THE EFFECT OF LOW INTENSITY LASER THERAPY ON POST NEEDLING SORENESS IN TRIGGER POINT 2 OF THE UPPER TRAPEZIUS MUSCLE

BY

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I, Mishka Dhai, do declare that this dissertation is representative of my own work in both conception and execution (except where acknowledgements indicate the contrary)

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DEDICATION

This dissertation is dedicated to:

My late father, Amod Dhai, for always having believed that I could do whatever I put my mind to. I miss you every day, but I know that you would have been proud to see how far I have come.

My mother, Wendy Elvia Dhai, for being my support and my encouragement through everything.

The man who has my heart, Jacques van Heerden, for being my rock, my pillar of strength, the one I could turn to, no matter what.

To my sister, Nadia Dhai, for encouraging and supporting me, always.

I love you all.

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And finally, to all the Patients that participated in this study, without you this project would never have been possible. A heartfelt thanks to each and every one of you for taking the time to participate in my research study.

ABSTRACT

Introduction: Myofascial pain syndrome is a condition of collective sensory, motor and autonomic symptoms caused by myofascial trigger points, which are hyper-irritable foci in a muscle and palpated as a taut, tender, ropey band. There are many types of treatment for myofascial pain syndrome; dry needling is one of the most effective forms. Dry needling involves the insertion of a needle into the myofascial trigger points in order to break up the contractile elements and any somatic components that may contribute to trigger point hyperactivity, and to stimulate sensitive nerve ending in the area. Although therapeutic, an unpleasant side effect of dry needling is the post-needling soreness. Various modalities have been utilised to decrease post-needling soreness, such as ice, heat and action potential simulation, to mention a few, however no study has been conducted to date that documents low intensity laser therapy and its effect on post-needling soreness. This study therefore aimed to evaluate the effect of low intensity laser therapy on post-needling soreness in trigger point 2 of the upper trapezius muscle.

Methodology: This study was designed as a randomised, controlled pre-test and post-test experimental trial. Forty participants were randomly allocated into two equal groups of 20 participants each. Group 1 received the needling and laser therapy; Group 2 received needling and placebo laser. Algometer and Numerical Pain Rating Scale 11 (NRS 11) readings were taken immediately before the dry needling procedure; after the laser or placebo laser therapy; and again, at the follow-up visit 24 hours later. Subjects used a 24-hour pain diary which was completed at three-hour intervals, to record any post-needling soreness. The NRS 11 scale was used immediately before the needling and again at the follow-up visit 24 hours later.

Results: Statistical analysis was done using SPSS version 24.0 to conduct inferential and deductive statistics. A significance of p=0.05 was set. Baseline demographics and outcome measurements were compared between the two groups using t-tests or ANOVA where appropriate. An inter-group analysis revealed that objectively and subjectively all groups experienced some degree of post-needling soreness, which deceased significantly over time. This decrease of pain was not significantly related to the treatment group, and there is no evidence of the differential time effect with the treatment. An inter-group analysis yielded no statistically significant results regarding the effectiveness of the treatments received by the patients. This could be because of the small sample size or because low intensity laser therapy is not a useful intervention.

Conclusion: The results from this study revealed that both treatment groups responded equally in the alleviation of pain. It can thus be concluded that low intensity laser therapy had no significant beneficial effects on post-needling soreness.

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CHAPTER ONE

INTRODUCTION

1.1 The Problem and its Setting

Myofascial pain syndrome (MPS) is caused by myofascial trigger points (MFTPs), which are hyperirritable spots in the muscle fibres presenting as taut, ropey bands on palpation. The MFTPs may refer pain spontaneously and/or on digital compression. This pain may be associated with paresthesias and/or autonomic phenomena/symptoms within the same region as the pain. These symptoms tend to be peculiar for each muscle (Travell and Simons 1999).

The international prevalence of myofascial pain syndrome (based on the above description), is predicted to be between 21% and 85% of individuals presenting with musculoskeletal dysfunction (Tekin *et al*. 2012). Myofascial pain syndrome is the second most frequently diagnosed condition in South Africa (Walker, Odendaal and Esterhuyse 2006). The study therefore showed that myofascial pain syndrome was a common condition in South Africa. Several treatment methods are utilised to alleviate the pain experienced by MPS, as well as the pain experienced by the MFTP itself. These include: a) non-invasive therapies such as: moist heat (Hou *et al.* 2002; Rickards 2006), spray and stretch (Hanten *et al*. 2000), ice (Chonan 2008), heat (Govender 2011), and ischaemic compression (Shacksnovis 2005); and b) invasive therapies such as dry needling (Dommerholt, Mayoral del Moral and Gröbli 2006; Travell and Simons 1999), injectables (Ho and Tan 2007), and medication (Kvien and Viktil 2003).

Dry needling has been shown to be one of the most effective treatment regimens for MFTPs (Abbaszadeh-Amirdehi *et al*. 2013). Several proposed mechanisms explain the effectiveness of dry needling in the deactivation of MFTPs. One mechanism proposed that dry needling is able to mechanically cause a disruption in the muscle bundle or nerve fibres, thus ceasing the pain-spasm cycle (Manga 2008; Ferreira 2006; Travell and Simons 1999). Elevated levels of extracellular potassium caused by the mechanical disruption of muscle fibres by the needle leads to the depolarization of nerve fibres, which causes a local twitch response (Hong and Hsueh 1996; Marieb and Hoehn 2013). Nerve sensitising substances are removed by local haemorrhage and interruption of the central feedback mechanism (Travell and Simons 1999). Even so, post-needling soreness remains an unpleasant side effect experienced after dry needling (Dommerholt, Mayoral del Moral and Gröbli 2006; Huguenin 2004). The post-needling soreness is thought to be induced by micro-trauma of the needle tip touching or stimulating nerves in the area of the MFTP (Hong 2006), as well as by micro-trauma to the muscle fibres in the trigger point together with leakage of intracellular potassium to the extracellular space (Ilbuldu *et al*. 2004). Micro-haemorrhaging is also caused by damage to the tissue at the needled site and is associated with post-needling soreness (Alvarez and Rockwell 2002). Both single insertions and fanning dry-needling methods were found to cause post-needling soreness (Ferreira 2006).

Post-needling soreness is an entirely separate entity and is not the same as myofascial pain (Lewit 1979). Following the dry needling procedure, patients have reported experiencing a continuous 'pressure' or a 'dull aching' sensation. This sensation associated with post-needling soreness discourages patients from seeking further treatment through dry needling (Travell and Simons 1999; Govender 2011), thereby lengthening the patient's discomfort (Govender 2011). The interruption of patient management is further complicated by the fact that post-needling soreness hinders any subsequent needling of the same region for three to four days post-treatment (Travell and Simons 1999).

Low intensity laser therapy (LILT) has been shown to alleviate the pain in MFTPs as well as other soft tissue lesions (Ilbuldu *et al*. 2004; Kannan 2012) in comparison with placebo laser therapy. The laser causes cells in the area under treatment to vibrate at the same frequency as that of tissue healing, thereby causing a decrease in inflammation, swelling and pain concomitant with improved healing time (Snyder-Mackler *et al.* 1989; Ceylan, Hizmetli and Silig 2003; Ilbuldu *et al*. 2004; Kannan 2012). Limited research has been undertaken, however, on the effect of laser on post-needling soreness.

The intention of this study was therefore to evaluate the effect of low intensity laser therapy in alleviating post-needling soreness in trigger point two (TP2) of the upper trapezius muscle. A comparison between laser therapy and the sham laser was undertaken to determine the effectiveness of laser therapy in alleviating post-needling soreness. Inferential and deductive statistics were conducted using SPSS version 24.0. A 95% confidence interval was set with a *p*-value of 0.05 considered as significant. Baseline demographics as well as outcome measurements were compared between the two groups using t-tests or ANOVA where appropriate.

1.2 Research problem, Aims and Objectives of the Study

Post-needling soreness has often been treated by time-consuming, uncomfortable modalities. Low intensity laser therapy has been found to be effective in healing tissue damage in a shorter period of time without discomfort. To date, however, no research study has been conducted to establish the efficacy of laser therapy on post-needling soreness. The aim of the study was to establish the efficacy of LILT in alleviating post needling soreness in trigger point two (TP2) of the upper trapezius muscle.

Objective 1

To determine the effectiveness of low intensity laser therapy on post-needling soreness in terms of pain according to the Numerical Pain Rating Scale (NPRS), 24-hour pain diary, and pressure threshold algometer.

Objective 2

To determine the effectiveness of sham laser on post-needling soreness in terms of pain according to the Numerical Pain Rating Scale (NRS - 11), 24-hour pain diary and pressure threshold algometer.

Objective 3

To compare the results in terms of subjective and objective measurements between the groups in terms of pain according to the Numerical Pain Rating Scale (NRS - 11), 24-hour pain diary and pressure threshold algometer.

1.3 The Rationale

Whilst dry needling has been documented as a very good modality for treating trigger points (Abbaszadeh-Amirdehi *et al.* 2013), post-needling soreness has emerged as an unpleasant side effect. The post-needling soreness is caused by micro trauma to the muscle fibres in the trigger point, and leakage of intracellular potassium to the extra-cellular space (Ilbuldu *et al*. 2004). Patients may therefore avoid dry needling and select less invasive but less effective modalities for treatment, thereby prolonging their pain and decreasing the rate of recovery (Edwards and Knowles 2003).

Post-needling soreness can be managed and its effects decreased by using various treatments over the affected areas. However, although various treatments have been identified in decreasing post needling soreness, to date no study has been conducted to determine the effect of LILT on post-needling soreness. Low intensity laser therapy is non-invasive, inexpensive and the periods of short exposure required also cuts back on time constraints that often affect treatment. Coupling LILT with other chiropractic treatment such as cervical manipulation has also shown a significant improvement in the management of neck pain when compared with using either LILT or cervical manipulation on its own (Saayman, Hay and Abrahamse 2011).

1.4 **Benefits**

The patients will benefit from this study as the results produced a method of treating post-needling soreness in a limited amount of time with reduced discomfort or without any discomfort at all. Practitioners will benefit from this study as it will encourage them to use a time-efficient modality to treat patients, thus giving them more time to treat more patients in the day as well as providing a better treatment regime for their patients. This will result in better patient satisfaction. Furthermore, the benefit of this study for health economics is that the public will be more inclined to visit a chiropractor without hesitation, to receive the best invasive treatment for myofascial pain, which is dry needling (Dommerholt, Mayoral del Moral and Gröbli 2006).

1.5 **Limitations**

Patients were expected to answer subject tools honestly and openly, reflecting their reality, and not because they wished to please the researcher; this is identified as the Observer effect or the Hawthorne Effect. This is the change due to cognisance of being observed and active compliance with the supposed requirements of researchers, due to special attention received or positive response to the stimulus being introduced. The terms Hawthorne Effect or Observer effect, are also used as the social equivalent of the ‘placebo effect’ (Wickström and Bendix 2000).

1.6 **Conclusion**

Myofascial trigger points are treated using various methods, both invasive and non-invasive. One of the most effective, invasive methods for treating MFTPs, is dry needling. The ache that is felt after a muscle has been needled is referred to as post-needling soreness. While many modalities are used to alleviate this post-needling soreness, none are quick and free of discomfort. Thus, the aim of the research study was to determine the effect of LILT on post-needling soreness, which in turn will contribute to the improvement of the treatment of myofascial pain syndromes.

In the next chapter, pertinent empirical literature of dry-needling, post dry-needling soreness and interventions undertaken to alleviate this pain, will be reviewed.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Musculoskeletal discomfort is widely considered as a significant health care and economic challenge (Walker, Odendaal and Esterhuyse 2006). Myofascial pain syndrome (MPS) is the manifestation of pain due to a disorder in a muscle or its related fascial components (Bennett 2007). It is a condition of collective sensory, motor and autonomic symptoms that are caused by myofascial trigger points (MFTPs), or spots of hyper-irritability in a muscle or its related fascia which in turn cause a spasm presenting as a taut, ropey band when palpated (Tekin *et al*. 2012). Additionally, MFTPs inhibit the overall muscle function, leading to muscle weakness without atrophy (Dommerholt *et al*. 2006). Upon stimulation, a MFTP will elicit two important clinical phenomena: referred pain and a local twitch response (Kalichman and Vulfsons 2010).

Dry needling is a common management technique in orthopaedic manual physical therapy (Dommerholt *et al*. 2006). While a number of dry needling methods exist, the more common and best supported method targets MFTPs (Dommerholt *et al*. 2006). Physical therapists and other health care providers, such as physiotherapists (Edwards and Knowles 2003) and dentists (de Abreu Venâncio, Alencar and Zamperini 2008), often utilise dry needling as part of their clinical management of MPS and trigger points (Dommerholt *et al*. 2006). Myofascial trigger point dry needling is a minimally invasive technique in which an acupuncture needle is inserted through the skin and into the muscle, to relieve the spasm and associated local and referred pain (Dommerholt *et al*. 2006).

This chapter reviews the literature concerning MPS, MFTPs, the trapezius muscle and its trigger points, post-needling soreness and its management, as well as low intensity laser therapy (LILT) and the effects that it may have on post-needling soreness.

2.2 Prevalence and Incidence of Myofascial Pain Syndrome

International prevalence of MPS range from 21-85% among patients with musculoskeletal dysfunction, however, the South African statistic is 23.19%

(Walker, Odendaal and Esterhuyse 2006; Tekin *et al*. 2012). While the range of ages affected varied between 20 and 84 years, those in their forties were more likely to be identified as having MPS (Walker, Odendaal and Esterhuyse 2006. Although MPS has been detected in both genders, it has been observed to be more predominant in females than males (Ilbuldu *et al.* 2004; Walker, Odendaal and Esterhuyse 2006). This widespread condition is often seen in sedentary workers, such as those who undertake office or desk work, and is hardly seen in active workers due to the protective effect of heavy daily activity (Ilbuldu *et al.* 2004). An individual will spend more time in static postures than in motion in a sedentary lifestyle, leading to dynamic muscles becoming progressively inhibited and lax while postural muscles become progressively tight and inflexible. An imbalance between the dynamic and postural muscles will gradually develop. The muscle imbalance may lead to MFTPs and musculoskeletal pain (Yap 2007).

2.3 **Predisposing and Perpetuating Factors**

Several risk factors for musculoskeletal pain have been identified (Alvarez and Rockwell 2002; Cummings and Baldry 2007; Cimmino, Ferrone and Cutolo 2011; Walker, Odendaal and Esterhuyse 2006; Huang *et al*. 2011), which include:

- Ages 18 to 60: the working class of society.
- Gender: females are affected more often than males.
- Smoking.
- Low education.
- Low physical activity, leading to strain when doing activities that are of high-energy demand.
- Poor social interaction.
- Low family income.
- Depression, which leads to poor posture in turn leading to muscle tension and pain.
- Anxiety and sleep disorders, leading to stress and muscle tension.
- Performing repetitive manual work: repetitive manual work leads to muscular and joint strain.
- Separated or divorced: emotional stress often results in physical strain on the body.
- Trauma directly to the muscle, as well as overloading and overuse.
- Muscle atrophy and ischemia.

- Visceral pain referral: contraction of overlying muscles in response to the pain from the underlying viscera.
- Radiculopathic compression of motor nerves.
- Climatic causes: cold leads to muscle stiffness and contraction.

2.4 **Myofascial Trigger Points**

Myofascial trigger points are defined as spots or foci of hyperirritability in skeletal muscle and/or its fascia that are associated with a hypersensitive palpable nodule in a taut band. The spot is painful on compression and can give rise to distinctive referred pain, referred tenderness, motor dysfunction, and autonomic phenomena (Travell and Simons 1999). Nearly half of the human body mass is comprised of skeletal muscle, which suggests that MFTPs can develop almost anywhere in the body (Eng-Ching 2007). Myofascial trigger points can be present in a) the active state in which they cause pain, even at rest, and may even cause a referred pain pattern; or, b) the latent state in which pain can only be elicited upon physical examination and palpation of the trigger point (Dommerholt *et al*. 2006; Abbaszadeh-Amirdehi *et al*. 2013). Upon physical examination of a trigger point the examiner may illicit pain and the patient may feel tenderness in the area of the trigger point. Palpation reveals taut bands of muscle and may reproduce any referred pain that the patient may feel (Figure 2.1).

