if this is less than 90 degrees as originally described (Sklaar 2000). However, the use of a Nicholas Manual Muscle tester represented a departure from the original methodology in which a pound-denominated spring balance was used. This was in the interests of scientific rigour as the Nicholas Manual Muscle tester is a validated, reliable instrument with a history of usage in shoulder strength measurements (Sklaar 2000). ROM measurements were made in upright sitting as originally described. Only active ROM is considered in the C-M scale.

Ellenbecker (1997) recommended the use of simple goniometry plus a manual anterior containment force to measure shoulder range of movement. This was not described in the original C-M scale, but is a reasonable precaution to take in view of the invariably composite nature of glenohumeral motion. As a result, a second set of readings was taken in which a manual anterior containment force was applied to the affected shoulder.

3.10. DATA COLLECTION

Demographic data was collected as per “Patient Demographic information sheet” (Appendix A). Pre- and post-intervention scores were entered on the data collection forms (Appendices D and E).

3.11. STATISTICAL CONSIDERATIONS

Sample size: At the outset of the study, it was determined that for a full size study, when the sample size in each of the 4 groups is 16, a one way analysis of variance will have 90% power to detect (at the 0.05 level of significance) a difference between the mean changes in the 4 groups anticipated to be 8;10;15 and 24 points on the modified C-M scale. This calculation assumes a common standard deviation of 12.5 points. This standard deviation is based on the range of possible anticipated change in the Kleinhenz et al study (1999). A sample size of 20 per group was planned and would have made provision for a 25% drop out rate. These sample size calculations were made using nQuery Advisor V5 software (Elashoff 2002). The pilot study however utilised a sample size of just 20 participants.

Data analysis: In the primary analysis, the change in C-M scores from baseline to the end of the study (visit 5) was compared in a one-way analysis of covariance (ANCOVA) with the baseline value as covariate. In a similar way, a secondary analysis was also done by assessing the change within visits 1 to 4 and between visits i.e. end of previous visit and onset of current visit. As data was skewed, the above analyses have been performed using ANCOVA for ranks followed by pair-wise comparison between groups to assess specific differences. Testing was done at the 0.05 level of significance.

4. RESULTS

4.1. General results

4.1.1. Demographics

25 participants were entered into the study of which 20 completed the full study. This represents a relatively high drop-out rate of 20%. The group demographic breakdown is summarised in table 4.1. The group allocation was slightly skewed as one participant was incorrectly randomised. DDN=6, PDN=4, SDN=5, CON=5.

Summary of demographic data				
Group	**Median Age**	**Gender m / f**	**Affected side L / R**	**Dominance L / R**
CON (n=5)	37	2/2	1/3	0/5
DDN (n=6)	37	1/5	1/2	2/4
SDN (n=5)	33	2/3	1/4	0/5
PDN (n=4)	36	3/1	3/1	0/4
Total n=20	Mean = 36			

Table 4.1: Summary of demographic data

4.1.2. Frequency and distribution of MTrPs in muscles of the rotator cuff

The breakdown of the incidence of involved muscles by therapeutic group is given in Table 4.2. and Fig 4.2.

Number of MTrPs in each muscle by therapeutic group (n=20)				
	Supraspinatus	**Infraspinatus**	**Teres Minor**	**Subscapularis**
CON	3	10	2	1
DDN	7	18	2	6
SDN	7	7	4	4
Placebo	5	10	2	4
Total	22	45	10	15
% Incidence	**23.9**	**48.9**	**10.9**	**16.3**

Table 4.2: Number of MTrPs in each muscle by therapeutic group

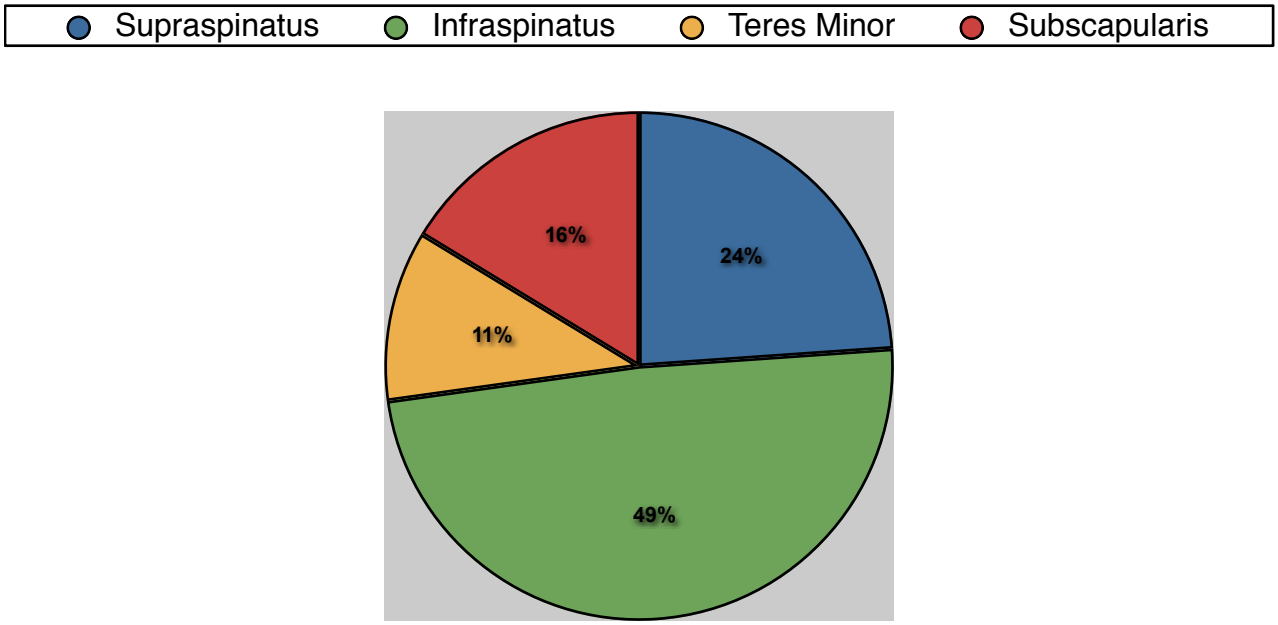

Figure 4.1: Relative frequency of involved muscles

There was a greater incidence of MTrPs in the Infraspinatus muscles than in the other cuff muscles, with almost half of the MTrPs occurring within the Infraspinatus muscles. The significance of this will be discussed below.

4.2. Adverse events

There were no reports of adverse events relating to the treatment modalities employed in the study from those who completed the study. However, no comment can be made as to the incidence of adverse events among those who did not complete the study as they did not respond to repeated attempts to follow them up.

4.3. Results of specific research objectives

The objectives detailed in 1.6 are recapitulated below.

Compare the changes in Constant-Murley scale scores between patients treated with the four interventions on a pre-trial / follow up visit basis for each group.

Compare the changes in Constant-Murley scale scores, ROM, Power in patients on a pre-intervention / post-intervention (intra-treatment) basis at each treatment for each group.

Compare the changes in Constant-Murley scale scores in patients on a between intervention (inter-treatment) basis at each treatment for each group results of each of the variables were analysed accordingly.

The significant results are summarised in 4.6.1. (Table 4.14)
In addition, in order to make direct comparisons with the comparator study (Kleinhenz et al 1999), the mean C-M differences and standard deviations of the current study were also calculated.

4.3.1. THE CONSTANT-MURLEY SCALE

4.3.1.1. TREATMENT EFFECT PRE & POST TRIAL: There was a highly significant difference between the groups when analysed over the course of the study when analysed by ANCOVA for ranks. Specifically, DDN was superior to CON ($p \leq 0.05$), and to SDN ($p \leq 0.02$) (see Figure 4.2).

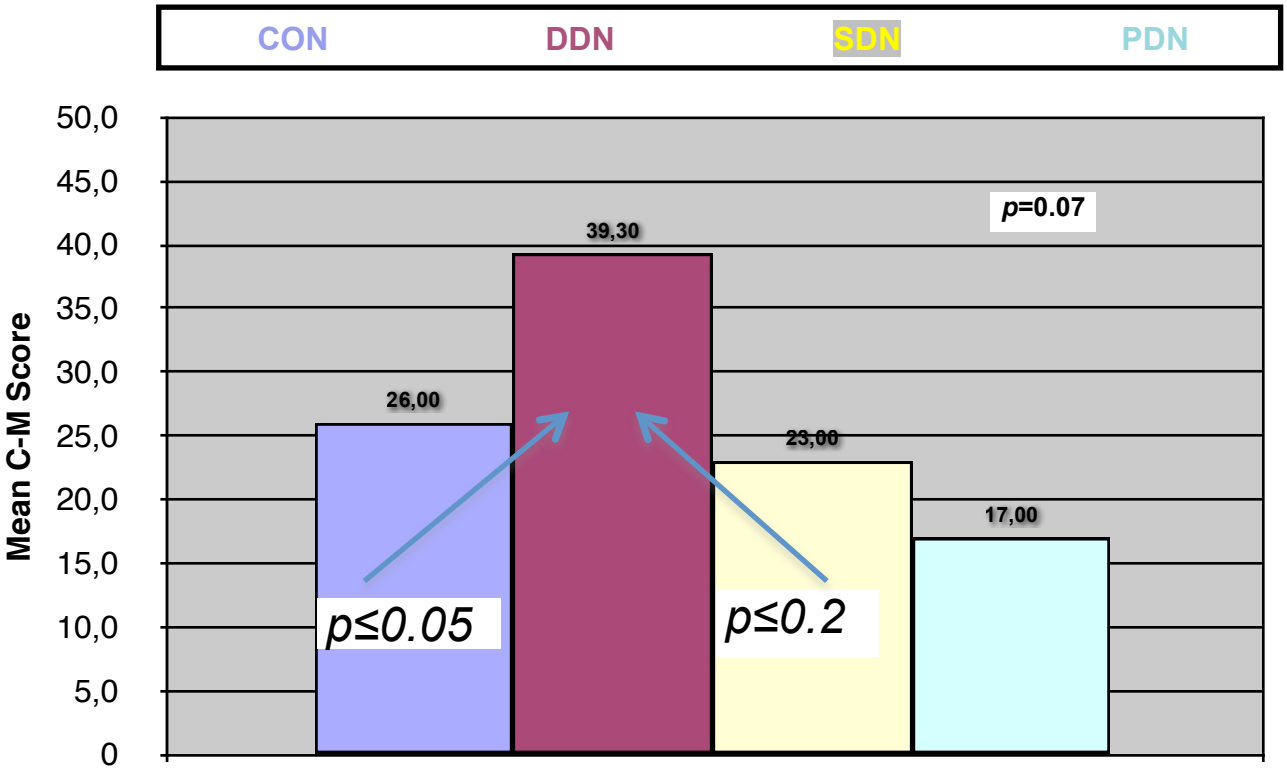

Figure 4.2 Mean C-M score change Pre-Post trial

4.3.1.2. INTRA-TREATMENT EFFECTS: There was a significant difference between the groups at session 3 (p<0.01) when analysed by ANCOVA for ranks. In particular, this difference is explained by the difference between DDN and CON (p<0.01), DDN and SDN (p<0.01), and DDN and PDN (p<0.01). In all cases DDN performed worse than the comparators.