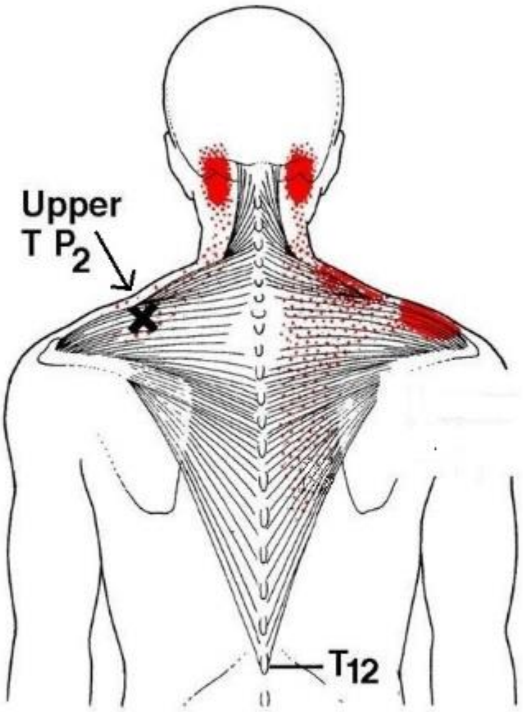

Figure 2.1: Location of TP2 myofascial trigger point in the upper trapezius muscle (adapted from Travell and Simmons 1999).

There are various theories of pathogenesis that can describe the aetiology of MFTPs. Although the aetiology of MFTPs is unclear the two most commonly recognized theories (energy crisis theory and motor endplate hypothesis), when combined, become an integrated hypothesis called the 'ATP energy crisis' (Ruiz-Sáez *et al*. 2007), which provides a probable explanation (Huguenin 2004).

2.4.1 Energy Crisis Theory

The energy crisis model refers to the sustained local contraction of muscle fibres. This is seen to arise due to excessive acetylcholine (ACh) release, shortening of the sarcomere and secretion of sensitizing substances, three crucial features which relay between each other in a positive feedback cycle (Kuan 2009). An elevated ACh release in the neuromuscular junction (also known as the motor endplate) can precipitate an elevation of the muscle fibre tension (also known as the taut band) that contains an MFTP, thereafter causing a contributing factor towards an energy crisis due to raised metabolic activity. The contraction of muscle fibres causes compression of blood vessels, leading to local ischemia with hypoxia (Edwards and Knowles 2003). In this circumstance, the release of sensitizing substances can be raised to incite discomfort and pain. The sensitizing substances can additionally incite anomalous ACh secretion to create a vicious cycle (Kuan 2009). There is also an increased energy demand from the sustained contraction, which is not able to be met due to the local hypoxia (Edwards and Knowles 2003). This cycle is known as the Energy Crisis Theory.

2.4.2 Motor End Plate Hypothesis

The motor neuron synapses with a muscle cell at the motor endplate. Hubbard and Berkoff (1993) have found that each trigger point contains minuscule loci that generate distinctive electrical activity. These loci are predominant at the motor endplate zones (Simons 2001; Simons, Hong and Simons 2002). The endplate noise observed on EMG is believed to signify an elevated secretion rate of ACh from the nerve terminal. While minute amounts of activity at the motor endplate zone is not sufficient to induce a muscle contraction, it can lead to the propagation of action potentials a small distance along the muscle cell membrane. This degree of propagation may be sufficient to incite activation of a few contractile elements and be responsible for some degree of muscle shortening (Manga 2008).

2.5 **Physiology of Muscle**

Muscles are the functional structures in the body that create movement and contribute to homeostasis by moving substances through the body, as well as creating heat to maintain normal body temperature (Tortora and Derrickson 2009). The muscles are connected to the skeletal structure of the human body by tendons. Movement is as a result of the alternating contraction and relaxation of muscles.

2.5.1 Muscle Types

Muscles can be classified into three types: Smooth muscle tissue, cardiac muscle tissue and skeletal muscle tissue. Smooth muscle tissue is located in most internal organs in the abdominopelvic cavity as well as in blood vessels and airways. It is regulated by neurons that are part of the autonomic (involuntary) division of the nervous system and by the hormones released by endocrine glands (Marieb and Hoehn 2013). Cardiac muscle is located in the heart wall and in parts of the great vessels close to the heart. Cardiac muscle tissue is also regulated by neurons that are part of the autonomic (involuntary) division of the nervous system (Tortora and Derrickson 2009). Skeletal muscle tissue is so named as it moves most bones of the skeleton, with the exception of a few muscles that do not attach to bone. Skeletal muscle activity can be consciously controlled by neurons that are part of the somatic (voluntary) division of the nervous system (Tortora and Derrickson 2009).

2.5.2 Skeletal Muscle Structure

Understanding the basic structure and function of a skeletal muscle aids the understanding of the nature of MFTPs. Each muscle in the body is an organ consisting of hundreds to thousands of muscle cells, connective tissue, blood vessels, and nerve fibres. Each muscle is covered externally by epimysium (Marieb and Hoehn 2013) and is made up of muscle cell bundles called fascicles, which are separated from the rest of the muscle by the perimysium (Tortora and Derrickson 2009). A single muscle fascicle in turn contains a number of muscle fibres which are individually surrounded by the endomysium. Muscle fibres are elongated, multinucleated cells that are composed of numerous muscle fibres that contract when stimulated and are striated in appearance (Marieb and Hoehn 2013; Tortora and Derrickson 2009). Each muscle fibre is surrounded by the endomysium (Figure 2.2).

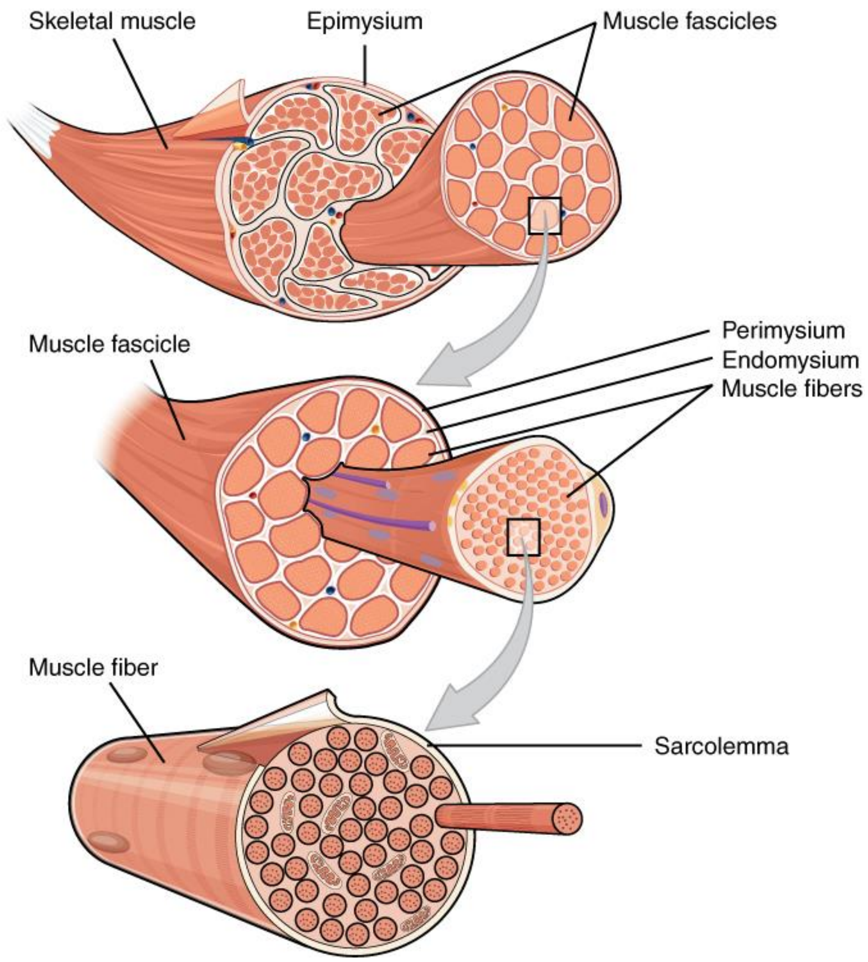

Figure 2.2: Details of the structure of skeletal muscle as well as connective tissue layers (adapted from OpenStax College 2013).

A muscle fibre consists of many rod-like contractile elements called fibrils or myofibrils, which occupy most of the muscle cell volume and lay parallel to each other (Tortora and Derrickson 2009). The myofibrils give the impression that they are banded, with groups of adjacent myofibrils arranged in rows. The sarcoplasm of the muscle fibre has other structures or organelles that assist in the contraction of the myofibrils (Marieb and Hoehn 2013). These include: a) substantial amounts of glycogen which can be used to produce adenosine triphosphate (ATP); b) energy producing mitochondria that produce the ATP; and c) myoglobin, a protein only found in muscles (Tortora and Derrickson 2009) which binds oxygen that is diffused into the myofibrils through the interstitial fluid. When there is a need, the myoglobin releases the oxygen, which is used by the mitochondria for the production of ATP.

Myofibrils, are smaller units composed of sarcomeres arranged end-to-end. The sarcomere is the functional contractile unit of the muscle (OpenStax College 2013). Each sarcomere is composed of myofilaments made up of contractile proteins, namely actin and myosin. A great number of myofibrils run parallel to the length of each muscle fibre. The myofibrils, which are a width of 1–2 µm each, are so compact in the fibre that the nuclei, mitochondria and other organelles give the impression that they are enfolded amongst them. Numerous myofibrils are in a single muscle fibre, largely dependent on its size, and account for about 80% of cellular volume. The myofibrils encompass the contractile elements of skeletal muscle (Tortora and Derrickson 2009).

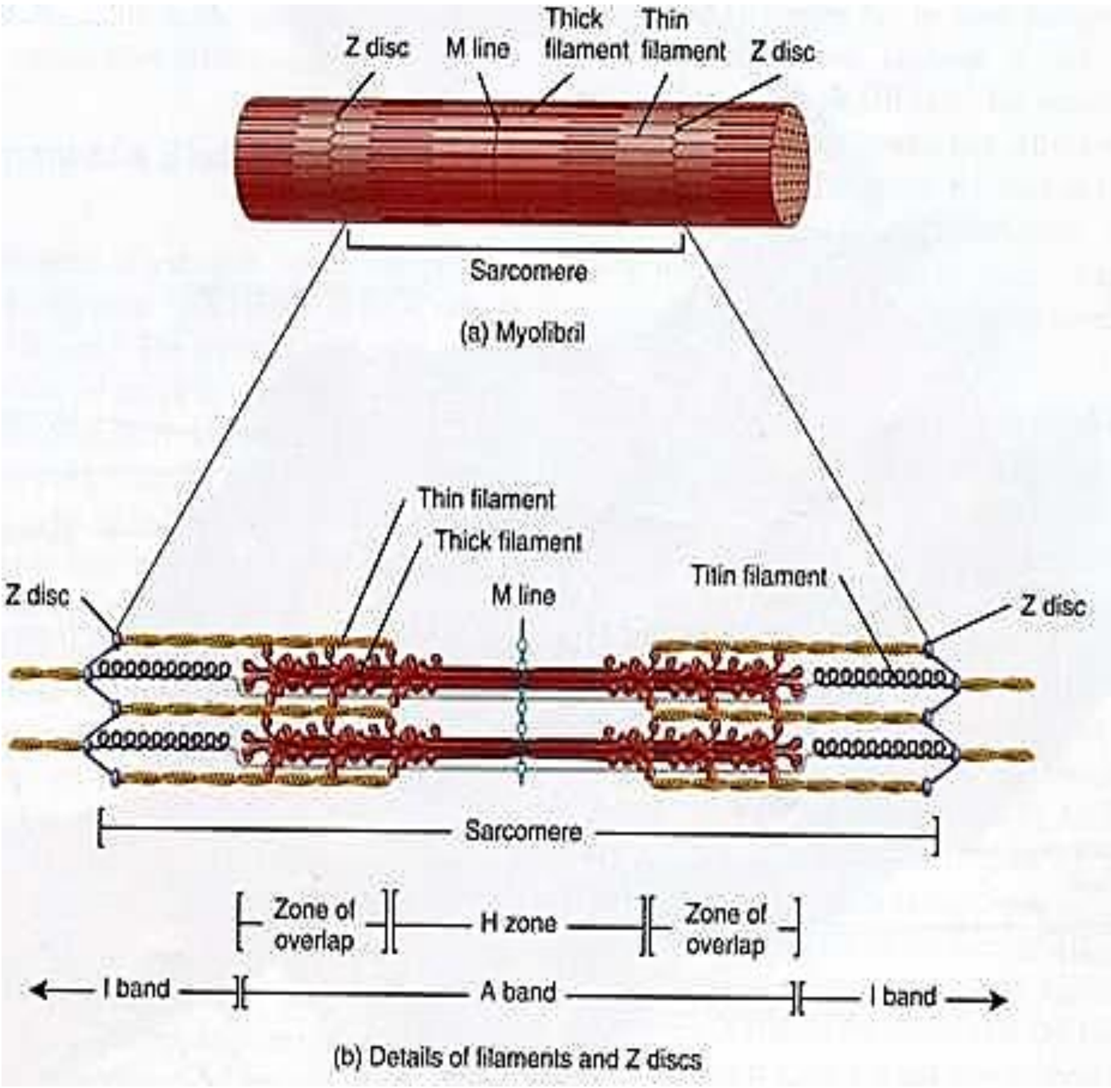

Figure 2.3: (a) Structure of a Myofibril, (b) Sliding filament mechanism of muscle contraction (adapted from Tortora and Derrickson 2009).

Striations are located in the myofibril (Figure 2.3). These are a repeating sequence of dark **A** bands and light **I** bands, and are apparent along the length of each myofibril. In a muscle fibre, the **A** and **I** bands are nearly seamlessly aligned with one another, giving the cell as a whole its striated appearance (Tortora and Derrickson 2009). Each **A** band has a lighter stripe in its midsection called the **H** zone (**H** for 'helle', a German term for 'bright'). The **H** zones are only noticeable in relaxed muscle fibres (Marieb and Hoehn 2013). Each **H** zone is divided into two sections by a dark vertical stripe called the **M** line. The **I** bands also have a darker midline disruption called the **Z** disc (or **Z** line). A muscle segment known as a sarcomere (Tortora and Derrickson 2009) is the region of a myofibril between two consecutive **Z** discs. This means that it contains an **A** band flanked by half an **I** band at each end. The sarcomere is the smallest contractile unit of a muscle fibre with an average length of 2 µm (Marieb and Hoehn 2013). Sarcomeres are therefore the functional units of skeletal muscle when they are aligned end-to-end in a myofibril. At the molecular level the banding pattern of a myofibril is seen to arise from an organised arrangement of two types of even smaller structures within the sarcomeres, myofilaments or filaments (Tortora and Derrickson 2009).

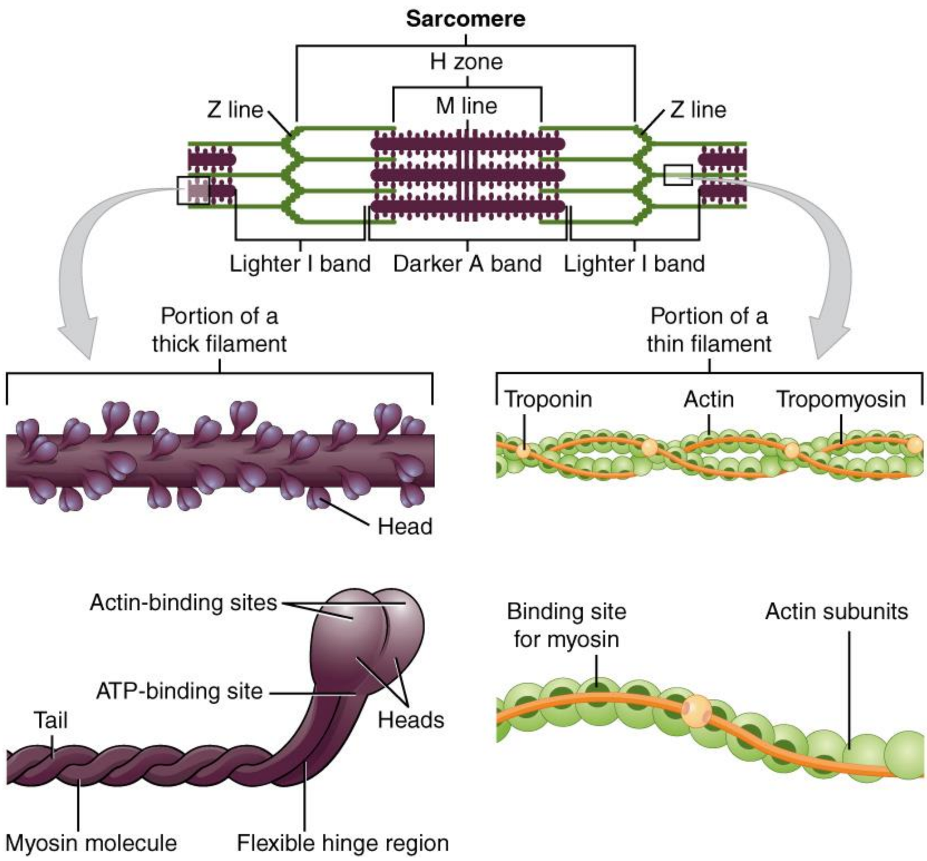

Figure 2.4: Structure of thick and thin filaments (adapted from OpenStax College 2013).