4.3.1.2.1. There was a significant difference between the groups at session 4 (p≤0.03) when analysed by ANCOVA for ranks. This difference is explained by the difference between groups DDN and CON (p<0.01), DDN and PDN (p<0.03). Again, DDN performed worse than the comparators (see Figure 4.3).

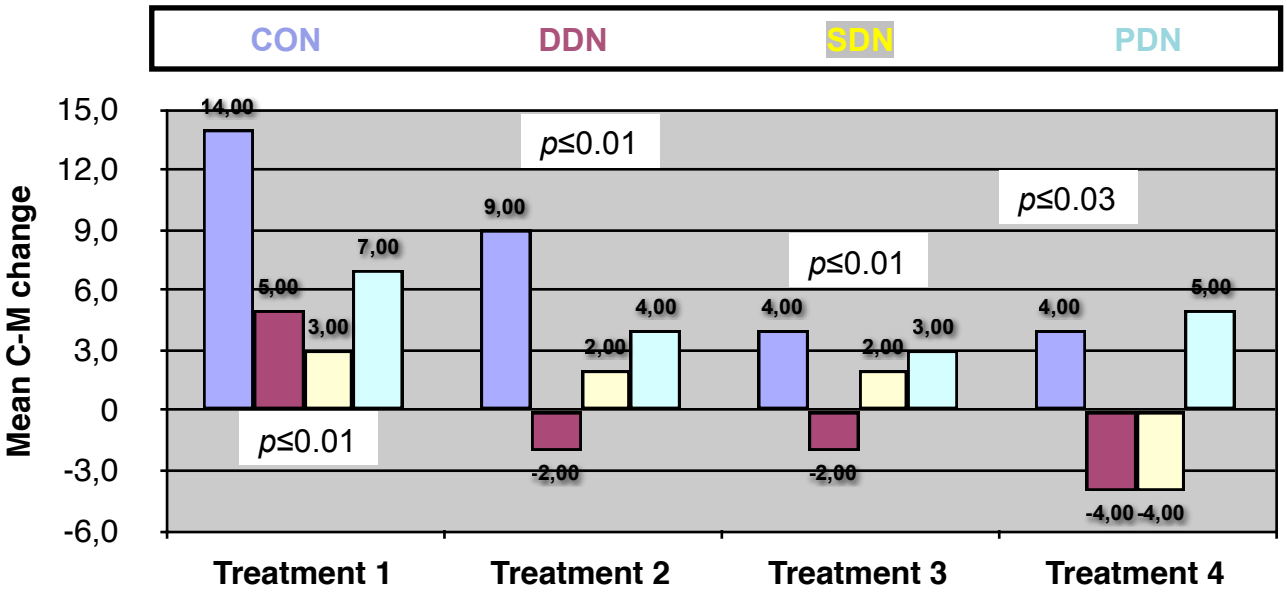

Figure 4.3: Mean intra-treatment change: C-M

4.3.1.3. INTER-TREATMENT EFFECT: The groups were also analysed to see if there were differences that may have occurred *between* the treatment sessions regarding C-M score changes. There was a marginally significant difference between the groups when the groups were analysed by ANCOVA for parametric data for the interval between the end of session 1 and the beginning of session 2 (p=0.09). This is explained by the difference between DDN and CON (p=0.03) and between groups DDN and PDN (p=0.08) (Figure 4.4).

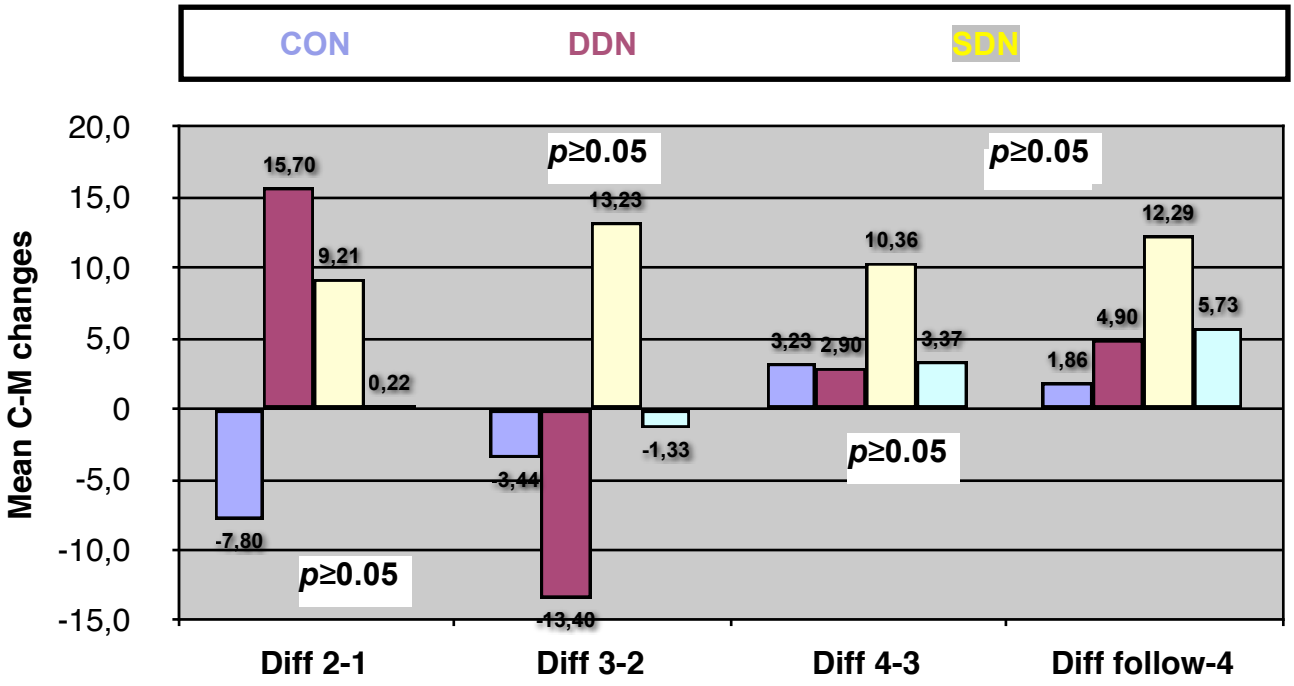

Figure 4.4: Mean Inter-treatment changes: C-M scores

4.3.2. EXTERNAL ROTATION POWER

4.3.2.1. TREATMENT EFFECT PRE & POST TRIAL: There were no significant differences (p=0.46) between the groups for the pre trial-post trial interval (see Figure 4.5).

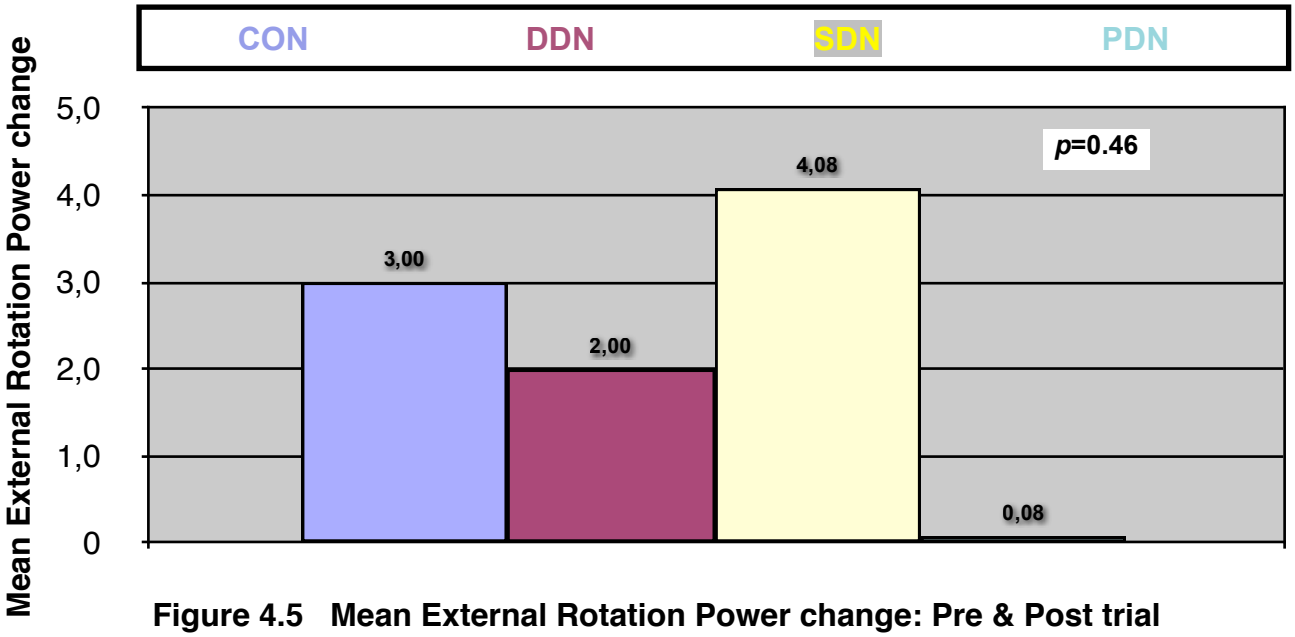

Figure 4.5 Mean External Rotation Power change: Pre & Post trial

4.3.2.2. INTRA-TREATMENT EFFECT: There was a highly significant difference between the groups at session 2 (p=0.036) when analysed by ANCOVA on a parametric basis. This difference is explained by the difference between CON and DDN (p=0.03), and CON and SDN (p<0.05) (Figure 4.6).

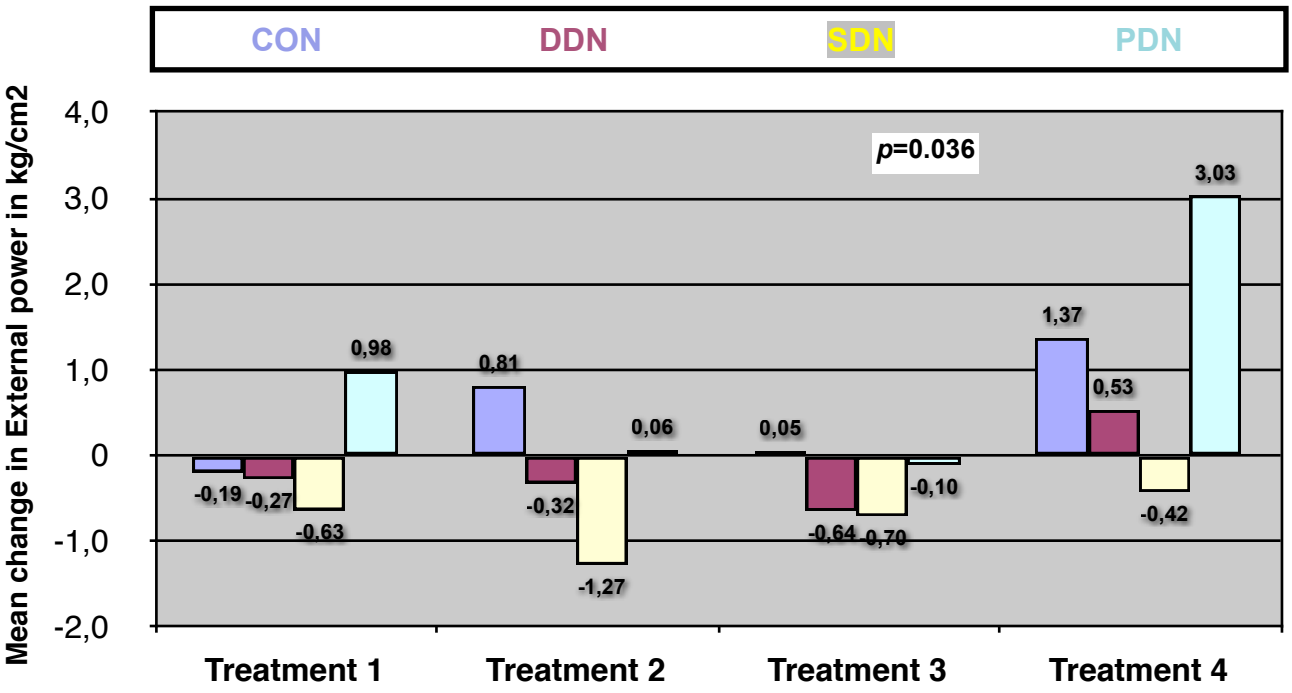

Figure 4.6: Mean External Rotation Power change: Intra-treatment

4.3.3. INTER-TREATMENT EFFECT. There were no significant differences between the groups for any of the inter-treatment periods.

4.3.4. Internal Rotation Power

4.3.4.1. Treatment effect Pre & Post trial: There were no significant differences (p=0.3) between the groups for the pre trial-post trial interval.

4.3.4.2. Intra-Treatment effect. There were no significant differences between the groups for this variable.

4.3.4.3. Inter-treatment effect. There were no significant differences between the groups for this variable.

4.3.5. Extension Power

4.3.5.1. Treatment effect Pre & Post trial: There were no significant differences (p=0.46) between the groups for the pre trial-post trial interval

4.3.5.2. Intra-Treatment effect: There were no significant differences between the groups for this variable.

4.3.5.3. Inter-treatment effect: There were no significant differences between the groups for this variable.

4.3.6. Abduction Power

4.3.6.1. Treatment effect Pre & Post trial: There were no significant differences between the groups for this variable (p=0.79).

4.3.6.2. Intra-Treatment effect:There were no significant differences between the groups for this variable.

4.3.6.3. Inter-treatment effect: There were no significant differences between the groups for this variable.

4.4. FLEXION RANGE OF MOTION:

4.4.1. TREATMENT EFFECT PRE & POST TRIAL: There were no significant differences between the groups for this variable (p=0.79) (see Table 4.7). All groups had mean end of trial readings within 7 degrees of each other despite differing baselines.

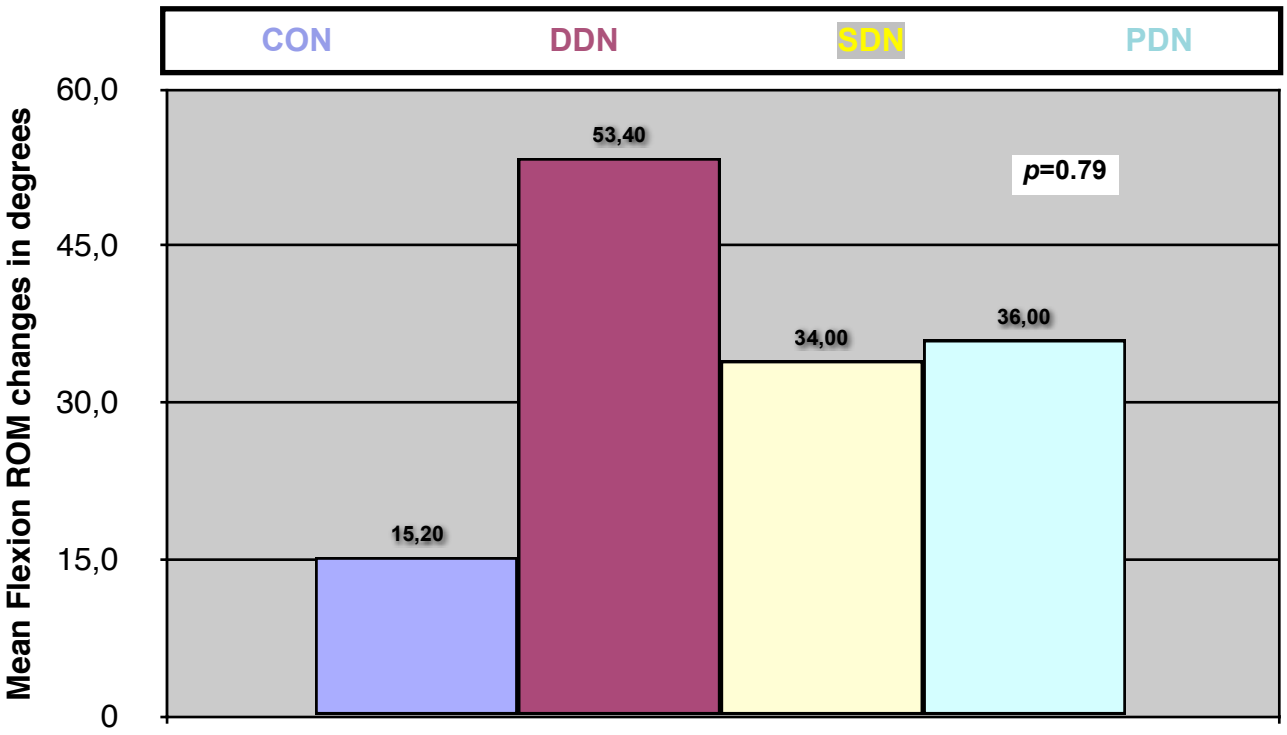

Figure 4.7: Mean Flexion ROM change: Pre & Post trial

4.4.2. INTRA-TREATMENT EFFECT: There was a significant difference between the groups at session 2 (p=0.04) when analysed by ANCOVA for ranks. This difference is explained by the difference CON and PDN (p<0.01), DDN and PDN (p≤.05) (see Figure 4.8).

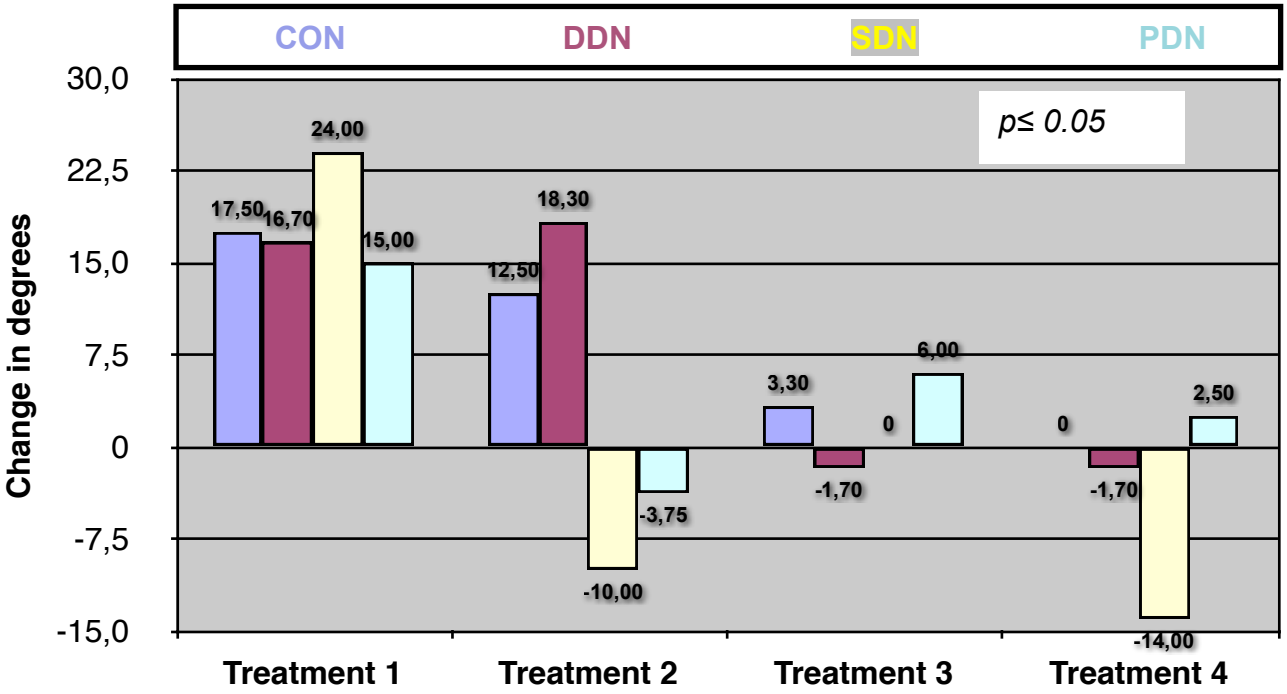

Figure 4.8: Mean Flexion ROM change: Intra-treatment

4.4.3. INTER-TREATMENT EFFECT: There were no significant differences between the groups for this variable.

4.5. Internal Rotation Range of Motion

4.5.1. **Treatment effect Pre & Post trial:** There were no significant differences between the groups for this variable (p=0.86) (see Table 4.9).[8]