The central thick filaments extend the entire length of the **A** band (see Figure 2.4). The thin filaments extend across the **I** band and partially into the **A** band. The **Z** disc is composed of the protein nebulin (Marieb and Hoehn 2013). It secures the thin filaments and connects each myofibril to the next throughout the width of the muscle cell (Tortora and Derrickson 2009). The **H** zone of the **A** band has the appearance of being less dense because the thin filaments do not reach into this region. The midpoint of the **H** zone, the **M** line, is slightly darker due to the copiousness of fine protein strands that secure adjacent thick filaments together in that region. Each thick filament is enclosed by a hexagonal setting of six thin filaments in areas where there is an overlap of thick and thin filaments (Marieb and Hoehn 2013). Thick filaments (approximately 16 nm in diameter) (Tortora and Derrickson, 2009) are made predominantly of myosin, which is a protein (Figure 1.4). Each myosin molecule has a rod-like tail ending in two globular heads. Two intertwined heavy polypeptide chains make up the tail of the myosin molecule (Marieb and Hoehn 2013). Its bulbous heads are the ends of the heavy chains of myosin. The heads link the thick and thin filaments together by forming cross bridges during contraction. These cross bridges act as the 'ignition' to initiate and to generate the tension developed by the contraction of the muscle cell.

Approximately 200 myosin molecules are bundled together within a single thick filament (Marieb and Hoehn 2013). The central portion of the thick filament is formed by their tails and their heads angle in opposite and outward directions and at each end. In addition to the actin binding sites, the heads comprise of ATP binding sites and ATPase enzymes that divide ATP, which generates energy for muscle contraction (Tortora and Derrickson 2009). Thin filaments are composed primarily of the protein actin and are 7–8 nm thick (Marieb and Hoehn 2013). The polypeptide subunits of actin, also known as globular actin (**G** actin), accept the active sites to which the myosin heads bind to throughout contraction. The **G** actin monomers are long polymerized actin filaments known as fibrous, or **F** actin. An actin filament twists back on itself, creating a helical structure and forming the core component of each thin filament (Tortora and Derrickson 2009). A number of regulatory proteins exist in the thin filament. Tropomyosin, a rod-shaped protein, consists of two strands which spiral around the actin core and help to support it.

Continuous tropomyosin molecules are organized one after the other along the actin filaments. The purpose of the tropomyosin is to block the actin's active sites so that the myosin heads cannot bind to the thin filaments when the muscle fibres are relaxed (Marieb and Hoehn 2013). The other major protein in the thin filament, is a three-polypeptide complex, called troponin. An inhibitory polypeptide subunit, TnI, binds to actin; another subunit, TnT, binds to tropomyosin and supports its position on actin. The third, TnC, binds calcium ions. The myosin-actin exchanges involved in contraction are controlled and aided by both troponin and tropomyosin.

A protein called titin is an elastic filament that reaches from the **Z** disc to the thick filament (Marieb and Hoehn 2013). It is found within the thick filament and attaches itself to the **M** line. It has two basic functions: (1) holding the thick filaments in place, therefore assisting in maintaining the organization of the A band; and (2) aiding the muscle cell to spring back into shape after being stretched. The second function of unfolding when the muscle is stretched and recoiling when the tension is released is carried out by the extensible part of the titin that spans the **I** bands. Titin does not counter elongation in the normal range of extension, however it becomes rigid as it straightens, thereby aiding the muscle in countering excessive stretching, which might pull the sarcomeres away from each other.

Two groups of intracellular tubules are contained within skeletal muscle fibres. They contribute to the regulation of muscle contractions (Tortora and Derrickson 2009): (1) the sarcoplasmic reticulum; and (2) the T-tubules. The sarcoplasmic reticulum (SR) is endoplasmic reticulum which is intricate and smooth. Around each myofibril is a mesh-like pattern of interconnecting tubules. The majority of these interconnecting tubules run longitudinally along the myofibril. At the **A** band–**I** band junctions larger, perpendicular cross channels are formed. These cross channels are called terminal cisternae and always occur in pairs. The sarcoplasmic reticulum's main function is to regulate intracellular levels of ionic calcium (Tortora and Derrickson 2009): Calcium is stored in it and released on demand when the muscle fibre is stimulated to contract.

At the junction of each **A** band–**I** band, the sarcolemma of the muscle cell infiltrates into the cell interior to form an elongated tube called the **T** tubule (T for 'transverse'). The extracellular space is continuous as the lumen of the **T** tubule (Tortora and Derrickson 2009). As each **T** tubule runs between the paired terminal cisternae of the SR, it projects deep into the cell forming triads (terminal cisterna, **T** tubule and terminal cisterna). The **T** tubules also circumscribe each sarcomere as they traverse from one myofibril to the next (Tortora and Derrickson 2009). Muscle contraction is ultimately controlled by neuronal electrical impulses that travel along the sarcolemma. Impulses can be conducted to the deepest regions of the muscle cell and to every sarcomere, since **T** tubules are continuations of the sarcolemma. These impulses signal for the release of calcium from the adjacent terminal cisternae, ensuring that every myofibril in the muscle fibre contracts at practically the same time (Tortora and Derrickson 2009).

The **T** tubules and SR play a role in providing signals for contraction and are strongly interconnected. A triad is formed where these organelles come into closest contact, and integral proteins protrude into the intermembrane spaces (Tortora and Derrickson 2009). The integral proteins of the **T** tubule act as voltage sensors; the foot proteins of the SR are receptors that regulate the release of Calcium ions from the SR cisternae.

For a muscle contraction to begin the neurotransmitter ACh is released from the nerve ending of the motor neuron that innervated the muscle. Depolarization occurs along the **T** tubules. Calcium ions (Ca^{2}+) flood into the cytosol of the muscle cells and begin a contraction of the muscle. With the flood of Ca^{2}+ into the myofibril the thin filaments slide in toward each other, the **Z**-discs approximate and the sarcomere shortens. The decrease in the level of Ca^{2}+ in the cytosol causes the contraction to end (Tortora and Derrickson 2009). During a contraction, there is an activation on myosin cross bridges which are the force-generating sites in the myofibril. When the tension produced by the cross bridges on the thin filaments surpasses the forces opposing shortening, there is a shortening of the sarcomere. When the cross bridges become inactive and the tension generated declines, this induces relaxation of the myofibrils and contraction ceases, which in turn causes relaxation of the muscle fibre.

In 1954 Hugh Huxley proposed the sliding filament theory of contraction (Huxley 2004). This theory states that the thin filaments slide past the thick ones so that the actin and myosin filaments overlap to a greater degree during contraction. In a relaxed muscle fibre, the thick and thin filaments overlap only slightly. The cross bridges latch onto myosin binding sites on actin in the thin filaments, and the sliding begins when muscle fibres are stimulated by the nervous system (Tortora and Derrickson 2009). There is attachment and detachment of each cross-bridge several times during a contraction, this generates tension and propels the thin filaments to the centre of the sarcomere. The muscle cell shortens as this event occurs simultaneously in sarcomeres throughout the cell. As the thin filaments slide toward the centre of the sarcomere, the **Z** discs are pulled toward the thick filaments. Overall, the distance between successive **Z** discs is reduced, the **I** bands shorten, the **H** zones disappear, and the adjoining **A** bands move closer together but do not change in length.

2.6 Trapezius Muscle Overview

The trapezius muscle (Figure 2.5) is the largest muscle in the cervical, thoracic and shoulder regions of the body (Johnson *et al.* 1994).

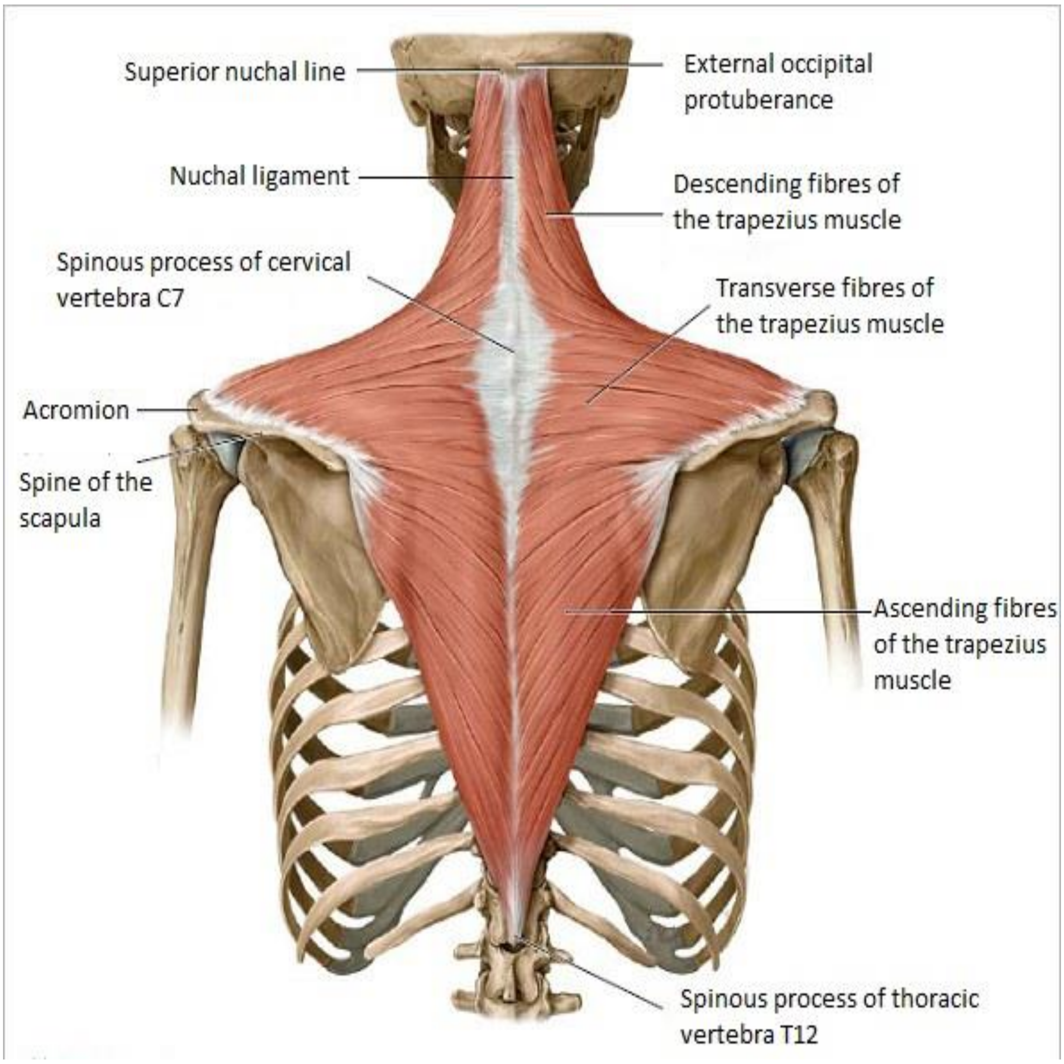

Figure 2.5: Diagram of the Trapezius Muscle (adapted from Rotator Cuff Rehab n. d.).

2.6.1 Attachments

Proximally the trapezius extends from the medial third of the superior nuchal line, the external occipital protuberance, the nuchal ligament and the spinous process of cervical vertebra C7 and the spinous processes of the thoracic vertebrae T1–T12. The trapezius inserts on the lateral third of the clavicle, as well as to the acromion and spine of the scapula (Moore, Dalley and Agur 2010).

2.6.2 Innervation

Motor function of the trapezius is supplied by the spinal accessory nerve (CN XI). Sensation, including pain and proprioception, travel via the ventral rami of the third (C3) and fourth (C4) cervical nerves. Since it is a muscle of the upper limb, the trapezius is not innervated by dorsal rami despite being placed superficially in the back (Moore, Dalley and Agur 2010)

2.6.3 Blood Supply

The blood supply of the trapezius muscle comes from the transverse cervical artery (Moore, Dalley and Agur 2010).

2.6.4 Function of the Trapezius Muscle

The trapezius muscle is a postural and active movement muscle, used to tilt and turn the head and neck into flexion, extension, lateral flexion and assist in rotation. It is also used to shrug and stabilize the shoulders, and with the assistance of latissimus dorsi, it twists the arms into internal and external rotation. The trapezius elevates, depresses, rotates, and retracts the scapula (Moore, Dalley and Agur 2010).

2.7 Management of Myofascial Trigger Points

Myofascial trigger points are a large component of MPS and is an important concept to keep in mind when treating musculoskeletal dysfunction. Chiropractors use different treatment procedures when treating and managing the short- and long-term effects of MPS, and more importantly, the myofascial trigger points themselves.

The most popular treatment procedures include: ischaemic compression; heat therapy; cryotherapy; electrical therapy; and dry needling (Hou *et al.* 2002; Vernon and Schneider 2009).

2.7.1 Ischaemic Compression

Ischaemic compression involves a painless and slow increase of pressure with the digit or thumb over the MFTP until a tissue resistance barrier is felt. This amount of pressure is maintained until release of the tissue barrier is felt, at which time pressure is increased until a new barrier is reached (Gemmell, Miller and Nordstrom 2008). The process is normally repeated for 90 seconds or until no pain or tenderness is felt in the affected muscle. The slow and steady application of pressure over the MFTP is enough to cause the skin to blanch. It changes the circulatory perfusion of the skin, making it an ideal modality in treating muscles that are quite deep as well as those that lie over bones (Hou *et al.* 2002). Gemmell, Miller and Nordstrom (2008) stated that Travell and Simons (1999) revised their first look at the term 'ischaemic compression' and changed it to 'trigger point pressure release'. Trigger point pressure release uses the ATP energy crisis model (Figure 2.6), which indicates that MFTPs are caused by abnormal depolarisation of the motor end plates thereby causing the MFTPs themselves to form in areas of hypoxic tissue. The constant and abnormal depolarisation of the motor endplates causes an involuntary shortening, which is due to the injury and overstress of the muscle fibres (Hou *et al.* 2002).

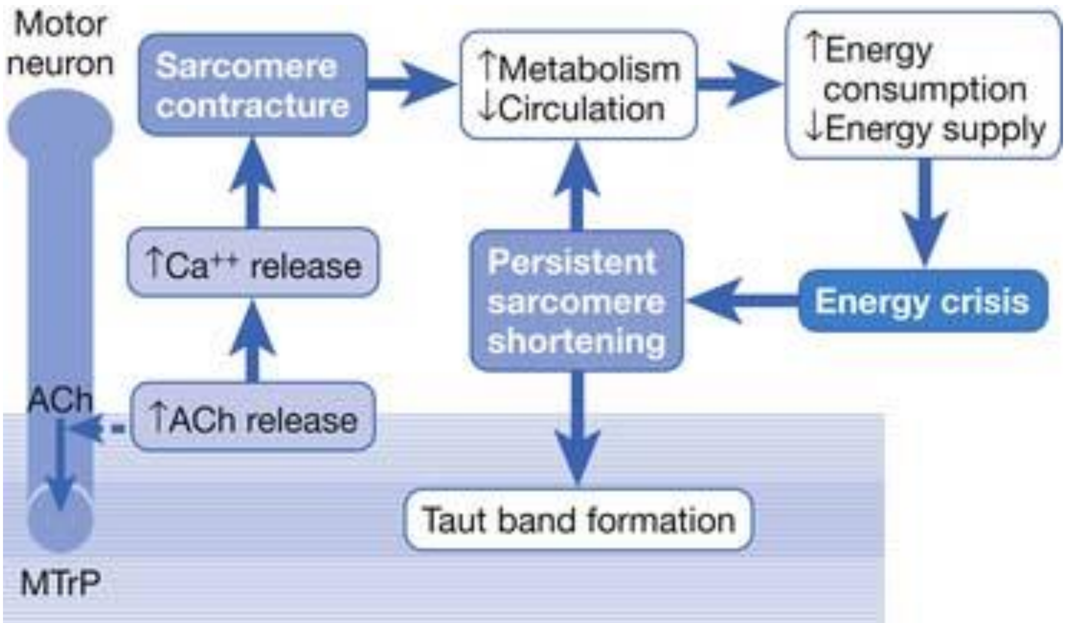

Figure 2.6: Diagram of excessive Acetylecholine (ACh) leakage which causes energy crisis and taut band formation in a muscle (adapted from iKnowledge, Clinical Gate n.d).