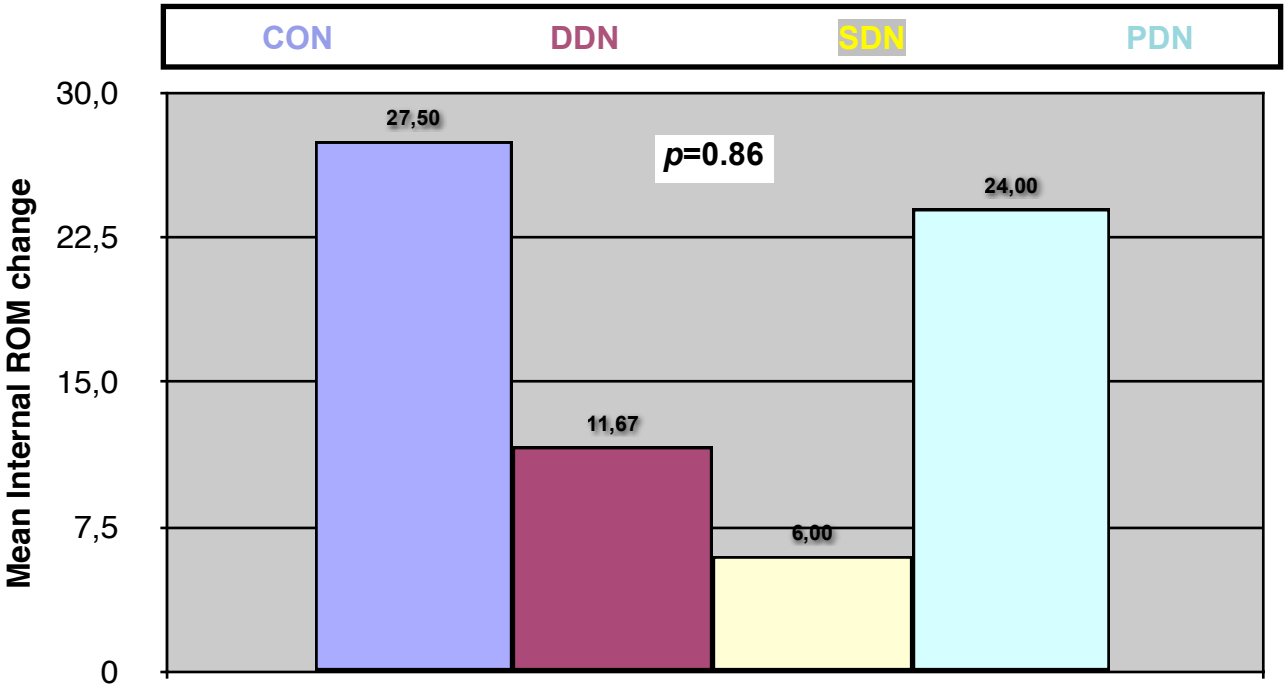

Figure 4.9: Mean Internal ROM change: Pre & Post trial

[8] The apparently larger effect in the CON group is due to to a lower mean baseline in that group.

4.5.1.1. INTRA-TREATMENT EFFECT: There was a highly significant difference between the groups at session 3(p=0.015) when analysed by ANCOVA for ranks. This difference is explained by the significant differences between CON and DDN ($p \leq 0.05$). There were also marginally significant differences between CON and SDN (p=0.07), DDN and SDN (p=0.06), and DDN and PDN (p=0.07) (see Figure 4.10).

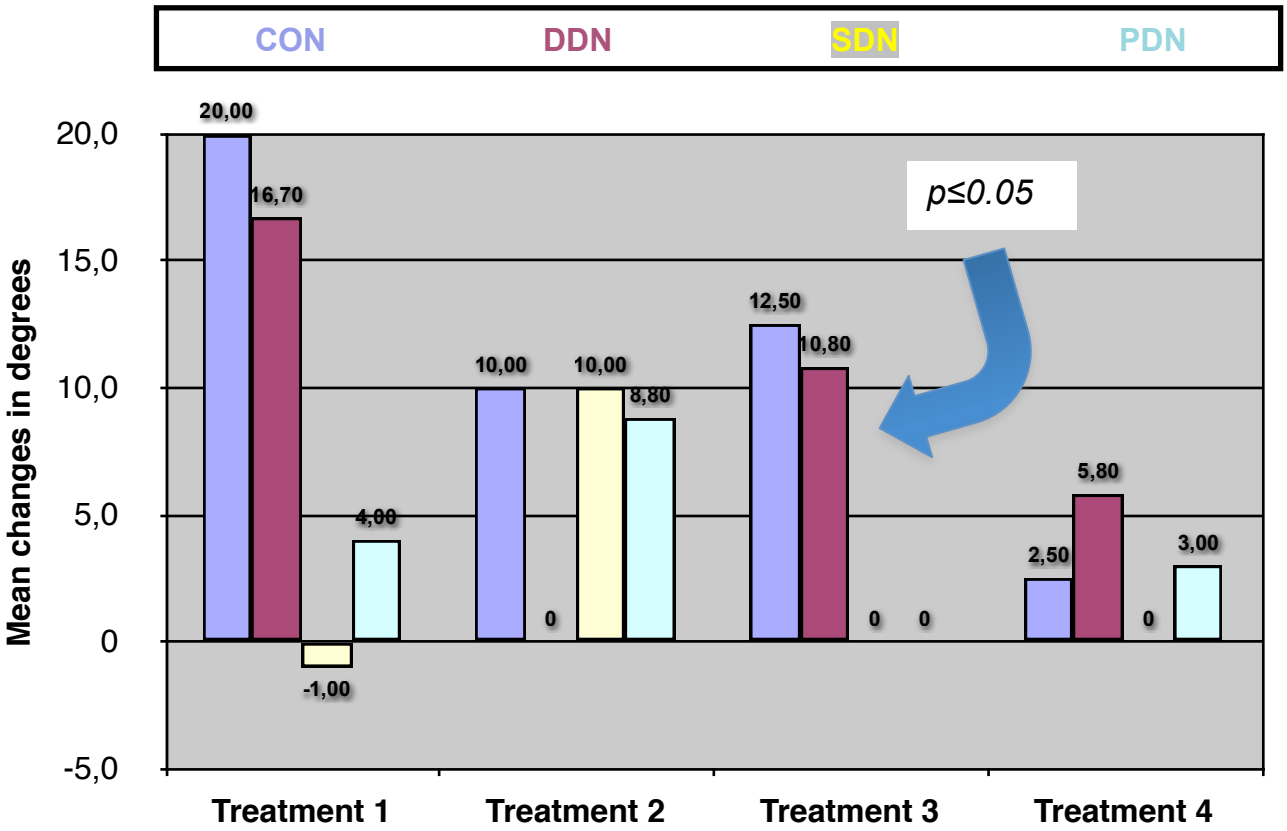

Figure 4.10: Mean Internal ROM change: Intra-treatment

4.5.1.2. INTER-TREATMENT EFFECT: There was a highly significant difference between the groups when analysed by ANCOVA for ranks between the beginning of treatment 4 and the end of treatment 3 (p=0.03). This difference is explained by the differences between DDN and CON (p=0.03), DDN and SDN (p=0.01) and DDN and PDN (p=0.02). This same effect was marginally significant when analysed by ANCOVA for parametric data (p=0.88) (see Figure 4.11).

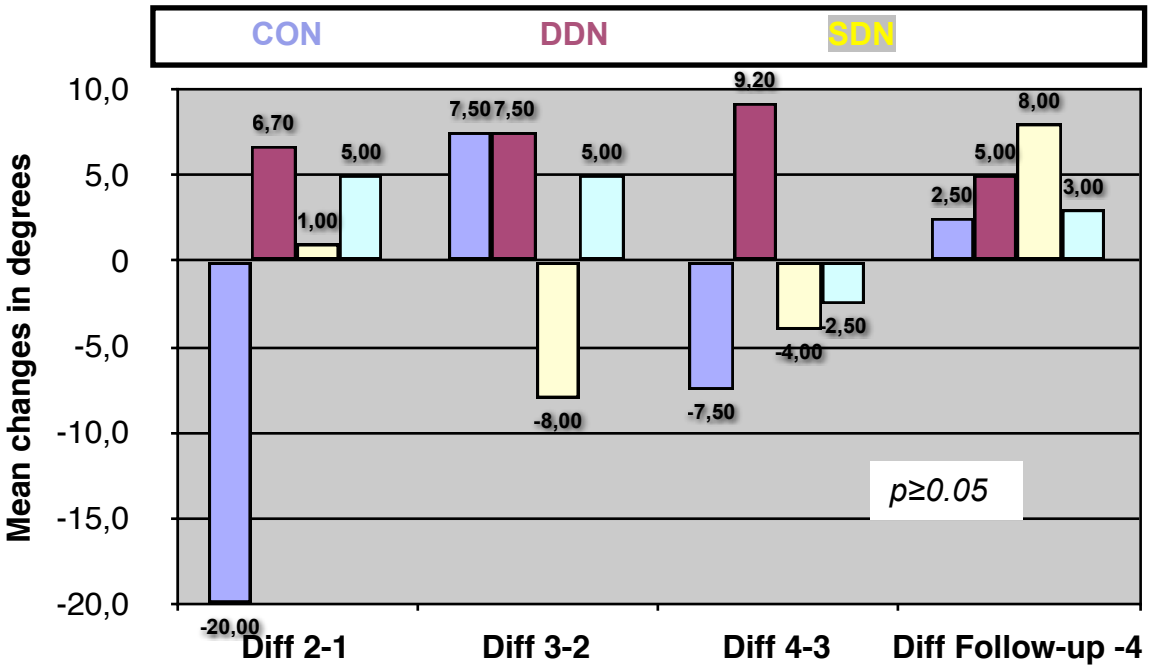

Figure 4.11: Mean Internal ROM change: Inter-

4.5.2. EXTERNAL ROTATION RANGE OF MOTION

4.5.2.1. **TREATMENT EFFECT PRE & POST TRIAL:** There were no significant differences between the groups for this variable (p=0.75) (see Figure 4.12).

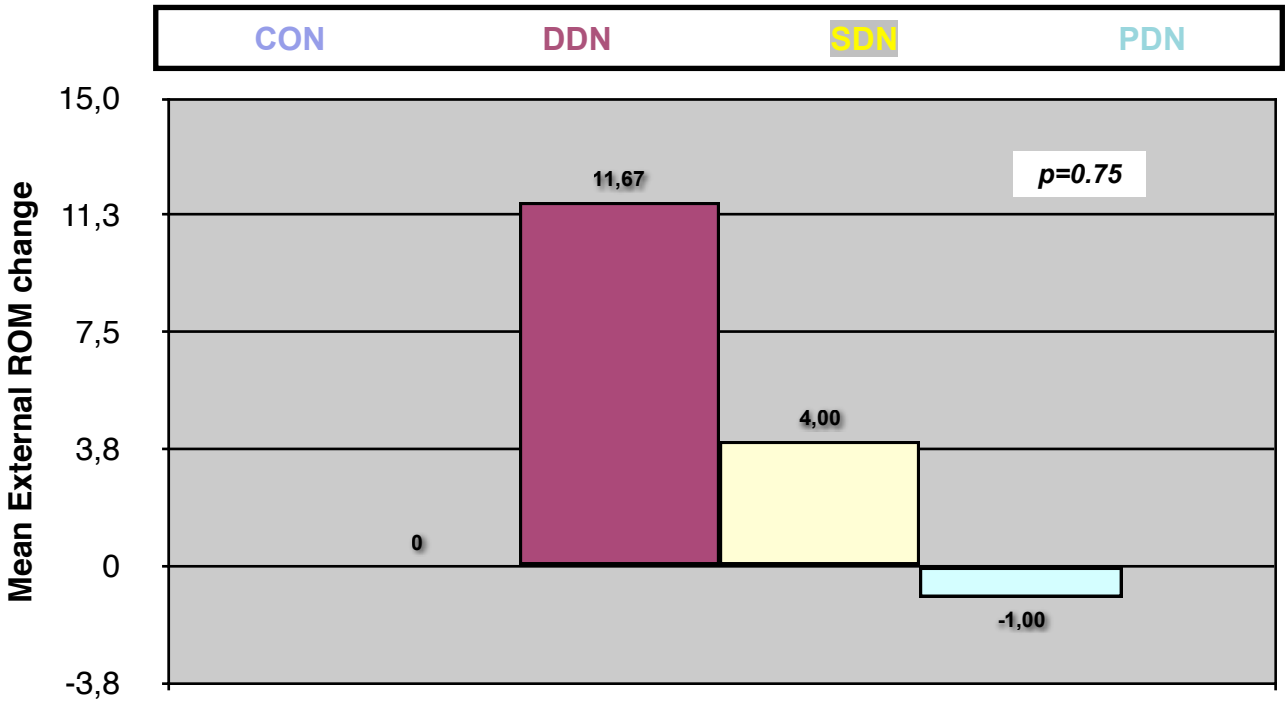

Figure 4.12: Mean External ROM change: Pre & Post trial

4.5.2.2. INTRA-TREATMENT EFFECT: There were no significant differences between the groups for this variable.

4.5.2.3. INTER-TREATMENT EFFECT: There was a significant difference between the groups when analysed by ANCOVA for ranks between the beginning of treatment 3 and the end of treatment 2 (p=0.05). This is explained by the difference between DDN and SDN (p=0.08) and DDN and PDN ($p<0.01$) (see Figure 4.13).

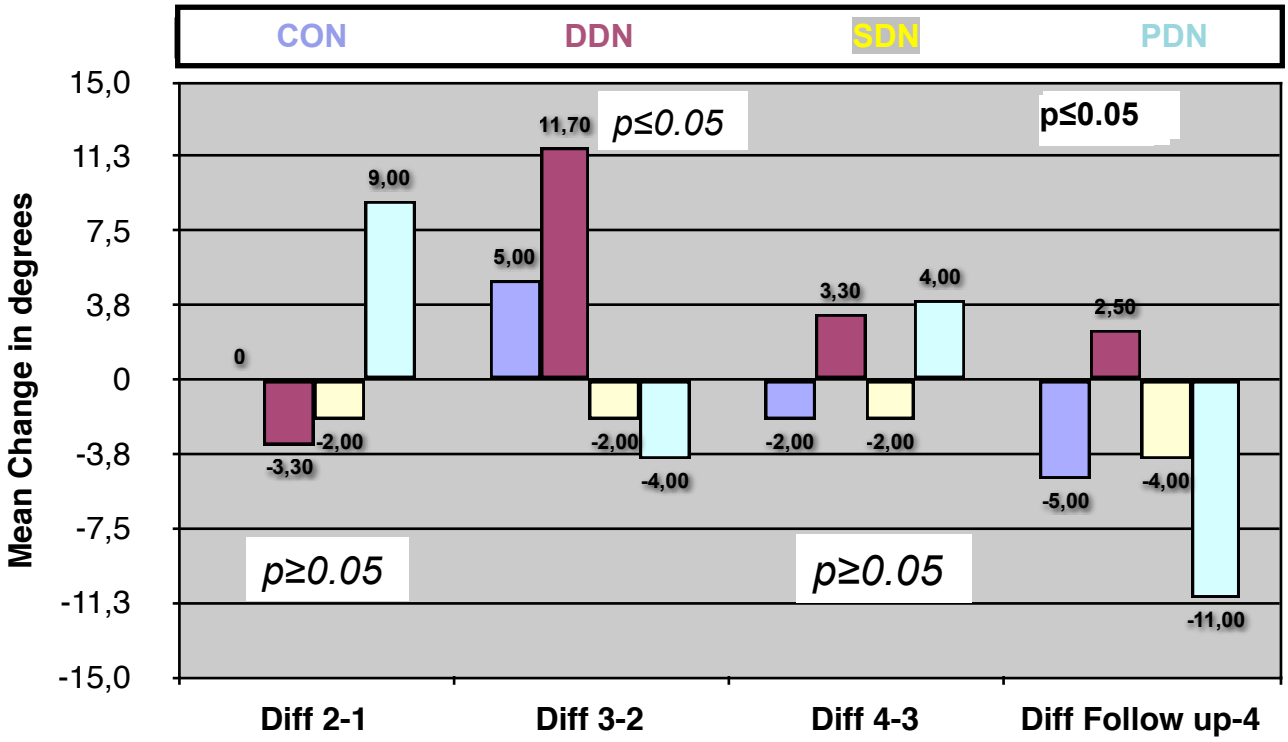

Figure 4.13: Mean External ROM change: Inter-treatment

4.6. SUMMARY OF SIGNIFICANT RESULTS

4.6.1. A summary of the significant results is given in Table 4.3 below. Note that in each of the significant results, DDN plays a determining role in the treatment effect size.

Summary of the statistically significant findings

Variable	Level of significance <0.05 = High <0.1 = Marginal	Interval	Group causing difference Positive influence + Negative influence -
C-M	*p*=0.01, *p*=0.04	Post-Pre trial	DDN + (vs SDN, CONT)
C-M	*p*<0.00	Intra-treatment session 3	DDN -
C-M	*p*=0.03	Intra-treatment session 4	DDN -
C-M	*p*=0.09	Inter-treatment 2-1	DDN +
External rotation power	*p*=0.04	Intra-treatment session 2	CON + DDN - SDN -
Flexion range of movement	*p*=0.04	Intra-treatment session 2	PDN- DDN + CON +
Internal range of movement	*p*=0.02	Intra-treatment session 3	DDN +
Internal range of movement	*p*=0.03	Inter-treatment 4-3	DDN +
External rotation range of movement	*p*=0.05	Inter-treatment 3-2	DDN +

Table 4.3: Summary of the statistically significant findings

5. DISCUSSION

The discussion that follows will expand on the primary outcome measure (C-M) results. The secondary outcome measures (power and range) results will also be discussed in the light of the C-M results. These analyses were used to form the basis of the conclusions drawn. Only the results with statistical significance will be discussed. The significance of the frequency and distribution of MTrPs in the infraspinatus muscle will be assessed with reference to the study objectives

5.1. The Constant-Murley Scale

5.1.1. Treatment effect Pre & Post trial The DDN group showed a highly significant improvement over both the SDN and CON groups over the course of the study (p=0.01 for SDN, and p=0.04 for CON). The DDN group in this pilot study had a mean change of 39.3 points which was 56% greater than the mean of the other groups which were closely grouped (CON=26, SDN=23 and PDN=17). The mean C-M scores were comparable for those groups with comparators in the Kleinhenz et al (1999) study values on a pre trial / post trial basis (see Table 5.1). This was expected as this study was used as a methodological and statistical base for the pilot study under discussion. There was slight variance (especially with the placebo groups) which may be explained by the addition of a common physiotherapy regime to this study, but which was absent from the comparison study[13]. Thus the CON group did not have a comparator.

Similarly, there was no *true* DDN group in the Kleinhenz et al (1999) study. The Kleinhenz et al (1999) study published results in terms of mean changes in C-M scores and standard deviations therefrom. This comparison study showed a mean change from baseline in the C-M score of 19.2 points (SD 16.1, but with a wide variance (-13 to 50)) for the acupuncture group, and 8.37 points (SD 14.56 (-20 to 41)) for the placebo needle group. The comparable groups in the current study were the SDN and PDN groups. SDN had a mean change of 23 points (SD 20.1(-3 to 52.76)). This is comparable with the Kleinhenz et al (1999) study values. PDN had a mean change of 17 points (SD 21.64(0-59.35)) which is larger than the Kleinhenz et al (1999) study but still of a similar magnitude to both SDN and CON.

The sample size of the study is not large enough to draw firm conclusions, but it seems there is a trend toward a larger treatment effect in the DDN group than any of the other

groups . This may be explained by the elicitation of LTRs from the MTrPs in the muscles being treated, and re-iterates the need to distinguish between acupuncture-like needling techniques and LTR-obtaining dry needling. The Integrated hypothesis explanation for the MTrP phenomenon whereby a local hypoxia is reversed by the facilitation of local bleeding rather than by a neural mechanism may be supported by this result.

5.1.2. INTRA-TREATMENT EFFECTS. A non-parametric/ranked ANCOVA test revealed that there was a highly significant difference (p<0.00) between DDN and all of the other groups by the time the post-treatment observations were made. The difference is due to the relatively poor performance of the DDN group scores. DDN is consistently worse off immediately after treatment. This may be due to pain inhibition following the local trauma caused by the technique, or the trauma itself ((see Hong et al (1994b)[9]. This finding is similar to Srbely et al (2010) who indicated that DDN PPT is transiently reduced immediately following needling.

This was similarly true of the C-M results at the end of treatment 4. Here the difference is again highly significant (p=0.03). However, it must be emphasised that DDN showed a trend to greater clinical benefit than the others on a pre-trial/ post-trial analysis (see 5.1.1 above) and it was anticipated that an analysis of changes in C-M scores beween treatments (see 5.1.3) may reveal when the clinical gains occurred.