The results of Hou *et al.* (2002) showed that a higher pressure applied to a MFTP for 90 seconds, produced significant reduction in pain. Travell and Simons (1999), however, posited that a lighter pressure over a longer time also produced significant pain relief. Furthermore, applying too great a pressure and thereby causing ischaemia in the tissue was shown as unnecessary, as this would lead to further pain and tissue injury, eg: bruising (Travell and Simons 1999).

2.7.2 Heat therapy

Heat therapy increases vascular circulation and tissue distensibility and thus decreases muscle spasm and pain; it is used to decrease pain, relieve muscle spasm and stiffness (Hong 2006; Nadler, Weingand and Kruse 2004; Nadler *et al.* 2003). Heat packs provide superficial heat with limited subcutaneous penetration. Ultrasound, which is also a good heat modality, provides deep heat with higher subcutaneous penetration. Heat is seen as one of the most important modalities in treating soft tissue lesions. It is suggested that heat should be used before and after any treatment with manual therapy, as it can improve focal circulation which facilitates in the healing process (Hong 2006). Healing is facilitated by heat as it increases blood flow to the area being treated, which supplies protein, nutrients and oxygen at the site of injury (needling point), all of which are important in the healing process. A 1ºC increase in tissue temperature is associated with a 10% to 15% increase in local tissue metabolism. This increase in metabolism aids the healing process by increasing both catabolic and anabolic reactions needed to degrade and remove metabolic by-products of tissue damage and provides the ideal environment for tissue repair (Nadler, Weingand and Kruse 2004). Contraindications of heat therapy include circulatory insufficiency, sensory or cognitive impairment, malignancy and inflammation.

2.7.3 Electrical therapy

Electrical therapy is mainly used for pain control and improved vascular circulation to remove inflammatory by-products from the painful location, thus aiding in the relief of muscle spasm and oedema (Yap 2007). It should not be used over carotid sinus or pregnant uterus and in patients with a cardiac pacemaker or defibrillator, malignancy or infection (Yap 2007). Transcutaneous electronic nerve stimulation, or TENS, is an effective modality that is used in temporary pain control and nerve stimulation. It is often recommended as the muscle contractions which are caused by the electrical stimulation are like a focal massage in the area of application (Hong 2006).

2.7.4 Dry Needling

Dry needling, one of the most commonly used and most effective treatments of MPS (Dommerholt *et al*. 2006; Edwards and Knowles 2003; Travell and Simons 1999), involves the insertion of a needle into the MFTP without injecting any medication (Abbaszadeh-Amirdehi *et al*. 2013). It is believed that the inserted needle breaks up the contractile elements, thereby disrupting any somatic components that may contribute to trigger point hyperactivity (Ilbuldu *et al.* 2004). Another theorised mechanism by which the dry needling of a MFTP alleviates pain, is that the inserted needle interrupts muscle and nerve fibres through mechanoreceptor and nociceptor stimulation, thus ceasing the pain-spasm cycle through neuromodulation (American Physical Therapy Association 2013; Dommerholt *et al*. 2006). Alhough therapeutic, an unpleasant side effect of dry needling is the post-needling soreness (Dommerholt *et al.* 2006).

Post-needling soreness is attributed to micro haemorrhage and inflammation at the site of needle insertion due to the injury to muscle fibres in the MFTP (Travell and Simons 1999). This is caused by micro trauma to the muscle fibres when the needle is inserted directly into the myofascial trigger point, causing leakage of intracellular potassium into the extra-cellular space (Ilbuldu *et al*. 2004). Ferreira (2006) reported post-needling soreness in the majority of patients who are needled and found that both single point insertion and fanning caused post-needling soreness. A delay in treatment and recovery can occur as a result of post-needling soreness, as the tissue damage prevents treatment of the same area using dry needling for three to four days after treatment (Travell and Simons 1999). Patients may therefore avoid dry needling due to the post-needling soreness.

2.8 Management of Post-Needling Soreness

Post-needling soreness can be managed and its effects decreased by using various treatments over the affected area. Treatments that have been identified in decreasing post-needling soreness include cryotherapy (Chonan 2008), heat therapy (Govender 2011), and ischaemic compression (Shacksnovis 2005). As explained by Chonan (2008), the application of cryotherapy assisted in depressing nerve endings and elevated the pain threshold. This form of treatment is often used in soft tissue injuries. The NRS-101 results of the study indicated, however, that the pain felt by participants was initially worse in the combination group (cryotherapy and dry needling) than that of the control group (needling only). Govender (2011) reported both groups displayed similar levels of pain, concurrently, the analysis of the 24-hour pain diary revealed that most participants in both groups reported pain after the six-hour mark and had a decrease in pain up to the 24-hour mark. Ferreira (2006) investigated the effect of dry needling on asymptomatic participants with respect to post-needling soreness, results indicated none of the subjects reported pain between 12-24 hours. The relative effectiveness of myofascial manipulation versus ischaemic compression in treating MFTPs was investigated by Shacksnovis (2005), study findings indicated no statistical difference in treatment outcome and that both groups improved at the same rate.

The pain rating scale used in this research study (NRS 11) is a subjective form of pain evaluation in which the patient rates their pain on a scale of 0 to 10, 0 being no pain and 10 being the worst pain they have ever felt. A change of 2 points is regarded as clinically significant, as it will determine whether the treatment helped in alleviating the pain or not (Farrar *et al.* 2001, Van der Laan 2010). The 24-hour pain diary is a subjective measurement tool that allows the patient to relay to the researcher what they experienced, from after the initial treatment up until the next treatment and evaluation 24 hours later. An algometer is an objective measurement tool used to determine the patient's pain pressure threshold (Nussbaum and Downes 1998), which is defined by Fischer (1987) as the pain or discomfort that is induced by minimum pressure (force) applied to one square centimetre (Chonan 2008). A general decrease in measurements will indicate a rise in pain, whereas a general increase in measurements will indicate a decrease in pain. Chesterton *et al*. (2007) showed the reliability of algometer readings in their study using multiple raters and found consistent rates throughout. A change of 1.77 kg/cm^2 in the pain pressure threshold measurement represents a true difference or change (Chesterton *et al*. 2007). The NRS 101 is similar to the NRS 11 in the way pain is reported, however it is rated on a scale of 0 to 100 whilst the NRS 11 is rated on a scale of 0 to 10.

2.9 **Low Intensity Laser Therapy**

While LILT has been found to be effective in the treatment of MFTPs, its use as a treatment for post needling soreness has to date not been investigated (Ceylan, Hizmetli and Silig 2003; Ilbuldu *et al*. 2004; Kannan 2012). Low intensity laser therapy, or cold laser, causes spinning electrons in a tissue medium to vibrate at a higher velocity equal to that of the laser. The vibrations spread through the tissue medium making adjacent cells vibrate at the same frequency of the wavelength. The beneficial wavelength identified in increased wound healing, decreased inflammation and decreased pain, is 632.8-nm (Snyder-Mackler *et al.* 1989; Ceylan, Hizmetli and Silig 2003; Ilbuldu *et al*. 2004; Kannan 2012). While the mechanism through which pain is reduced is not fully understood, research has suggested that cold laser changes neuronal activity which then causes photochemical reactions (Ceylan, Hizmetli and Silig 2003).

2.10 **Sham Laser**

Sham laser is a placebo method of laser therapy that does not activate somatosensory receptors (Irnich *et al.* 2001). Chow, Heller and Barnsley (2006) hypothesized that the placebo group or sham laser would show significantly less improvement than that of the group receiving actual laser therapy.

2.11 **Conclusion**

Whilst dry needling has been shown to cause micro trauma to the muscle (Chonan 2008) and LILT has been recognized as an effective treatment in wound healing (Ceylan, Hizmetli and Silig 2003; Ilbuldu *et al*. 2004; Kannan 2012), its use in the treatment of post-needling soreness has not fully been researched. The aim of this study is therefore to determine the effect of LILT on post-needling soreness.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter outlines the methodology for this research and includes a description of the study design, sample selection, treatment and analysis.

3.2 Research Design and Sample Population

This study was designed as a randomised controlled clinical trial, conducted using a pre-test and post-test experimental structure. Ethical approval (Ethics number 126/15) was obtained from the Durban University of Technology Research Ethics Committee (Appendix N). Permission was also obtained from the Clinic Director of the Chiropractic Day Clinic at the Durban University of Technology to conduct the research on site (Appendix K). As per rules and regulations stated, the research study was registered with the Department of Health (Appendix O).

Participants for the study were sourced from the general population residing in the eThekwini municipality through advertisements (Appendix A). These advertisements were posted on free notice boards outside shopping centres and businesses after permission was sought from the owners. Interested participants were subjected to a screening process (via telephonic interviews) to determine their eligibility for the study. The questions asked during the screening are reflected in Appendix F. A separate book and duplicate of the telephonic interviews was kept by the researcher as an extra record.

Forty participants eligible for the study were selected. The selected participants were randomly allocated into two groups of 20 each. The study groups were as follows:

- Group 1: Laser therapy group.
- Group 2: Sham laser therapy group.

Participants were required to bring their Identity Documents to the first consultation.

3.3 **Inclusion criteria:**

The study included all potential male and female participants:

- Between the ages of 18 and 50.
- With generalised neck pain.
- With a pain level of three or more on the Numerical Rating Scale for pain (NRS 11).
- With a unilateral, active TP2 in the upper trapezius muscle.
- Who had received dry needling in TP2 of the upper trapezius muscle for the treatment of myofascial trigger point pain as part of this study.
- Who had read and signed the Informed Consent form (Appendix B).
- Who had undergone a complete case history and physical examination (Appendix G and Appendix H).

3.4 **Exclusion criteria:**

- Potential participants with contra-indications to dry needling were excluded from the study.
- Potential participants with contra-indications to laser therapy were excluded from the study.
- The contra-indications and reasons for the exclusions are provided in Table 3.1 below.

Table 3.1: Contra-indications and exclusions (Tilley 2009; Bsoul and Terezhalmy 2004; Travell and Simons 1999).

Contra-indication	***Reason for exclusion***
Pacemakers	The use of laser therapy on the anterior thorax is contraindicated and should not be used.
Photosensitivity	The laser could trigger an adverse reaction.
Pregnancy	The use of laser or needles on the back is a risk (there are several acupuncture points which should not be needled in the first trimester).
Smoking	Tobacco increases capillary fragility due to lowered vitamin C levels (Bsoul and Terezhalmy 2004; Travell and Simons 1999), smokers have a greater tendency to bleed.
Tumours	Laser and needling could cause an adverse reaction, or cause tumour cells to metastasize.
Use over the thyroid	It is a photosensitive organ in the body and any irradiation may cause a fluctuation in plasma thyroid hormones (Tilley 2009).

In addition to the above exclusion criteria, any individual was excluded from the study if they:

- Were currently on analgesic medication or had taken any analgesics three days prior to treatment (Travell and Simons 1999).
- Had experienced significant trauma to the neck (e.g. from a motor vehicle accident).
- Had experienced surgery to the neck.
- Did not develop post-needling soreness. This was determined after analysing the outcome measurement tool results.
- Were not available for the post-treatment follow-up.
- Were unable to commit to the 24-hour follow-up appointment for post-treatment evaluation.

Any aberrant findings during the physical examination that could be deemed a contra-indication automatically excluded the participant from the study.

3.5 **Sample size**

The sample size was calculated with a significance level of alpha set at 5%, the power of the study (1-beta) was expected to be 95%. An increase in the primary outcome measure of 10% in the control group to 60% in the experimental group revealed that 36 participants were required. The sample was then rounded off to 40 participants (as a minimum number). Ms G. Matthews, from the Statistics Department at the Durban University of Technology, was retained as the statistician in this study.

3.6 **Procedure:**

A: PARTICIPANT SELECTION

Potential participants were screened through a telephonic interview. Those who passed the interview stage were then invited to a screening assessment at the Chiropractic Day Clinic, which required that:

- All potential participants read the letter of information (Appendix B).
- All potential participants completed the consent form (Appendix B).

- All potential participants were screened with a case history (Appendix G), physical examination (Appendix H) and regional examination (Appendix I).

The above process provided information to enable potential participants to be selected based on the inclusion and exclusion criteria. Once the potential participant was considered a suitable candidate the participant was asked to fill out the Numerical Rating Scale – 11 (Appendix E). Participants were randomised into one of the two groups in the study. A randomisation list was drawn up prior to the study with the help of a statistician, and was not seen by the researcher. Participants were allocated according to the list that the statistician had drawn up. This list was only made available to the clinic administrative staff at the beginning of the study to ensure blinding. The researcher did not see the allocation list until the end of the study.

B: PATIENT PREPARATION

Location of the affected muscle:

- TP2 (seen in Figure 3.1, marked by an "X") of the trapezius muscle was cleaned using the aseptic technique and marked with henna to ensure the same area was used to take algometer readings at each visit as well as to be needled. Algometer reading 1 was taken (Appendix C). The active trigger point was then needled.

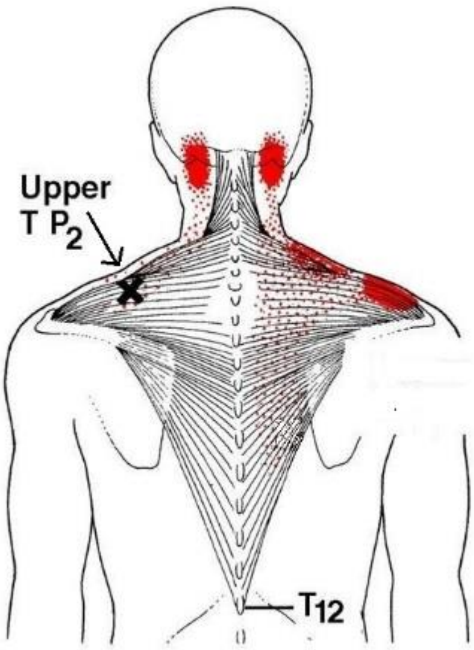

Figure 3.1: Trigger point 2 in the Upper Trapezius muscle (adapted from Travell and Simons 1999).

- Aseptic technique: a) the patient's skin (the area around TP2 on the upper trapezius) was cleaned with an alcohol swab; b) the researcher's hands were cleaned with antiseptic gel; and c) a new, sealed needle was used for each patient at all times.

C: DRY NEEDLING AND LASER THERAPY

- TP2 was held by pincer palpation and a 30mm needle was inserted into TP2 with the contralateral hand until a twitch response was felt. Thereafter, the needle was fanned 10 times to ensure that "all or most sensitive loci in the MFTP are encountered (Hong 2006). The method was applied to all participants.

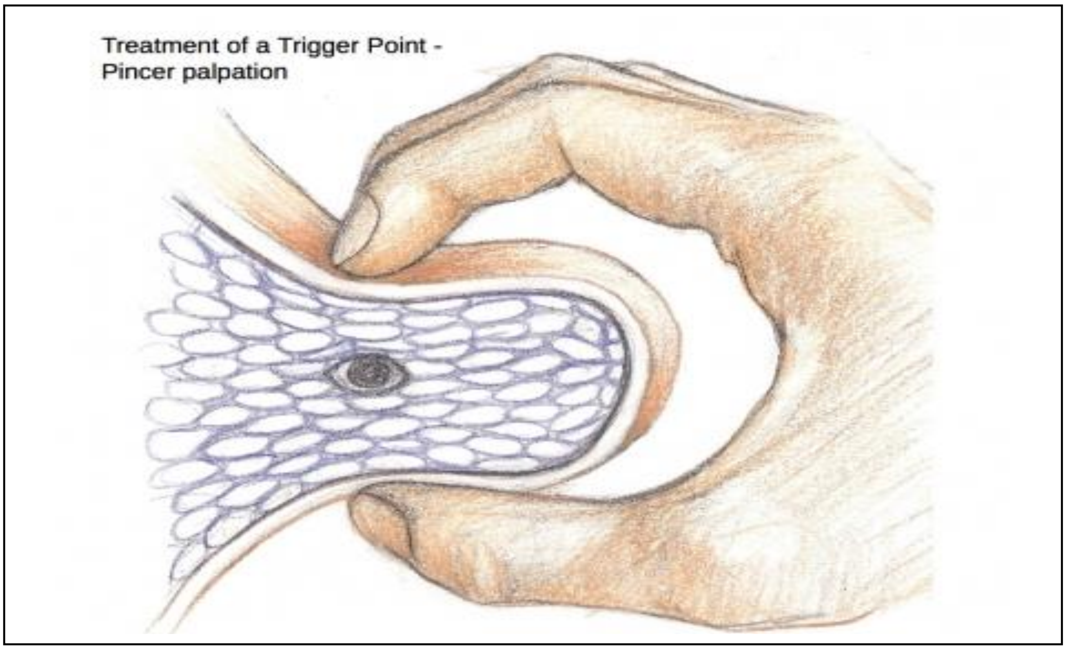

Figure 3.2: Pincer Palpation of a Trigger point (adapted from Whelan 2015).

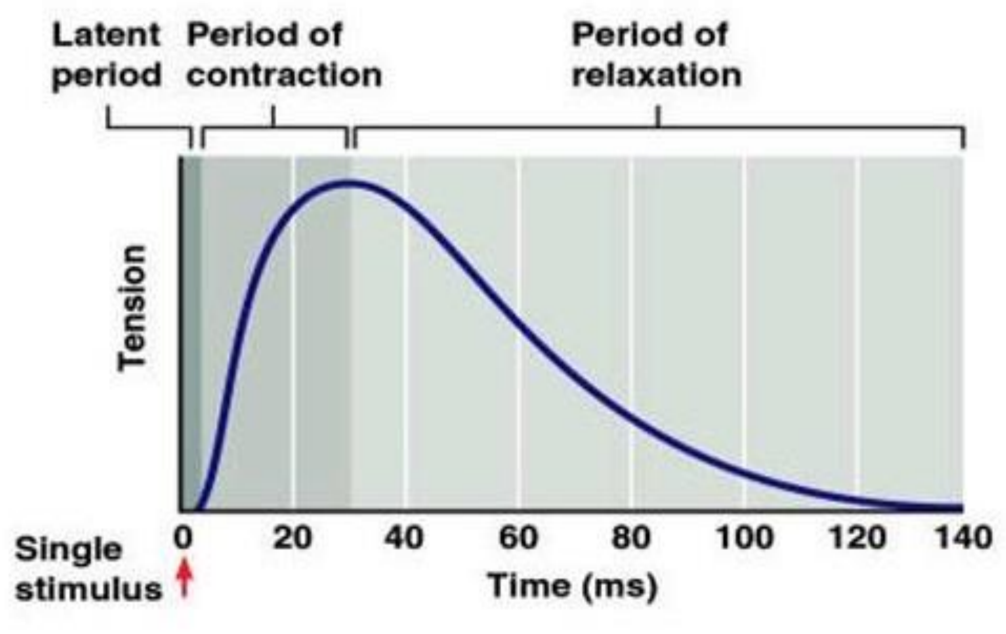

Figure 3.3: Myogram of a muscle twitch (adapted from Marieb and Hoehn 2013).

- After the patient had been needled the needles were removed and disposed of in a 'sharps' container provided in the Chiropractic Day Clinic.

- Ten minutes after the needling, laser or sham laser was applied to the needled area by the researcher. The laser that was used was an 850nm Single Laser Diode Probe 100mW at 4 J/cm² at <100 Hz for acute wound healing (Gallo and Wijting 2006).

Table 3.2 - General Treatment Protocols at a Glance.

Indication	Dosage	Frequency	Application
Inflammation	2 – 5 J/cm²	5000 Hz	Over inflamed tissue
Neuralgia	10 – 12 J/cm²	Continuous	Along course of nerve
Pain, acute	6 J/cm²	Continuous	Over pain area or TP
Pain, chronic	12 J/cm²	Continuous	Over pain area or TP
Soft tissue injury, acute	4 – 8 J/cm²	<100 Hz	Over lesion
Soft tissue injury, chronic	12 J/cm²	Continuous	Over lesion
Tendinitis/Bursitis	2 – 10 J/cm²	5000 Hz	Over inflamed tissue
Trigger points	5-12 J/cm²	Continuous	Over TP
Wounds, acute	8 J/cm²	700 Hz	In and around wound bed
Wounds, chronic	1 – 6 J/cm²	Continuous	In and around wound bed
Joint Disorders, chronic	Finger: 0.5 J/cm² Knee: 6 J/cm² Spine: 12 J/cm²	Continuous	Over joint surface

(Adapted from Gallo and Wijting 2006).

- Both the patient and researcher wore protective eyewear during the application of the laser and sham laser. The method was applied to all participants.

- The laser was applied for 40 seconds over the site of insertion with brief intervals in between (Gallo and Wijting 2006), for a total duration of three minutes or six applications (Ceylan, Hizmetli and Silig 2003). The laser armed itself after administering the 4 J/cm² and then the researcher was required to press the button on the head of the laser to begin the next application of the laser. The settings of this laser provide pain relief and healing of soft tissue injuries.

- The patient did not experience any heat or discomfort from the laser as it was a Low Intensity Laser or 'cold laser' that lacked the ability to produce heat (Snyder-Mackler *et al.* 1989).

- Energy density is a unit of measurement that describes the amount of energy delivered per unit area. It is measured in Joules/cm². This is the preferred method of dosing LILT. It represents the actual amount of energy delivered to each cm² of the treatment area. This is shown in the equation below (Bjordal *et al*. 2003):

The procedure protocol for sham laser followed the same steps as that of the actual laser, however the laser was not turned on nor emitting a visible beam.

- Algometer reading 2 was then taken (Appendix C).

- Participants were sent home with a 24-hour Pain Diary (Appendix D) and were asked to fill it in accordingly at set intervals. The participants were asked not to take any analgesic medication nor apply any analgesic ointment or any topical creams to the area of needling. Twenty-four hours later, the participants returned to the Chiropractic Day Clinic for the follow-up examination. Upon arrival at the follow-up examination an Algometer reading 3 (Appendix C) and NRS 11 were taken and a one-hour leeway was given to all participants for their follow-up examination.

3.7 **Measurement tools**

Numerical Rating Scale (NRS 11) – (Appendix E)

The patient had to rate the pain on a scale from 0 to 10, with 0 being no pain and 10 being the worst pain they had ever felt.

A 24-Hour Pain Diary (Appendix D)

The pain diary had five time points (3, 6, 9, 12 and 24 hours) beginning immediately after the treatment; participants were then required to either tick 'yes' or 'no' to whether or not they were experiencing pain at that point. Furthermore, the pain diary required participants to record at which time, in hours, they experienced the most pain.

Pressure Threshold Algometer

The patient's pain pressure threshold was recorded using an algometer. Readings were recorded at three different time intervals: 1] prior to needling; 2] ten minutes post-needling; and 3] twenty-four hours post-needling.

3.8 **Statistics**

Data was captured on an Excel spreadsheet and analysed using SPSS version 24.0. Outcome measures were tested for the normality of distribution and if found to be normally distributed, repeated measures ANOVA testing was used for intra- and inter-group comparisons. Profile plots were generated to assess the direction and trend of the effect. T-tests with equal variance were used where necessary.

3.9 **Ethical considerations**

There was minimal risk to the patients. Informed consent was obtained in line with the ethical principle of autonomy and justice. The patient was not harmed in any way; this was in line with the ethical principle of non-malfeasance. As needling is a form of treatment, all the participants benefitted from the study, whether they were in the control group or not; this was in line with the ethical principle of beneficence.

CHAPTER FOUR

RESULTS

The results displayed in this chapter are tabulated per the group in which the participants received treatment (dry needling and laser or placebo laser). The tables and graphs therefore reflect the results for ‘dry needling coupled with laser’ and ‘dry needling coupled with placebo laser’. The ‘dry needling coupled with laser’ group will be denoted as Group 1; the ‘dry needling coupled with placebo laser’ group will be denoted as Group 2. The results displayed in this chapter were generated using the IBM SPSS 24.

4.1 Demographics by groups

Table 4.1: Mean and standard deviation for collective data of participants.

Group		N	Minimum	Maximum	Mean	Std. Deviation
1	Age	19	20	47	27.26	8.556
	Initial NRS	19	3	8	5.53	1.712
	Final NRS	19	0	6	1.74	1.996
	Algometer reading 1	19	1.7	8.4	4.653	1.8271
	Algometer reading 2	19	1.2	9.6	4.195	2.7355
	Algometer reading 3	19	1.3	10.0	5.495	2.8019
	Pain experienced at worst (hours)	19	.0	15.0	3.526	3.6112
	Total	19				
2	Age	21	19	35	25.10	5.449
	Initial NRS	21	4	9	6.10	1.261
	Final NRS	21	0	4	1.38	1.359
	Algometer reading 1	21	2.0	8.5	4.286	1.7459
	Algometer reading 2	21	1.8	9.1	4.248	2.2254
	Algometer reading 3	21	1.8	9.5	5.357	2.2194
	Pain experienced at worst (hours)	21	.0	12.0	4.071	3.8900
	Total	21				

Table 4.1 depicts that forty participants were randomized into two groups (Group 1: n=19; Group 2: n=21). The mean age of Group 1 was 27.26 years (SD 8.556

years); the mean age of Group 2 was 25.10 years (SD 5.449 years). The mean age was higher in the dry needling and laser group when compared with the dry needling and placebo laser group. Three different measurement tools were used to record results:

1) <u>Numerical Rating Scale (NRS 11) – (Appendix E):</u>

Participants were required to rate their pain on a scale from 0 to 10, with 0 being no pain and 10 being the worst pain they had ever felt. This was a subjective measurement in which the participant could determine the change in pain that they felt during the research study. The NRS was taken over the two days while the participants were part of the study.

2) <u>A 24-Hour Pain Diary (Appendix D):</u>

The pain diary was also a subjective measurement. It had five “time points” (3, 6, 9, 12 and 24 hours); beginning immediately after the treatment, participants were then required to either tick ‘yes’ or ‘no’ to whether or not they were experiencing pain at that point. The pain diary also required participants to record at which time, in hours, they experienced the most pain.

3) <u>Pressure Threshold Algometer:</u>

The patient’s pain pressure threshold was recorded using an algometer. Pressure was applied to the point at which the participant felt pain in the TP2. A downward force was applied to the area of the painful TP2. The participants were required to tell the research assistant the point at which the pressure they felt started becoming painful; that point became the reading of recorded. Readings were recorded at three different time intervals: 1] prior to needling; 2] ten minutes post-needling; and 3] 24 hours post-needling.

4.2 Demographics by gender

Table 4.2: Cross Tabulation of gender by treatment group.

			Gender		Total
			Male	Female	
Group	Dry needling with laser	Count	8	11	19
		% within group	42.1	57.9	100
	Dry needling with placebo laser	Count	4	17	21
		% within group	19	81	100
Total		Count	12	28	40
		% within group	30	70	100

Table 4.2 shows that the percentage distribution of females and males was dissimilar in the two groups. Within the laser group, males made up 42.1% of the participants while female participants accounted for 57.9%. In the placebo laser group, 19% of the participants were male and 81% of the participants were female. Across groups, males made up 30% of the participants with females making up the remaining 70%. The majority of participants were female (70%).

Table 4.3: Comparison of Initial Pain NRS readings by gender.

	GENDER	N	Mean	Std. Deviation	Std. Error Mean
Initial NRS Reading	Female	28	6.14	1.433	.271
	Male	12	5.08	1.443	.417

To be included in the study, participants needed to have a NRS reading of 3 or above. The initial pain readings across both groups subjectively showed that the female participants experienced greater pain levels before participating in the study, as displayed in Table 4.3. The difference in the means between females and males was 1.06.

4.3 Comparison of Initial NRS Readings

Table 4.4: Comparison of Initial Pain NRS readings by groups.

	Group	N	Mean	Std. Deviation	Std. Error Mean
Initial NRS Reading	1	19	5.53	1.712	.393
	2	21	6.10	1.261	.275

The mean of group 1 was 5.53 and the mean of group 2 was 6.10. The standard deviation of group 1 was 1.712 and the standard deviation of group 2 was 1.261.

Table 4.5: T-test comparison of Initial Pain NRS readings by groups.

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Initial NRS Reading	Equal variances assumed	4.744	.036	-1.205	38	.236	-.569	.472	-1.525	.387
	Equal variances not assumed			-1.186	32.884	.244	-.569	.480	-1.545	.407

Table 4.5 indicates that there was no significant difference in the initial pain NRS readings when comparing the means of the two groups using a t-test (*p*=0.24 which is greater than 0.05).

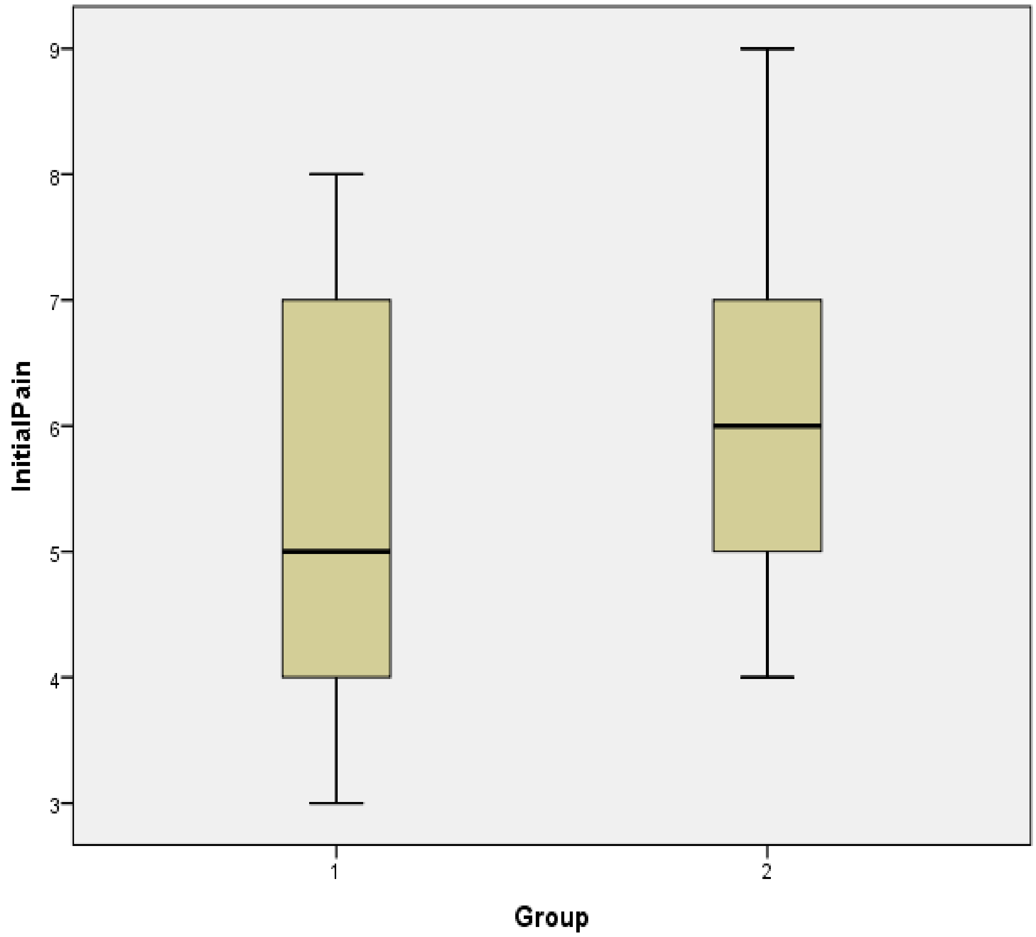

Figure 4.1: Box Plot showing the difference in initial pain and its range.

Figure 4.1 showed that there is a difference in the initial pain and its range. The placebo group (Group 2) had higher pain at the initial visit than the participants of Group 1. This also indicated that Group 2 had a higher pain tolerance than that of Group 1.

4.4 **Comparison of Final NRS Readings**

Table 4.6: Final Pain NRS readings across groups.

	Group	N	Mean	Std. Deviation	Std. Error Mean
Final Pain NRS	1	19	1.74	1.996	.458
	2	21	1.38	1.359	.297

Table 4.6 shows that the mean of the final pain readings using the NRS were not significantly different. The mean for Group 1 and Group 2 were recorded as 1.74 and 1.38 respectively.

Table 4.7: T-test Final Pain NRS readings across groups.

		t-test for Equality of Means						
							95% Confidence Interval of the Difference	
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Final NRS -Reading	Equal variances assumed	.665	38	.510	.356	.535	-.728	1.440
	Equal variances not assumed	.652	31.317	.519	.356	.546	-.756	1.468

Table 4.7 displays the final pain readings of the NRS across groups. A t-test was performed to determine whether there was a significant difference between the means for the two groups. The *p*-value of 0.510 was greater than the level of significance (0.05), which showed that there was no significant difference between the means of the groups.

4.5 **Comparison of Algometer Readings**

Table 4.8: Comparison of difference in Algometer readings across group.

	Group	N	Mean	Std. Deviation	Std. Error Mean
Comparison of Algometer 2 – 1 of both groups	1	19	-.4579	1.34053	.30754
	2	21	-.0381	1.39337	.30406
Comparison of Algometer 3 – 2 of both groups	1	19	1.3000	1.28668	.29519
	2	21	1.1095	1.40175	.30589

Table 4.8 depicts the comparison of the differences between the pre-intervention readings (baseline measurements) and post intervention readings. No significant difference was found between the means of the groups.

Table 4.9: T-test of Algometer readings.

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference Lower	Upper
Algometer 2 – 1 of both groups	Equal variances assumed	-.969	38	.339	-.41980	.43333	-1.29703	.45743
	Equal variances not assumed	-.971	37.844	.338	-.41980	.43247	-1.29541	.45581
Algometer 3 – 2 of both groups	Equal variances assumed	.446	38	.658	.19048	.42696	-.67385	1.05481
	Equal variances not assumed	.448	37.989	.657	.19048	.42509	-.67008	1.05103

Table 4.9 shows the comparison of the differences of the algometer readings. The difference between the immediate post-intervention and pre-intervention (Algometer Reading 2 minus Algometer Reading 1). The *p*-value for this

comparison was 0.339 which is greater than 0.05. Thus, there was no significant difference in the pre- and immediate post-intervention readings.

The difference between the 24-hour reading and the immediate post-intervention reading (Reading 3 minus Reading 2) is also shown in the table 4.9. The *p*-value of this comparison was 0.658, which is greater than 0.05. No significant difference emerged in the 24-hour reading and the immediate post-intervention reading.

4.6 Pain Diary Results

Table 4.10: Pain Diary Results: Pain at worst (hours).

	Group	N	Mean	Std. Deviation	Std. Error Mean
Pain Diary – Pain at worst	1	19	3.526	3.6112	.8285
	2	21	4.071	3.8900	.8489

Table 4.10 displays the mean of the pain diary results. The comparison between the mean of Group 1 compared with Group 2 shows that there was no significant difference between the final results of the pain diary where the participants reported the pain when they felt it the worst. The mean of Group 1 showed that the majority of the participants felt pain at its worst around the 3.5-hour mark, while the mean of Group 2 showed that the majority of the participants felt pain at its worst around the 4-hour mark. The overall pain felt was experienced between hours 3 and 4 across the groups. This would also indicate that the pain subsided between the 3 and 4 hour mark.

Table 4.11: T-test - Pain Diary Results: Pain at worst (hours).

		t-test for Equality of Means						
							95% Confidence Interval of the Difference	
		t	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Pain Diary – Pain at worst	Equal variances assumed	-.458	38	.650	-.5451	1.1907	-2.9555	1.8653
	Equal variances not assumed	-.460	37.969	.648	-.5451	1.1861	-2.9464	1.8562

The t-test results for the pain diary indicating when the participants felt the pain at its worst, resulted in a *p*-value of 0.650, which is greater than 0.05. This indicated that there was no significant difference in the mean pain felt at its worst for Groups 1 and 2.

4.7 **Comparison of Subjective vs Objective Pain Readings**

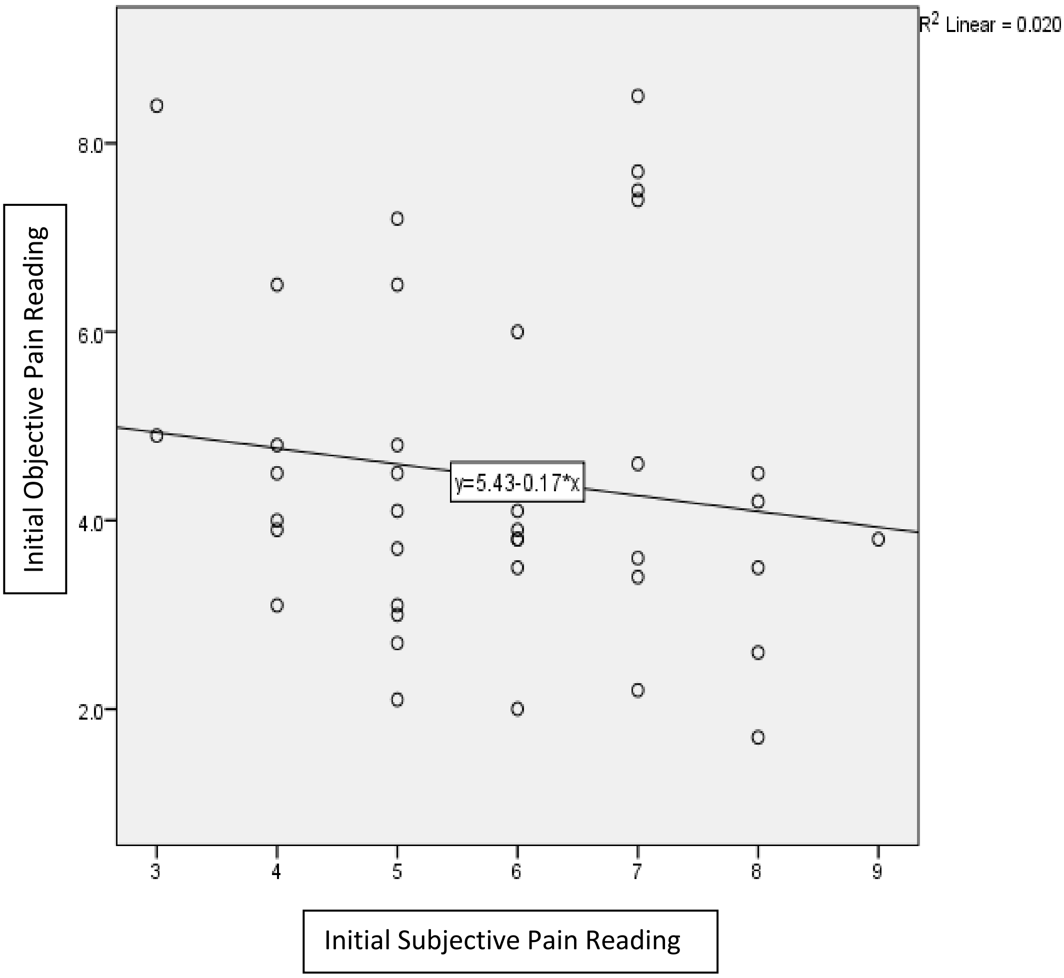

Figure 4.2: Comparison of Subjective and Objective Initial Pain readings.

The scatter plot in Figure 4.2 above shows the comparison and correlation of the initial objective pain reading (Algometer reading 1) and the initial subjective pain reading (NRS 11 reading 1). An interpretation of the correlation is that when a participant reported in their NRS initial reading that the pain was not that great (eg: their pain was a 3 on the NRS), then the corresponding algometer reading would show that the participant had quite a high pain threshold. This was by comparison with a participant reporting a high NRS initial reading. If a participant reported that the pain was significantly high (eg: their pain was at an 8 on the NRS), then the corresponding algometer reading would show that the participant had a very low pain threshold.

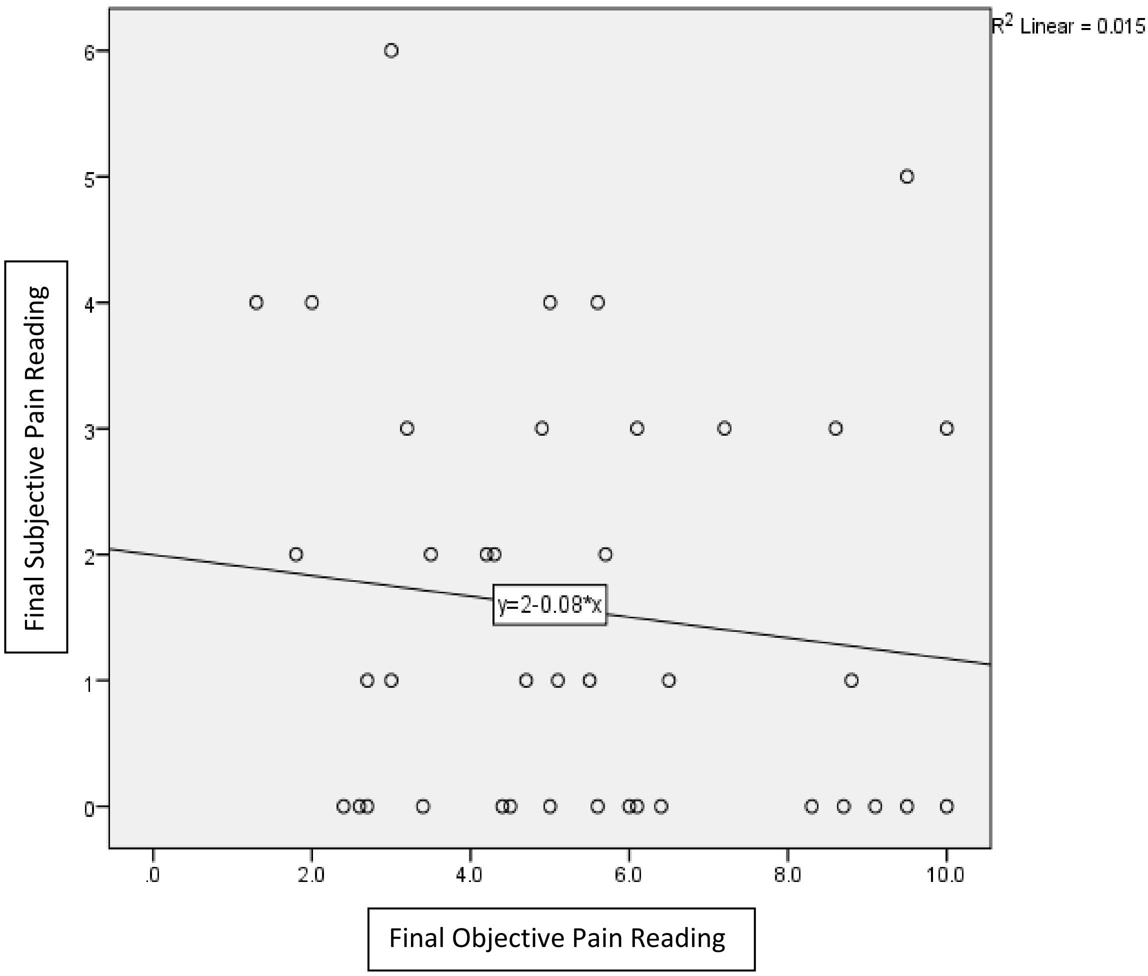

Figure 4.3: Comparison of Subjective and Objective Final Pain readings.

This scatter plot shows the comparison and correlation of the final objective pain reading (Algometer reading 3) and the final subjective reading (NRS 11 reading 2). The correlation can be interpreted such that when a participant reported in their NRS final reading that their pain was not that great, (eg: their pain was a 3 or lower on the NRS), then the corresponding algometer reading would show that the participant had quite a high final pain threshold. This was by comparison with a participant reporting a high NRS final reading. If a participant reported that their pain was significantly high (eg: their pain was at a 3 or above on the NRS), then the corresponding algometer reading would show that the participant had a very low pain threshold.

4.8 Comparison of Subjective vs Objective Correlation Coefficients

Table 4.12: Comparison of Subjective and Objective Initial Correlation Coefficient.

Initial Pain Correlations

		Initial Subjective Pain Reading	Initial Objective Pain Reading
Initial Subjective Pain Reading	Pearson Correlation	1	-.142
	Sig. (2-tailed)		.383
	N	40	40
Initial Objective Pain Reading	Pearson Correlation	-.142	1
	Sig. (2-tailed)	.383	
	N	40	40

Table 4.12 shows that there was a weak negative correlation between the initial subjective pain reading and the initial objective pain reading. The correlation coefficient was recorded as -0.142 but was not significant (p=0.383).

Table 4.13: Comparison of Subjective and Objective Final Correlation Coefficient.

Final Pain Correlations

		Final Subjective Pain Reading	Final Objective Pain Reading
Final Subjective Pain Reading	Pearson Correlation	1	-.122
	Sig. (2-tailed)		.454
	N	40	40
Final Objective Pain Reading	Pearson Correlation	-.122	1
	Sig. (2-tailed)	.454	
	N	40	40

Table 4.13 shows that there was also a weak negative correlation between the final subjective pain reading and the final objective pain reading. The correlation coefficient was recorded as -0.122 but was not significant (p=0.454).

CHAPTER FIVE

DISCUSSION OF RESULTS

5.1 Introduction

A discussion of the results from the statistical analysis of the demographic (age and gender), subjective data (Numerical Pain Rating Scale-11 (NRS-11) and 24-hour pain diary) and objective data (algometer readings) will be presented in this chapter.

5.2 Demographics

5.2.1 Age

The findings of the age analysis showed that there was a slight statistically significant difference in age between the subjects of both the intervention group and the control group. The control group had the age range of 19 to 35 years. The intervention group had the age range of 20 to 47 years, thus making the intervention group the one with the wider range. The age of subjects across groups ranged from 19 to 47 years. This range was similar to the study conducted by Chonan (2008), which investigated the effect of cryotherapy on post-needling soreness and included subjects ranging in age from 18 to 47 years. The age range of this study also correlates with the study by Manga (2008), which investigated the effect of action potential simulation on post-dry needling soreness in the treatment of active trapezius myofascitis and included subjects ranging from 18 to 45 years of age. The findings were similar to previous studies on post-needling soreness.

5.2.2. Gender

The percentage of females participating in this study was 70%, with the percentage of males in this study at 30%. This ratio of females to males was similar to Chonan (2008) and Manga (2008), who had a higher percentage of females in their study. Chonan (2008) had a 70% female participation and Manga (2008) had a 75% female participation. This difference in gender could possibly account for some of the differing results found in this study.

5.3 Subjective data

5.3.1. Numerical Rating Scale-11 (NRS-11)

The Numerical Rating Scale (NRS) can be verbally administered without the use of physical constituents. The clinician or researcher simply asked the participant how much pain she or he was experiencing using a number from 0 to 10, where 0 was no pain or hurt and 10 was the most or worst pain they had felt during the study. This variant of the Numerical Rating Scale is referred to as NRS-11 as it has 11 categories from 0 to 10; it is often used with children. Another common form, often used with adults, is the NRS-101 which is scored from 0 to 100 (von Baeyer *et al.* 2009).

The results from the NRS-11 revealed that both groups experienced a decrease in pain from the baseline. Both the treatment and control groups showed a sharp decrease in pain between NRS-11 reading time one (baseline measurement) and time two (measurement taken 24 hours after the intervention). The decrease in pain readings between these two time periods could be due to the development of post-needling soreness as well as the relaxation and subsiding of the inflammation caused by the needling process itself. Ferreira (2006) investigated the effect of dry needling of asymptomatic subjects with respect to post-needling soreness, and found that both intervention groups experienced some degree of soreness according to the findings from the NRS-101 (variation of the NRS-11). It would therefore appear that the needle insertion was responsible for post-needling soreness. Asymptomatic subjects were used in this study to exclude the effect of pain from an active trigger point. With respect to the NRS-101, this study showed similar results to Chonan (2008), who reported little difference in pain experienced by the participants between the control group and the cryotherapy intervention group and a decrease in pain 24 hours post-needling.

5.3.2. Pain Diary

Whilst all participants in Groups 1 and 2 reported pain within the first two to eight hours after needling, most participants reported pain in the three to four hour post-needling soreness period. The study also showed that there was subsiding of pain in both groups after the three to four hour mark during the 24 hour pain diary report. As highlighted by Chonan (2008), the majority of subjects reported pain in both the intervention (cryotherapy and dry needling) and control (dry-needling only) groups during the initial three hour post-needling soreness period. Interestingly, Govender

(2011) found that most participants reported their pain at its worst during the six hour mark in the pain diary. The delay of three hours to the onset of post-needling soreness in Chonan's (2008) cryotherapy study when compared with that of Govender's (2011) thermotherapy study may have occurred due to the effect of heat. As previously stated, heat causes an increase in blood flow to the area which facilitates tissue healing by supplying nutrients, protein and oxygen at the site of injury. This increase in tissue temperature is associated with an increase in local tissue metabolism which aids in the healing process by increasing both catabolic and anabolic reactions needed to degrade and remove metabolic by-products of tissue damage (Nadler, Weingand and Kruse 2004).

In this study the least amount of pain was reported by one participant in the laser group at fifteen hours post-needling, and one participant in the sham laser group at twelve hours post-needling. This finding differed from Ferriera (2006), who found that no subjects reported pain between 12-24 hours. An inter-group comparison of pain levels at the 24 hour mark showed that there was no significant difference between groups and that the pain decreased at a similar rate between groups.

5.4 Objective Data

5.4.1 Algometer readings

The results from the algometer readings indicated that the participants in both the laser group and the sham laser group showed a decrease in algometer measurement from reading one (measurement prior to dry needling) to reading two (measurement immediately after the intervention). Both groups displayed a decrease from algometer reading two (measurement immediately after the intervention) to algometer reading three (24 hours after the intervention). The p-value of this comparison is 0.658, being greater than 0.05. There was no significant difference in the 24-hour reading and the immediate post-intervention reading. Whilst the results were not statistically significant (p=0.658) they were consistent with the results reporting a decrease in the algometer reading within the studies of Chonan (2008), Ferreira (2006) and Govender (2011).