5.1.3. INTER-TREATMENT EFFECT: An analysis of the inter-treatment effect using the same statistical approach did not reveal a significant difference between the groups between the second, third and fourth treatment sessions as expected, but rather between the first and second treatments only[10]. The effect was particularly noticeable between the CON and DDN groups[11].

The pattern of increased clinical improvement between treatment sessions rather than directly after them is repeated in the analyses of changes to internal and external rotation

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[9] Hong et al (1994b) noted that patients had clinically significant pain related to the needling therapy, but also that the initial pain complaint was much improved by 8 hours post needling.

[10] This result is slightly anomalous and may be due to the small sample size.

[11] Graphically the SDN group appears to show greatest benefit in this analysis but it is an artefact of a variance in the base values of the groups

ranges of motion. This accords with the proposed humoral effect of DDN where the inflammatory cascade and normal healing response to the intramuscular insult take days rather than minutes to effect a response. This result speaks to the problems identified by Cummings and White (2001) above where they found no evidence of the efficacy of dry needling beyond that of placebo; it appears that there may well be a significant benefit in the use of TOIMS-type dry needling where the elicitation of a LTR is emphasised, but the timing of the measurements taken may play a role in the outcome of the study.

5.2. External rotation power

5.2.1. Intra-treatment effects.

There is a significant difference between CON and DDN (p=0.03) by the end of treatment 2, where CON has a greater effect than DDN. There is also a significant difference between CON and SDN (p=0.05) by the end of treatment 2, where SDN has a greater effect than CON. However, there is no significant difference by the pre-treatment 3 observations. This reinforces the observation that DDN suffers from a transient negative effect immediately post treatment which may be due to the pain of intramuscular needling.

5.3. Internal Rotation Range of motion

5.3.1. Intra-treatment effects:

There was a highly significant difference in the groups at pre-session 3 (p=0.02) when analysed by rank. This difference was explained by the significant differences between CON and DDN (p<0.00) where DDN was more effective than CON. There were also marginally significant differences between groups CON and SDN (p=0.07) where SDN was superior to CON, DDN and SDN (p=0.06) where DDN was superior to SDN, and DDN and PDN (p=0.07) where DDN was superior to PDN. DDN appeared to be consistently more effective than the other groups in effecting an improvement in internal rotation range of motion. This may be related to the high incidence of MTrPs in the infraspinatus muscle which is eccentrically involved in internal rotation control of the glenohumeral joint (see 5.6). The trend of the effect appears to reduce over the four treatment sessions as the participants ROM approached normal values. CON appears to show greater improvement over DDN at treatment 1, but this is not a significant difference as the baseline values for CON were lower, giving greater potential for improvement.

5.3.2. INTER-TREATMENT EFFECT: The DDN effect is also reflected in the highly significant difference (p=0.03) between the groups between treatment sessions 4 and 3 when the inter-treatment period was analysed. Internal rotation range of motion of the glenohumeral joint is check-reined by the Infraspinatus muscle. The significance of this correlation is discussed in 5.7.

5.4. FLEXION RANGE OF MOTION

5.4.1. INTRA-TREATMENT EFFECTS: There was a highly significant difference between the groups at the end of session 2 (p=0.04) when analysed by rank. This difference is explained by the difference between groups 1 and 4 (p<0.00), 2 and 4 (p=0.05). However, the difference may be due more to the poor performance of the PDN group than positive effects of the CON and DDN groups.

5.5. EXTERNAL ROTATION RANGE OF MOTION

5.5.1. INTER-TREATMENT EFFECT: There was a significant difference between the groups when analysed by ANCOVA for ranks between the beginning of treatment 3 and the end of treatment 2 (p=0.05). Patients treated with DDN showed a greater ability to recruit the external glenohumeral rotators than the other groups. This may be partly explained by the high incidence of MTrPs in the external rotator muscle Infraspinatus (see 5.7).

5.6. THE TIMING OF THE TREATMENT EFFECT

The effect of the time intervals between intervention and observation was not fully appreciated in the design of the study. There appeared to be a consistent improvement in the DDN variables with the majority of the treatment effect occurring before the fourth treatment session, but this was complicated by the observations made immediately after the interventions. Srbely et al (2010) identified very short term reductions in pressure point sensitivity (<10 minutes) after single episodes of intramuscular needling of MTrP-like entities which they refer to a secondary loci of hyperalgesia. They hypothesised that a greater effect would be seen if mutiple loci were needled at repeated interventions. The results reported herein indicate that this may be true, and that only three deep needling sessions may be required to show the majority of the clinical improvements when using DDN[12]. However, from this study, it does not appear to be helpful to analyse the effect of

the intervention immediately subsequent to it. Srbely et al (2010) strongly advocated a neurogenic model, and did not address local biomechanical issues. Although this study did not address pressure point sensitivity, other cardinal signs of MTrPs were assessed. Patient reported pain was transiently lessened in the SDN group, correlating with Srbely (2009). This was not seen in the DDN group. The effect of the elicitation of multiple LTRs through DDN is to cause local tissue trauma and bleeding, and this appears to negate some of the immediate reduction in pressure point sensitivity; the C-M scores were consistently worse immediately after treatment compared to pre-treatment levels, but showed a significantly better result a few days later.

Range of motion is one of the parameters affected my MTrPs (see Table 1.1). Huguenin et al (2005) discussed above used a *single*-intervention method to investigate the effect of needling on MTrP's in the gluteal muscles but did not find evidence that needling affected the range of hip flexion, which could be interpreted as evidence against the contention that DDN of MTrPs results in ROM increases. However, it appears from the current study that *more* than one needling session is required to see clinical change, but that the greatest proportional changes will seen before the third session. It may follow that just two to three sessions of DDN may be needed.

5.7. The significance of the relative incidence of MTrPs

This pilot study was not designed to investigate the incidence of MTrPs in the rotator cuff. Anecdotally, however, both research assistants independently reported that they experienced a greater number of LTRs from the infraspinatus muscle than the other muscles. This accords with literature reviewed above which identified a key role for the infraspinautus muscle in RCS. The co-incidence of rotator cuff symptoms which may be potentially linked to the functions of the infraspinatus muscle (decreased lateral rotation power and reduced medial rotation range of motion) with a high proportion of MTrPs in the Infraspinatus muscles is noted.

The co-incidence appears to warrant further investigation, and an examination of the relative contribution of each muscle of the rotator cuff to the RCS symptoms should be incorporated in the design of a full size study.

5.8. LIMITATIONS OF THE STUDY

The known effect of supraspinal changes in chronic MPS has not been controlled for, and no accounting has been made for any concomitant psychological issues (see Niddam 2009). The study is also limited by its small size. However, the study was conducted as a

Comparison of C-M scores between reference study and this one		
Group	**C-M change (this study)**	**C-M Change (Kleinhenz)**
CON	26	[redacted]
DDN	39,3	[redacted]
SDN	23	19.2
PDN	17	8.37

Table 5.1 Comparison of C-M scores between reference study and this one

pilot study with the aim of which was to identify which would be the most effective dry needling technique to investigate rotator cuff pathology in a larger study. This size of the treatment effect differences between the control and placebo groups and the active needling groups seems to indicate that these groups could be disposed of in a larger study with greater statistical powering.

It is possible that patients were misdiagnosed using the Hawkins-Kennedy and Neer's tests given the complex nature of glenohumeral biomechanics; scapula positioning was not controlled for (Lewis 2009). However, the study attempted to reflect common practice in making the diagnosis, and was not designed to discuss the validity of the tests used.

6.CONCLUSION

The aim of this pilot study was to investigate the relative effects of three different forms of dry needling and a common physiotherapy protocol on the symptoms of a rotator cuff syndrome. The results indicate that a there may be a significant benefit to the use of DDN in such patients when compared to either conventional physiotherapy, superficial dry needling, or placebo needling, as measured by changes in the Constant-Murley scale, glenohumeral external rotation power, and in glenohumeral internal rotation range of motion.

The maximum benefit from DDN appears to peak after the second treatment. The effect may be due to humoral mechanism. Consequently, greater subtlety regarding the timing of the measurements taken will be required in a fully powered study. It is proposed that just two or three sessions of DDN may be required as part of an integrated therapeutic approach to RCS.

The co-incidence of multiple infraspinatus MTrPs and beneficial improvements in glenohumeral function specifically related to the infraspinatus muscle bears further investigation.

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Appendix A: Demographic data collection form

These details will be kept separate from any other information generated in this study.

Name:_____

Age *(as of 1 May 2005)* _____Years Male/ Female *(Circle appropriate)*

Home address:_____

_____

_____

_____

Postal address:_____

_____

_____

Telephone numbers: *(h)*_____

*(w)*_____

*(cell)*_____

Medical history: Smoker Y/ N How many per day?_____
What medicines are you currently taking?

_____

_____

Please circle if any of these conditions apply to you:

Pregnant Previous shoulder surgery Had physio for shoulder in past month

Have had any form of needle therapy Haemophilia Needle phobia

Miscellaneous:

1. Are you currently under any treatment for your shoulder pain?
    a. If so, what treatment? _____

Office use only
Informed consent form ☐ *Inclusion criteria* ☐ *Exclusion criteria* ☐ *RA N* ☐

Appendix B: Patient information sheet

"A comparison of dry needling and myofascial release therapy using a single blind, placebo controlled, randomised control trial"

Hello.
My name is Bruce Barker. I am a physiotherapist and am currently conducting physiotherapy research for a Masters degree in physiotherapy.

In my study, I want to see what things physiotherapists can do to help people like you with shoulder problems get better quicker. I am particularly interested in seeing whether very thin needles can be used to help fix shoulder problems. This is what the experiment you are being asked to participate in is about; "Does the use of dry needling work to help people with shoulder pain?"

It is a scientific study. The University of the Witwatersrand's (WITS) Ethical committee has given me permission to carry it out. The Physiotherapy department, which is part of the WITS Faculty of Health Sciences (Medical School), is supervising the study.

What I am asking you to do for me is to voulenteer to take part in the study; you are under no obligation to do so. This means that if you voulenteer, you will be put into one of 4 groups, and your shoulder will be treated according to a set procedure that I have developed. Neither you nor I will know which group you are in. You will be treated 4 times, once every three days, and then come in for a check up without treatment 1 month after the last treatment. This is a total of 5 visits. Each treatment visit will take 30 minutes, but the last one only 15 minutes.

Not all the groups will have exactly the same treatment, but everyone will get effective treatment. All the treatments will be carried out by a qualified physiotherapist who has also been specially trained in dry needling treatments. All participants will receive "normal physiotherapy". This "normal physiotherapy" treatment will consist of gentle heating, some easy-to-do shoulder exercises, tight muscle releases, and joint movements. All of these should be pain free. In addition to this normal treatment, three of the groups will also have some form of needle treatment. One group will have needles put into muscles, and one group will have needles put into skin. These 2 groups will feel some discomfort during treatment. The third group will be treated with a newly designed placebo needle. You will not feel this needle as it only pretends to pierce the skin. Group 4 will be treated with normal physiotherapy only. All participants will have easy but important exercises to do at home.

A summary of these groups is in the table on the next page.

Group 1	Group 2	Group 3	Group 4
Gentle heating over the shoulder Easy-to-do shoulder exercises Tight muscle release Shoulder joint movements Home exercises	Gentle heating over the shoulder Easy-to-do shoulder exercises Tight muscle release Shoulder joint movements Needle treatment into the muscles (slight discomfort) Home exercises	Gentle heating over the shoulder Easy-to-do shoulder exercises Tight muscle release Shoulder joint movements Needle treatment in the skin (slight discomfort) Home exercises	Gentle heating over the shoulder Easy-to-do shoulder exercises Tight muscle release Shoulder joint movements Needle treatment (will not feel the needles) Home exercises

The technique is safe, but there are still a few things you need to know about the needling part of the treatment. You may experience an aching feeling for 24 hours after the treatment, as you would with any injection. This goes away, and doing the exercises helps a lot to ease the discomfort. You may have a small bruise, or you may feel quite tired. These are temporary. There is also a very small chance that a needle may puncture your lung if the wrong technique is used. However, the study is designed with maximum safety in mind to minimise these risks and side effects.

The experiment will last for 2 weeks, and you will need to come every three days for treatment. Do not forget about the follow up 3 months after this treatment period. I need you to keep all the appointments or I cannot use your results. You are however free to tell me you want to stop being a part of the experiment at any time, and you do not have to give me a reason unless you want to. Your privacy and anonymity will be maintained at all times

Please sign the attached consent form only if you have asked any questions you want to, are happy with the answers, and are happy to voulenteer to be part of the study.

Appendix C: Patient consent form

Patient Consent form

"A comparison of dry needling and myofascial release therapy using a single blind, placebo controlled, randomised control trial"

I, ……..
hereby agree to be part of the physiotherapy experiment called *"A comparison of dry needling and myofascial release therapy using a single blind, placebo controlled, randomised control trial"*.

I have read and understood everything in the information sheet provide to me.

I have had the opportunity to ask any questions that I want to, and have been given satisfactory answers.

I understand that I can withdraw from this study at any time.

I understand that my private details will be kept private, and not shared with any third party.

Signed:…….. Date: ……..

Randfontein

Witness: …… Date: ……...

Appendix D: Pre-intervention Constant-Murley Scale Data collection form

Data collection sheet 1

Date: Treatment number

Patient RAN:

Pre-intervention assessment

Pain		None	15	Mild	10	Moderate	5	Severe	0				/15
ADL	**Training**	Full training	4	Mildly reduced	3	Mod reduced	2	Severely reduced	1	Not possible	0		
	ADL	All possible	4	Mildly reduced	3	Mod reduced	2	Severely reduced	1	Not possible	0		
	Sleep	Unaffected	2	Waking up	1	Severely disturbed	0						
	ADL position	Above head	10	Top of head	8	Up to neck	4	Up to xiphoid	2	Up to waist	2	Unable to lift 0	/20
ROM	**Flexion**	151°-180°	10	121° - 150°	8	91°-120°	6	61°-90°	4	31°-60°	2	0°-30° 0	
(painless)	**Abduction**	151°-180°	10	121° - 150°	8	91°-120°	6	61°-90°	4	31°-60°	2	0°-30° 0	
	Internal rot8n	Hand interscap	10	Dorsum to T12	8	Dorsum to L3	6	Dorsum to SIJ	4	Dors. to buttock	2	To lateral thigh 0	
	External rot8n	(2 pts per position)		HBH elbow f/w d		HBH elbow back		Hand head; elb f/w d		Hand head; elbow back		Full elevation from hand on top of head	/40
Power	**abduction**	1 point for every (1kgx0.4536) of pressure max = 25 points (11.34kg)											/25

Active ROM with anterior containment force				**Flexion**	
				Abduction	
				Int. Rotation	
				Ext. rotation	

Active strength	**Flexion**			**Int. Rotation**	
	Extension			**Ext. rotation**	

TOTAL

Appendix E: Post-intervention Constant-Murley Scale Data collection form

Data collection sheet 2

Date: Treatment number
Patient RAN:

Post-intervention assessment

Pain		None	15	Mild	10	Moderate	5	Severe	0						/15
ADL	**Training**	Full training	4	Mildly reduced	3	Mod reduced	2	Severely reduced	1	Not possible	0				
	ADL	All possible	4	Mildly reduced	3	Mod reduced	2	Severely reduced	1	Not possible	0				
	Sleep	Unaffected	2	Waking up	1	Severely disturbed	0								
	ADL position	Above head	10	Top of head	8	Up to neck	4	Up to xiphoid	2	Up to waist	2	Unable to lift	0		/20
ROM	**Flexion**	151°-180°	10	121° - 150°	8	91°-120°	6	61°-90°	4	31°-60°	2	0°-30°	0		
(painless)	**Abduction**	151°-180°	10	121° - 150°	8	91°-120°	6	61°-90°	4	31°-60°	2	0°-30°	0		
	Internal rot8n	Hand interscap	10	Dorsum to T12	8	Dorsum to L3	6	Dorsum to SIJ	4	Dors. to buttock	2	To lateral thigh	0		
	External rot8n	(2 pts per position)		HBH elbow f/w d		HBH elbow back		Hand head; elb f/w d		Hand head; elbow back		Full elevation from hand on top of head			/40
Power	**abduction**	1 point for every (1kgx0.4536) of pressure max = 25 points (11.34kg)													/25

Active ROM with anterior containment force		**Flexion**	
		Abduction	
		Int. Rotation	
		Ext. rotation	

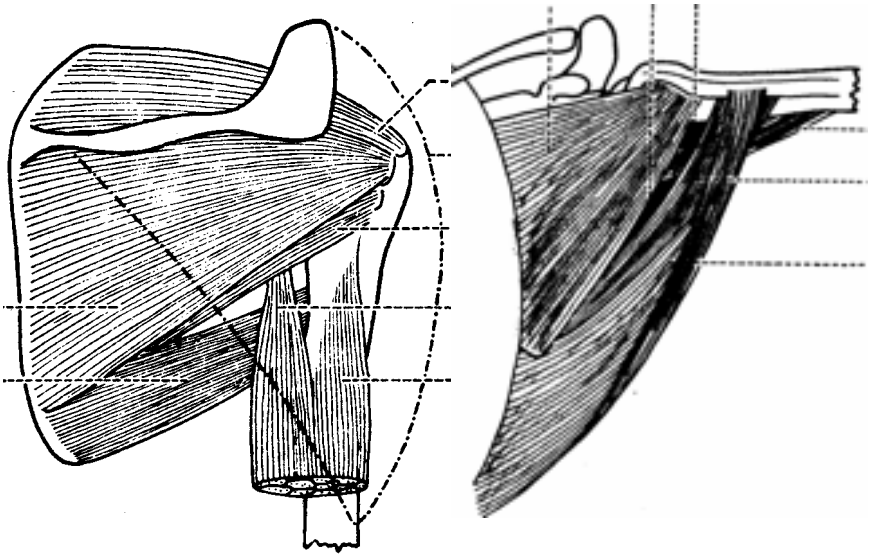
TOTAL

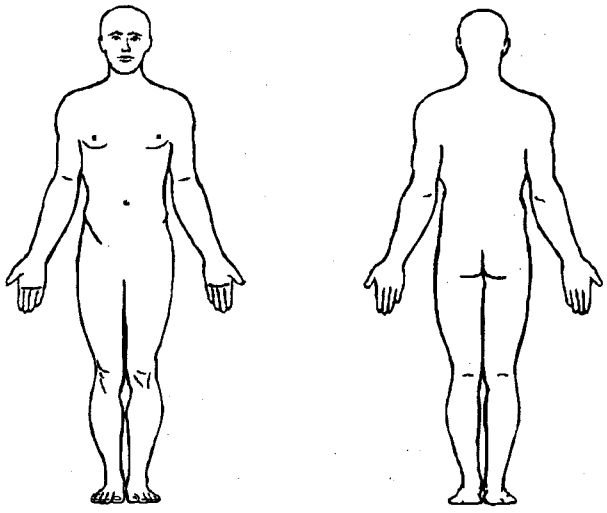
Active strength	**Flexion**		**Int. Rotation**	
	Extension		**Ext. rotation**	

Appendix F: Shoulder assessment tool

RAN: …….. Date: …/…/……
Occupation: …….
Sports/ Hobbies: ……
Dominant arm: **R** **L** Painful shoulder: **R** **L**

History of shoulder pain:
……
……
……
Previous medical history:
……
……
……
……
Aggravation factors:
……
Mitigation factors:
……





Posture type:
- ☐ Ideal
- ☐ Flat back
- ☐ Sway Back
- ☐ Upper cross
- ☐ Kyphosis-Lordosis

Appendix G: Shoulder exercises

Shoulder exercises

Please do 3 sets of each of these exercises,
Please do 3 sets of each of these exercises, and repeat this 3 times per day

A



B



A + B: Roll your arm all the way up and then all the way down as far as pain allows. Repeat 3 x 10

Remember to keep your shoulder rolled back & down

C



D



C: Pull your elbow down and across you body. Keep your nose pointed toward your opposite armpit. Repeat 3x30 seconds.

D: Pull your hand up behind your back along your spine. Repeat 3x30 seconds.