In an attempt to ensure consistency, the researcher employed the use of a research assistant in this study. To ensure no bias towards a particular group the study used a double-blinded procedure for the recording of the algometer readings. The examiner administered the treatment and was therefore aware of which treatment group each subject belonged to, however the research assistant who recorded the algometer readings of each participant was not privy to this information, thus ensuring no bias towards a particular group.

5.5 **Summary**

Three objectives were stated in determining the possible outcomes of this study; when they were compared with the results from the statistical analyses the following conclusions were made:

Objective 1/Outcome

The purpose of the first objective was to establish whether the control group would demonstrate an increase in post-needling soreness to a greater degree than the intervention group in terms of subjective clinical findings. The results of the NRS-11 and 24-hour pain diary revealed that both groups showed no statistical difference with regard to the pain experienced.

Objective 2/Outcome

The purpose of the second objective was to find out if the control group would demonstrate an increase in post-needling soreness to a greater degree than the intervention group in terms of objective clinical findings. The results of the algometer readings showed no statistical difference with regard to pain, although the baseline measurements showed a higher pain tolerance in the placebo group.

Objective 3/Outcome

The purpose of the third objective was to compare the inter-group results in terms of subjective and objective measurements in terms of pain according to the Numerical Pain Rating Scale (NRS - 11), 24-hour pain diary and pressure threshold algometer. Although there were certain trends regarding the benefits of low intensity laser therapy, there was no statistical evidence to support this. The LILT therefore does not appear to decrease post-needling soreness.

CHAPTER SIX

CONCLUSION

6.1 Conclusion

The aim of this study was to determine the effectiveness of low intensity laser therapy (LILT) on post-needling soreness in the upper trapezius muscle. The objective and subjective measurements from both the laser intervention and sham laser control groups showed the development of post-needling soreness. The study has shown no statistical evidence of a beneficial effect of LILT on post-needling soreness. The NRS 11 baseline measurements across both groups showed a slight difference in variance. The baseline of the sham laser group showed higher pain experienced at the initial visit, however it was not found to be statistically significant although it could have some clinical value which may need further investigation. There was a slight non-significant trend seen across groups, showing decreasing post-needling soreness in terms of subjective (NRS-11 and pain diary) and objective (algometer) findings. This was not found to be statistically significant, although it could have some clinical value which requires further investigation.

6.2 Recommendations

The following recommendations are made:

- Larger sample sizes should be used for future studies in order to allow for more statistically significant results. In addition, limiting subjects to one gender only to avoid differences in pain perception between genders as a confounding factor is recommended.

- Follow-up consultations conducted at various intervals greater than 24 hours should be used in further studies to obtain data on the long-term effects of dry-needling with respect to post-needling soreness. This will assist in obtaining a more accurate duration of post-needling soreness.

- In future studies, post-needling soreness should be investigated on only one side of the body of participants, as a possible cross-over effect and arm dominance could affect statistical analysis.

- Future studies on this or similar topics, could focus on one gender only. A study regarding the same gender in different decades could also help determine the susceptibility of participants to post-needling soreness and the likelihood of an individual to developing post-needling soreness in older individuals.

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Appendix A

ARE YOU BETWEEN THE AGES OF

18 TO 50?

A NON-SMOKER?

Have GENERALIZED NECK PAIN?

INTERESTED IN PARTICIPATING IN RESEARCH?

AT

THE DURBAN UNIVERSITY OF TECHNOLOGY

CHIROPRACTIC DAY CLINIC

(If you fit the research criteria)

The purpose of this study is to determine how low intensity laser therapy improves post needling soreness after dry needling.

CONTACT: MISHKA

(031) 373 2205 / 076 054 5201

Appendix B

Letter of Information

Dear Participant.

Welcome to my research study.

Purpose of the Study: The purpose of this study is to see if the use of low intensity laser therapy (LILT) on post-needling soreness helps relieve the pain from the muscle that has been dry needled.

Procedure: At the first consultation you will undergo a thorough examination. Following which you will be selected providing you fit the necessary requirements for the research. Once accepted into the study, you will receive one treatment involving a full neck examination, dry needling of the sore muscle followed by treatment with laser. After this, you will be required to complete the 24-hour pain diary, which will be provided. A follow-up assessment will take place 24 hours after the first treatment.

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

Reasons why you may be withdrawn from this study without your consent:

- If you are unable to attend your follow–up appointment.
- If you have changed any lifestyle habits during your participation in this study that may affect the outcome of this research (e.g. medication, supplements or treatment).
- If you suspect that you are pregnant.

Benefits: It is envisaged that laser treatment will provide you with pain relief. Your contribution to this study will also assist us as chiropractors to expand on our knowledge and hence improve on treatment regimens, thus enabling us to provide a more effective health care in the future.

PLEASE NOTE: AS A VOLUNTARY PARTICIPANT IN THIS RESEARCH STUDY, YOU ARE FREE TO WITHDRAW FROM THE STUDY AT ANY TIME, WITHOUT GIVING A REASON.

Remuneration: One free treatment will be provided after completion of the study.

Costs of study: None

Confidentiality: All patient information will be anonymized to ensure patient confidentiality. The results from this study will be used for research purposes only. Only the researcher and supervisor (Dr. A. Docrat) will be allowed access to these records. All data will be securely destroyed after study (+5 years).

Persons to contact should you have any problems or questions: Should you have any problems or questions that you would prefer being answered by an independent individual, please feel free to contact my supervisor (Dr. A. Docrat) on the number below. If you are not satisfied with a particular area of this study, please feel free to forward any concerns to the Durban University of Technology Research and Ethics Committee. Prof. Sibusiso Moyo. Email: moyos@dut.ac.za. Tel: 031 373 2576

Thank you for participating in my research study.

Mishka Dhai	Dr. A. Docrat	Mrs F. Ally
(Researcher)	(Supervisor)	(Co-Supervisor)
(031) 204 2205	(031) 204 2589	(031) 373 2389

Appendix B

Informed Consent

<u>Statement of agreement to participate in this study:</u>

I____ (Participant's full name), ID number ____, have read the above written information (Letter of Information) in its entirety and understand its contents. Any questions have been answered and explained sufficiently by _____________________________________. I am aware that the results of the study, including my personal details regarding my age, date of birth, sex, initials and diagnosis will be anonymously processed into a study report. I agree that the data collected during this study can be processed in a computerised system by the researcher. Furthermore, I understand that I may withdraw from this study at any stage without any penalty to me and my future health care. I therefore give my consent to fully participate in this research study.

Participant's name: _____________________________

Participant's signature: __________________________ Date: ____________________

I, ___________________________________ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Researcher's name: ___________________________

Researcher's signature: ________________________ Date: ____________________

Witness' name: ______________________________

Witness' signature: ___________________________ Date: ____________________

Appendix C

Algometer Readings:

PATIENT NAME:__________________			
ALGOMETER READING	PRIOR TO DRYNEEDLING	IMMEDIATELY AFTER THE INTERVENTION	24HOURS AFTER DRYNEEDLING

Average Algometer reading:

____

Appendix D

PAIN DIARY

Dear patient.

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

For this 24hr duration, please:

- do not apply ice to the needled area,
- do not take any medication (e.g. pain medication, anti-inflammatory drugs)
- do not apply any topical pain-relieving creams or ointments on the treated area.

Please fill in the following diary precisely according to the allocated times.

Did you experienced pain in the area that was needled at:	**YES**	**NO**
3 hours after receiving dry needling therapy		
6 hours after receiving dry needling therapy		
9 hours after receiving dry needling therapy		
12 hours after receiving dry needling therapy		
24hours after receiving dry needling therapy		

My pain was worst at _____ hours after receiving dry needling therapy.

Should you have any questions regarding the research, if you require aid or if the pain becomes intense, kindly contact:

- Mishka Dhai (researcher) on (031) 373 2205 or 076 054 5201
- Dr. A. Docrat (research supervisor) on (031) 373 2589

Please note that if (and only if) the pain becomes intense, it is advised that you ice the area and rest.

Patient Name:________________________ Signature:_____________

Research Student Name:______________ Signature:_____________

Appendix E

Numerical Rating Scale – (NRS-11)

Date:________________ File number:______________

Patient name:____

Visit 1:

Please indicate on the line below, the number between 0 and 10 that best describes the pain you experience **when it is at its worst**. A zero (0) would mean "no pain at all", and ten (10) would mean "pain as bad as it could be".

Please circle only one number.

0_1_2_3_4_5_6_7_8_9_10

Visit 2:

Please indicate on the line below, the number between 0 and 10 that best describes the pain you experience **when it is at its least.** A zero (0) would mean "no pain at all", and ten (10) would mean "pain as bad as it could be".

Please circle only one number.

0_1_2_3_4_5_6_7_8_9_10

Key:

Rating	Pain Level
0	No Pain
1-3	Mild Pain (nagging, annoying, interfering with ADLs*)
4-6	Moderate Pain (interferes significantly with ADLs)
7-10	Severe Pain (disabling; unable to perform ADLs)

*ADLs – Activities of daily living

Appendix F

Telephonic Interview:

Participant name: ___________________________________

Participant age: ____________________________________

Question:	Expected Answer	Actual Answer
Do you suffer from non-specific neck pain?	Yes	
Do you sometimes have to take pain relieving medication to relieve the pain in your neck?	Yes	
Have you taken any pain relieving medication in the last 3 days?	No	
Does the pain interfere with your daily routine?	Yes	
Are you on any blood thinning medication?	No	
Do you have a pacemaker?	No	
Are you a smoker?	No	
Do you have a history of malignancies?	No	
Are you on any current medication for cancer?	No	
Are you pregnant? (for females)	No	
If you suspect that you are pregnant, have you had a recent pregnancy test?	Yes to taking a pregnancy test.	
Are you comfortable with needles?	Yes	
Have you been diagnosed with hyper/hypothyroidism?	No	

Appendix G

CHIROPRACTIC PROGRAMME

CHIROPRACTIC DAY CLINIC

CASE HISTORY

Patient:__________________Date:_____________ File#:_________

Age: ________Sex:_______Occupation:______________________

Student:_____________Signature ___________________________

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: Signature:

Case History:

Examination:

Previous: Current:

X-Ray Studies:

Previous: Current:

Clinical Path. lab:

Previous: Current:

CASE STATUS:

PTT: Signature: Date:

CONDITIONAL:

Reason for Conditional:

Signature: Date:

Conditions met in Visit No: Signed into PTT: Date:

Case Summary signed off: Date:

Student's Case History:

1.Source of History:

2.Chief Complaint: (patient's own words):

3.Present Illness:

	Complaint 1(principle	**Complaint 2 (additional or secondary complaint)**
Location		
Onset :		
Initial:		
Recent:		
Cause:		
Duration		
Frequency		
Pain (Character)		
Progression		
Aggravating Factors		
Relieving Factors		
Associated S & S		
Previous Occurrences		
Past Treatment		
Outcome:		

4.Other Complaints:

5.Past Medical History:

General Health Status

Childhood Illnesses

Adult Illnesses

Psychiatric Illnesses

Accidents/Injuries

Surgery

Hospitalizations

6. Current health status and life-style:

Allergies

Immunizations

Screening Tests incl. x-rays

Environmental Hazards (Home, School, Work) Exercise and Leisure

Sleep Patterns Diet

Current Medication
Analgesics/week: Other (please list):

Tobacco Alcohol Social Drugs

7. Immediate Family Medical History:

Age of all family members Health of all family members
Cause of Death of any family members

	Noted	Family member		Noted	Family member
Alcoholism			Headaches		
Anaemia			Heart Disease		
Arthritis			Kidney Disease		
CA			Mental Illness		
DM			Stroke		
Drug			Thyroid Disease		
Epilepsy			TB		
Other (list)					

8. Psychosocial history:

Home Situation and daily life
Important experiences
Religious Beliefs

9. Review of Systems (please highlight with an asterisk those areas that are a problem for the patient and require further investigation)

General

Skin

Head

Eyes

Ears

Nose/Sinuses

Mouth/Throat

Neck

Breasts

Respiratory

Cardiac

Gastro-intestinal

Urinary

Genital

Vascular

Musculoskeletal

Neurologic

Haematological

Endocrine

Psychiatric

Appendix H

CHIROPRACTIC PROGRAMME

Chiropractic DAY CLINIC
PHYSICAL EXAMINATION

Patient:____File#:__________Date:________

Clinician:________________________________Signature:________________________

Student:________________________________Signature:________________________

1. VITALS

Pulse rate:
Respiratory rate:
Blood pressure: R L Medication if hypertensive:
Temperature:
Height:
Weight: Any change Y/N If Yes: how much gain/loss
Over what period

2. GENERAL EXAMINATION

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

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

1) Is this patient in **Cardiac Failure**?
2) Does this patient have signs of **Infective Endocarditic**?
3) Does this patient have **Rheumatic Heart Disease?**

Inspection - Scars

- Chest deformity:
- Precordial bulge:
- Neck -JVP:

Palpation: - Apex Beat (character + location):

- Right or left ventricular heave:
- Epigastric Pulsations:
- Palpable P2: Palpable A2:

Pulses:
- General Impression:
- Radio-femoral delay:
- Carotid:
- Radial:
- Dorsalis pedis:
- Posterior tibial:
- Popliteal:
- Femoral:

Percussion: - borders of heart

Auscultation: - heart valves (mitral, aortic, tricuspid, pulmonary)

- Murmurs (timing, systolic/diastolic, site, radiation, grade).

4. RESPIRATORY EXAMINATION

I) Is this patient in **Respiratory Distress**?

Inspection
- Barrel chest:
- Pectus carinatum/cavinatum:
- Left precordial bulge:
- Symmetry of movement:
- Scars:

Palpation
- Tracheal symmetry:
- Tracheal tug:
- Thyroid Gland:
- Symmetry of movement (ant + post)
- Tactile fremitus:

Percussion
- Percussion note:
- Cardiac dullness:
- Liver dullness:

Auscultation
- Normal breath sounds bilateral:
- Adventitious sounds (crackles, wheezes, crepitations)
- Pleural frictional rub:
- Vocal resonance - Whispering pectoriloquy:
- Bronchophony:
- Egophony:

5. ABDOMINAL EXAMINATION

I) Is this patient in **Liver Failure**?

Inspection -
Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:
- Masses (intra- or extramural)
- Aorta:

Percussion
- Rebound tenderness:
- Ascites:
- Masses:

Auscultation
- Bowel sounds:
- Arteries (aortic, renal, iliac, femoral, hepatic)

Rectal Examination - Perianal skin:

- Sphincter tone & S4 Dermatome:
- Obvious masses:
- Prostate:
- Appendix:

6. G.U.T EXAMINATION

External genitalia**:**
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

Gait and Posture - Abnormalities in gait:

- Walking on heels (L4-L5):
- Walking on toes (S1-S2):
- Romberg's test (Pronator Drift):

Higher Mental Function - Information and Vocabulary:

- Calculating ability:
- Abstract Thinking:

G.C.S.:
- Eyes:
- Motor:
- Verbal:

Evidence of head trauma:

Evidence of Meningism: - Neck mobility and Brudzinski's sign:

- Kernig's sign:

Cranial Nerves:

I Any loss of smell/taste: Nose examination:

II External examination of eye:
- Visual Acuity:
- Visual fields by confrontation:
- Pupillary light reflexes = Direct:
  = Consensual:
- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

V
a. Sensory
- Ophthalmic:
- Maxillary:
- Mandibular:

b. Motor
- Masseter:
- Jaw lateral movement:

c. Reflexes
- Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

VII
a. Motor - Raise eyebrows:
- Frown:

- Close eyes against resistance:
- Show teeth:
- Blow out cheeks:

b. Taste - Anterior two-thirds of tongue:

VIII General Hearing:
Rinne's = L: R:
Weber's lateralisation:
Vestibular function - Nystagmus:
- Romberg's:
- Wallenberg's

: Otoscope examination:

IX & X Gag reflex:
Uvula deviation:
Speech quality:

XI Shoulder lift:
S.C.M. strength:

XII Inspection of tongue (deviation):

Motor System:

a. Power
- Shoulder = Abduction & Adduction:
  = Flexion & Extension:
- Elbow = Flexion & Extension:
- Wrist = Flexion & Extension:
- Forearm = Supination & Pronation:
- Fingers = Extension (Interphalangeals & M.C.P's):
- Thumb = Opposition:
- Hip = Flexion & Extension:
  = Adduction & Abduction:
- Knee = Flexion & Extension:
- Foot = Dorsiflexion & Plantar flexion:
  = Inversion & Eversion:
  = Toe (Plantarflexion & Dorsiflexion):

b. Tone
- Shoulder:
- Elbow:
- Wrist:
- Lower limb - Int. & Ext. rotation:
- Knee clonus:
- ankle clonus:

c. Reflexes
- Biceps:
- Triceps:
- Supinator:
- Knee:
- Ankle:
- Abdominal:
- Plantar:

Sensory System:

a. Dermatomes - Light touch:
- Crude touch:
- Pain:
- Temperature:
- Two point discrimination:

b. Joint position sense - Finger:
- Toe:

c. Vibration: - Big toe:
- Tibial tuberosity:
- ASIS:
- Interphalangeal Joint:
- Sternum:

Cerebellar function:

Obvious signs of cerebellar dysfunction:

= Intention Tremor:

= Nystagmus:

= Truncal Ataxia: Finger-nose test

(Dysmetria):

Rapid alternating movements (Dysdiadochokinesia): Heel-shin test:

Heel-toe gait: Reflexes:

Signs of Parkinsons:

8. SPINAL EXAMINATION: (See Regional examination)

Obvious Abnormalities: Spinous

Percussion: R.O.M:

Other:

9. BREAST EXAMINATION:

Summon female chaperon.

Inspection - Hands rested in lap:
- Hands pressed on hips:
- Arms above head:
- Leaning forward:

Palpation - masses:
- tenderness:
- axillary tail:
- nipple:
- regional lymph nodes:

DUT DURBAN UNIVERSITY OF TECHNOLOGY

DEPARTMENT OF CHIROPRACTIC AND SOMATOLOGY

CHIROPRACTIC PROGRAMME

REGIONAL EXAMINATION – CERVICAL SPINE

Patient: ______________________________ File No: ______________

Date: __________ Student: ______________________________

Clinician: ______________________________ Sign: ______________________

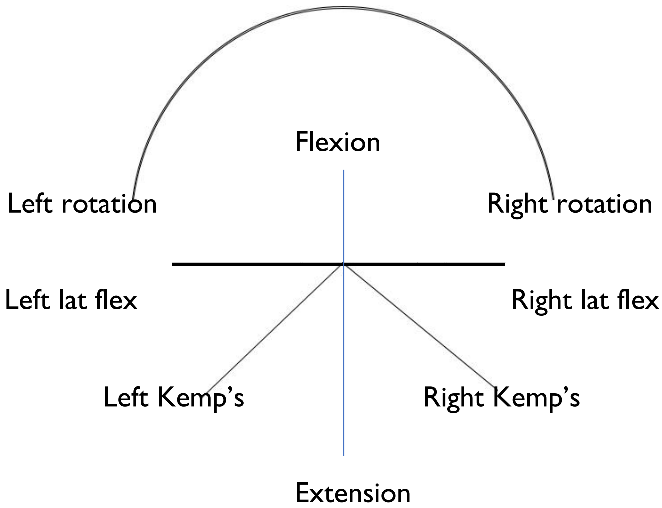
OBSERVATION:

Posture
Swellings
Scars, discolouration
Hair line
Body and soft tissue contours

Shoulder position
Left:
Right:
Shoulder dominance (hand):
Facial expression:

RANGE OF MOTION:

Extension (70°):
L/R Rotation (70°):
L/R Lat flex (45°):
Flexion (45°):



PALPATION:

Lymph nodes
Thyroid Gland
Trachea

MYOFASCIAL ASSESSMENT

Tenderness		Right	Left
Trigger Points:	SCM		
	Scalenii		
	Post Cervicals		
	Trapezius		
	Lev scapular		

ORTHOPAEDIC EXAMINATION:

	Right	Left		Right	Left
Adson's test			Halstead's test		
Brachial plexus test			Hyper-abduction test		
Cervical compression			Kemp's test		
Cervical distraction			Lateral compression		
Costoclavicular test			Lhermitte's sign		
Dizziness rotation test			Shoulder abduction test		
Doorbell sign			Shoulder compression test		
Eden's test					

NEUROLOGICAL EXAMINATION:

Dermatomes	**Left**	**Right**	**Myotomes**	**Left**	**Right**	**Reflexes**	**Left**	**Right**
C2			C1			C5		
C3			C2			C6		
C4			C3			C7		
C5			C4					
C6			C5					
C7			C6					
C8			C7					
T1			C8					
			T1					

Cerebellar tests:	Left	Right
Dysdiadochokinesis		

VASCULAR:	**Left**	**Right**		**Left**	**Right**
Blood pressure			Subclavian arts.		
Carotid arts.			Wallenberg's test		

MOTION PALPATION & JOINT PLAY:

Left: Motion Palpation:

Joint Play:

Right: Motion Palpation:

Joint Play:

<u>BASIC EXAM: SHOULDER</u>:

Case History:

ROM: Active:

Passive:

RIM:

Orthopaedic:

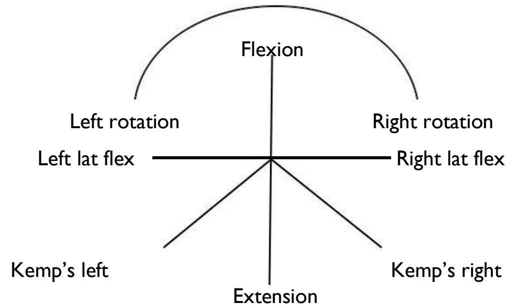
Neuro:

Vascular:

<u>BASIC EXAM: THORACIC SPINE:</u>

Case History:

ROM:



Motion Palpation:	
Orthopaedic:	
Neuro:	
Vascular:	
Observ/Palpation:	
Joint Play:	

DUT DURBAN UNIVERSITY OF TECHNOLOGY — DEPARTMENT OF CHIROPRACTIC AND SOMATOLOGY

CHIROPRACTIC PROGRAMME Appendix J

Patient Name: ***File number:*** ***Page:***

Date: ***Visit:*** ***Student:***

Attending Clinician: ***Signature:***

S: ***Numerical Pain Rating Scale (Patient)*** ***Least*** ***Student Rating*** ☐ ***A:***

0 1 2 3 4 5 6 7 8 9 10 ***Worst***

0: ***P:***

E:

Special attention to: ***Next appointment:***

Date: ***Visit:*** ***Student:***

Attending Clinician: ***Signature:***

S: ***Numerical Pain Rating Scale (Patient)*** ***Student Rating*** ***A:***

Least ***0 1 2 3 4 5 6 7 8 9 10*** ***Worst*** **O:** ☐

P:

E:

Special attention to: ***Next appointment:***

Date: ***Visit:*** ***Student:***

Attending Clinician: ***Signature***

S: ***Numerical Pain Rating Scale (Patient)*** ***Student Rating*** ***A:***

Appendix K

MEMORANDUM

To	:	Prof Puckree Chair : RHDC Prof Adam Chair : IREC
From	:	Dr Charmaine Korporaal Clinic Director : FoHS Clinic
Date	:	26.05.2015
Re	:	Request for permission to use the Chiropractic Day Clinic for research purposes

---

Permission is hereby granted to :

Ms Mishka Dhai (Student Number: 21011462**)**

Research title : "The effect of low intensity laser therapy on post needling soreness in trigger point 2 of the upper trapezius muscle".

It is requested that Ms Dhai submit a copy of her RHDC / IREC approved proposal to the Clinic Administrators before she starts with her research in order that any special procedures with regards to her research can be implemented prior to the commencement of her seeing patients.

Thank you for your time.

Kind regards

[redacted]

Dr Charmaine Korporaal

Clinic Director : FoHS Clinic

Cc: Mrs Pat van den Berg : Chiropractic Day Clinic

Dr L O'Connor : Research co-ordinator

Dr A Docrat : Research supervisor

Mrs F Ally : Research supervisor

Appendix L

Two Independent Proportions (Null Case) Power Analysis
Numeric Results of Tests Based on the Difference: P1 - P2
H0: P1 - P2 = 0. H1: P1 - P2 = D1 ≠ 0. Test Statistic: Fisher's Exact test

Power	Sample Size Grp 1 N1	Sample Size Grp 2 N2	Prop|H1 Grp 1 or Trtmnt P1	Prop Grp 2 or Control P2	Diff if H0 D0	Diff if H1 D1	Target Alpha	Actual Alpha	Beta
0.9085	20	20	0.1000	0.6000	0.0000	-0.5000	0.0500	0.0238	0.0915

Note: exact results based on the binomial were only calculated when both N1 and N2 were less than 100.

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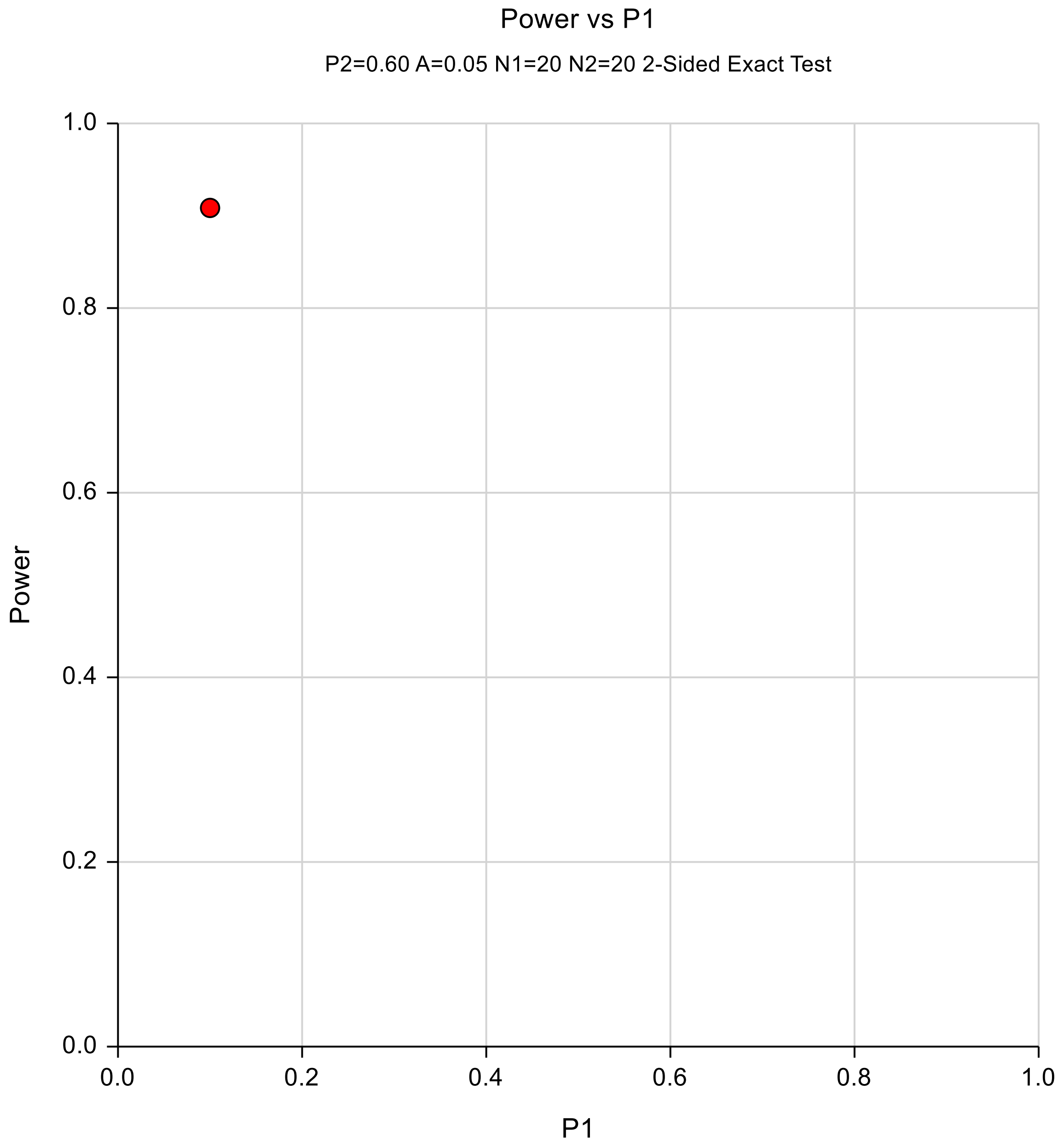
Report Definitions
'Power' is the probability of rejecting a false null hypothesis. It should be close to one.
'N1 and N2' are the sizes of the samples drawn from the corresponding populations.
'P1' is the proportion for group one under H1. This is the treatment or experimental group.
'P2' is the proportion for group two. This is the standard, reference, or control group
'Target Alpha' is the probability of rejecting a true null hypothesis that was desired.
'Actual Alpha' is the value of alpha that is actually achieved.
'Beta' is the probability of accepting a false null hypothesis.

Summary Statements
Group sample sizes of 20 in group one and 20 in group two achieve 91% power to detect a difference between the group proportions of -0.5000. The proportion in group one (the treatment group) is assumed to be 0.6000 under the null hypothesis and 0.1000 under the alternative hypothesis. The proportion in group two (the control group) is 0.6000. The test statistic used is the two-sided Fisher's Exact test. The significance level of the test was targeted at 0.0500. The significance level actually achieved by this design is 0.0238.

Two Independent Proportions (Null Case) Power Analysis

Chart Section



Appendix M

Statement of Agreement to Participate in the Research Study as a Research Assistant:

I ……………………......................., ID number……………………………………………… voluntarily agree to participate in this study: **"The effect of low intensity laser therapy on post needling soreness in trigger point 2 of the upper trapezius muscle."**, as a research assistant**.**

I will ensure that I maintain a level of confidentiality with regards to the research data that is collected.

Research assistant's name (print) …………………………………………………………………….

Research assistant's signature: ………………………………… Date: …………………………………

Researcher's name (print)…………………………………… Signature: ……………………………………….

Date: …………………………………

Witness name (print)……………………………………………Signature………………………………………

Date: ………………………………….

Appendix N

DUT
DURBAN
UNIVERSITY OF
TECHNOLOGY

Institutional Research Ethics Committee
Faculty of Health Sciences
Room MS 49, Mansfield School Site
Gate 8, Ritson Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2900
Fax: 031 373 2407
Email: lavishad@dut.ac.za
http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

26 October 2015

IREC Reference Number: **REC 95/15**

Ms M Dhai
14 Besembos Street
West Acres 7
Nelspruit
1200

Dear Ms Dhai

The effect of low intensity laser therapy on post needling soreness in trigger point 2 of the upper trapezius muscle

I am pleased to inform you that Full Approval has been granted to your proposal REC 95/15.

The Proposal has been allocated the following Ethical Clearance number **IREC 126/15**. Please use this number in all communication with this office.

Approval has been granted for a period of two years, before the expiry of which you are required to apply for safety monitoring and annual recertification. Please use the Safety Monitoring and Annual Recertification Report form which can be found in the Standard Operating Procedures [SOP's] of the IREC. This form must be submitted to the IREC at least 3 months before the ethics approval for the study expires.

Any adverse events [serious or minor] which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC SOP's.

Please note that any deviations from the approved proposal require the approval of the IREC as outlined in the IREC SOP's.

Yours Sincerely

[redacted]

Professor M N Sibiya
Deputy Chairperson: IREC

DUT DURBAN UNIVERSITY OF TECHNOLOGY
2015 -10- 26
INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
P O BOX 1334 DURBAN 4000 SOUTH AFRICA

NHREC

South African Human Research Electronic Application System

Appendix O

TRIAL APPLICATION

Application ID:	4190	**DOH Number**	**Pending**	Page:	1/2

Applicant Details

Organisation :	Durban University of Technology
Applicant Type :	Academic Investigator
Contact Name :	Aadil Docrat
Address :	Chiropractic Programme Durban University of Technology PO Box 1334 Durban 4000
Telephone :	0313732094
Fax :	
E-mail :	aadild@dut.ac.za
Responsible Contact person (for public)	A. Docrat
Telephone :	0313732094
Research contact person	M. Dhai
Telephone :	0313732205

Trial Application Details

Issue Date :	2015/08/12
Sponsors :	Durban University of Technology
Primary Sponsor :	
FundingType :	Not Funded
Research Site Names :	Durban University of Technology Chiropractic clinic
Primary Research Site Name :	
Total National Budget for Trial	R 4962.00
Protocol / Grant Reference Number	REC 95/15

Study Descriptive Information

Brief Tiltle of Study :	The effect of low intensity laser therapy on post needling soreness in trigger point 2 of the upper trapezius muscle
Full Title of Study :	
Anticipated Start Date :	2015/08/26
Anticipated End Date :	2015/08/31
Target Sample Size :	40
Study Phase :	Other Single
Study Scope :	Site
Study Type :	Interventional
Disease Type Heading :	Muscle, Bone and Cartilage Diseases
Disease Type Condition :	Myofascial Pain Syndromes
Intervention Name (Generic) :	Chattanooga low intensity Laser

Intervention Duration :	No.	Type
	3	Minutes