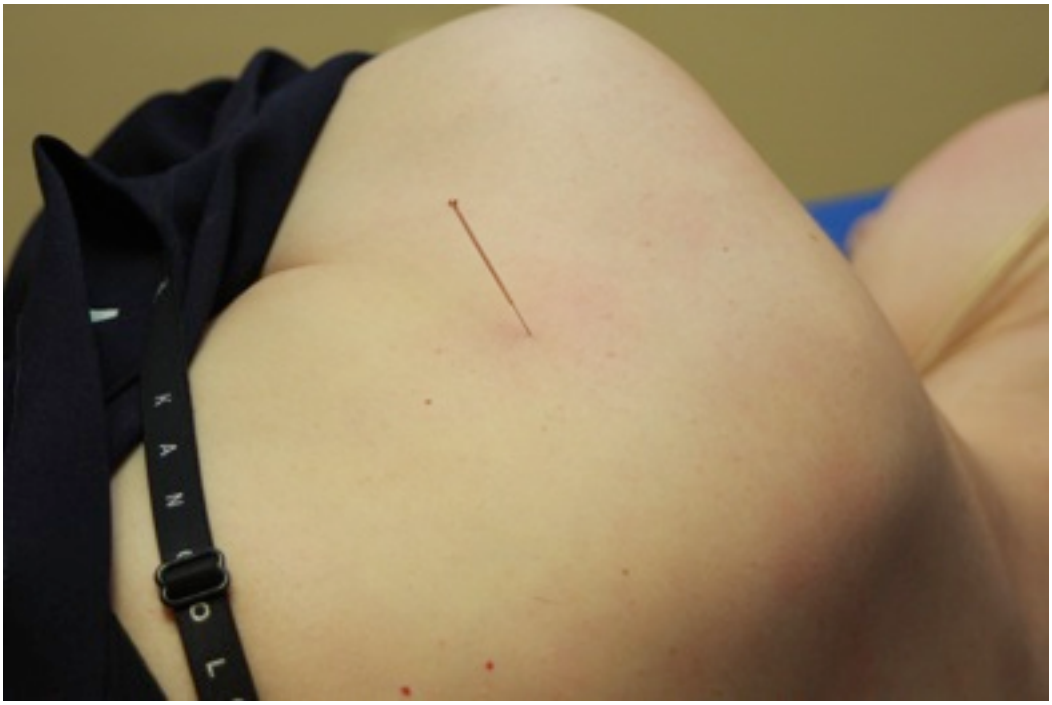
Appendix H: Photographs of the cuff muscles being needled



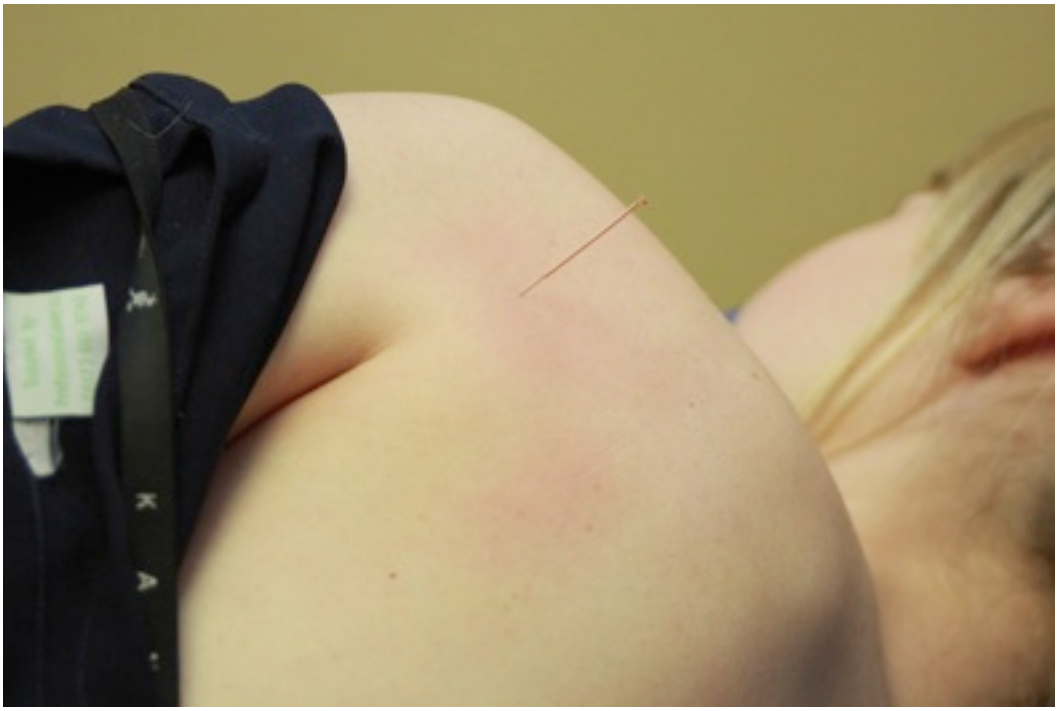
F1: Subscapularis (0.35x75mm)



F2: Supraspinatus (0.3x50mm)



F3: Infraspinatus (0.3x25mm)



F4: Teres Minor (0.3x30mm)

Appendix I: Results of ANCOVA of Treatment effect Part 1

Outcome	Analysis	*p* - Parametric	*p* - Ranked
C-M	Sess1diff\Sess1	0,3386	0,2497
C-M	Sess2diff\Sess2	0,3869	0,183
C-M	Sess3diff\Sess3	0,0716	0,0044
C-M	Sess4diff\Sess4	0,0319	0,0303
C-M	Final-Pre	0,9789	0,0695
abdpow	Sess1diff\Sess1	0,7042	0,7928
abdpow	Sess2diff\Sess2	0,5645	0,4359
abdpow	Sess3diff\Sess3	0,1379	0,4454
abdpow	Sess4diff\Sess4	0,5094	0,5769
abdpow	Final-Pre	0,7971	0,7836
abdrom	Sess1diff\Sess1	0,5107	0,617
abdrom	Sess2diff\Sess2	0,4452	0,2278
abdrom	Sess3diff\Sess3	0,9707	0,7187
abdrom	Sess4diff\Sess4	0,8048	0,7227
abdrom	Final-Pre	0,7802	0,8661
extpow	Sess1diff\Sess1	0,4612	0,8615
extpow	Sess2diff\Sess2	0,6845	0,5544
extpow	Sess3diff\Sess3	0,1682	0,091
extpow	Sess4diff\Sess4	0,1877	0,2873
extpow	Final-Pre	0,464	0,4181
flexpow	Sess1diff\Sess1	0,8283	0,9178
flexpow	Sess2diff\Sess2	0,1933	0,4221
flexpow	Sess3diff\Sess3	0,7263	0,8268
flexpow	Sess4diff\Sess4	0,4195	0,7972
flexpow	Final-Pre	0,0696	0,1131

Appendix I: Results of ANCOVA of Treatment effect Part 2

Outcome	Analysis	p - Parametric	p - Ranked
irotpow	Sess1diff\Sess1	0,752	0,4412
irotpow	Sess2diff\Sess2	0,9122	0,8995
irotpow	Sess3diff\Sess3	0,6059	0,5122
irotpow	Sess4diff\Sess4	0,4979	0,8633
irotpow	Final-Pre	0,3045	0,2254
xrotpow	Sess1diff\Sess1	0,5283	0,7384
xrotpow	Sess2diff\Sess2	0,0356	0,1268
xrotpow	Sess3diff\Sess3	0,4188	0,7281
xrotpow	Sess4diff\Sess4	0,0737	0,3969
xrotpow	Final-Pre	0,7926	0,5138
xrotrom	Sess1diff\Sess1	0,5398	0,4254
xrotrom	Sess2diff\Sess2	0,6421	0,6039
xrotrom	Sess3diff\Sess3	0,8149	0,7655
xrotrom	Sess4diff\Sess4	0,6671	0,6364
xrotrom	Final-Pre	0,7483	0,1935
lrotrom	Sess1diff\Sess1	0,7653	0,6271
lrotrom	Sess2diff\Sess2	0,399	0,1614
lrotrom	Sess3diff\Sess3	0,0645	0,0149
lrotrom	Sess4diff\Sess4	0,8015	0,8567
lrotrom	Final-Pre	0,8601	0,9351
flexrom	Sess1diff\Sess1	0,7283	0,5915
flexrom	Sess2diff\Sess2	0,2836	0,04
flexrom	Sess3diff\Sess3	0,1397	0,281
flexrom	Sess4diff\Sess4	0,4025	0,2968
flexrom	Final-Pre	0,7927	0,3853

Appendix J: Results of ANCOVA of Inter-treatment

Outcome	Analysis	p - Parametric	p - Ranked
CM	Begin 2-End 1	0,0944	0,1569
CM	Begin 3- End 2	0,7627	0,4355
CM	Begin 4 - End 3	0,9659	0,9194
CM	Follow -End 4	0,8954	0,9917
AbdPow	Begin 2-End 1	0,5945	0,8319
AbdPow	Begin 3- End 2	0,6694	0,8094
AbdPow	Begin 4 - End 3	0,7544	0,8708
AbdPow	Follow -End 4	0,6162	0,737
AbdRom	Begin 2-End 1	0,5904	0,435
AbdRom	Begin 3- End 2	0,2662	0,454
AbdRom	Begin 4 - End 3	0,9045	0,9648
AbdRom	Follow -End 4	0,9698	0,9248
ExtPow	Begin 2-End 1	0,9182	0,7039
ExtPow	Begin 3- End 2	0,2483	0,2198
ExtPow	Begin 4 - End 3	0,9614	0,5856
ExtPow	Follow -End 4	0,4801	0,4866
FlexPow	Begin 2-End 1	0,8464	0,7247
FlexPow	Begin 3- End 2	0,2017	0,2373
FlexPow	Begin 4 - End 3	0,3746	0,6027
FlexPow	Follow -End 4	0,8296	0,9971
IrotPow	Begin 2-End 1	0,3725	0,3409
IrotPow	Begin 3- End 2	0,9699	0,9964
IrotPow	Begin 4 - End 3	0,7952	0,8396
IrotPow	Follow -End 4	0,2666	0,1016
XrotPow	Begin 2-End 1	0,4739	0,4702
XrotPow	Begin 3- End 2	0,1082	0,2616
XrotPow	Begin 4 - End 3	0,3535	0,437
XrotPow	Follow -End 4	0,8219	0,5912
XrotRom	Begin 2-End 1	0,3838	0,7573
XrotRom	Begin 3- End 2	0,047	0,0501
XrotRom	Begin 4 - End 3	0,7454	0,7937
XrotRom	Follow -End 4	0,7242	0,1703
IrotRom	Begin 2-End 1	0,5619	0,1042
IrotRom	Begin 3- End 2	0,6273	0,2855
IrotRom	Begin 4 - End 3	0,0882	0,0331
IrotRom	Follow -End 4	0,9801	0,7383
FlexRom	Begin 2-End 1	0,3289	0,3445
FlexRom	Begin 3- End 2	0,3361	0,1095
FlexRom	Begin 4 - End 3	0,4811	0,5684
FlexRom	Follow -End 4	0,9573	0,9361

Appendix K: Ethical clearance.

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Barker

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M051144**
PROJECT	A Comparison of Dry Needling and Myo-fascial Release Using a Single-Blind Placebo Controlled, Randomised Control.....
INVESTIGATORS	Mr B Barker
DEPARTMENT	Physiotherapy
DATE CONSIDERED	05.11.25
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 06.02.24 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Mrs N Mbambo

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES