The effectiveness of the Impulse iQ[®] Adjusting Instrument compared to ischaemic compression in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain

By

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic

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

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DEDICATION

I dedicate this dissertation to:

My Father and Mother, Edgar and Violet; without your love, patience, sacrifices and emotional support I would never have had the opportunity to go beyond my own capabilities and achieve my dream. Thank you for always believing in me. I love and appreciate you both dearly.

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ABSTRACT

Aim: This study aimed to compare the effectiveness of the Impulse iQ[®] Adjusting Instrument and ischaemic compression on trigger points in pain relief and quality of life in adults presenting with non-specific neck pain.

Methodology: This study was a randomised single-blinded clinical trial which consisted of 40 participants residing in the eThekwini municipality, divided into two groups of 20 each. The participants were randomly assigned using concealed allocation to one of two treatment groups of 20 viz. Impulse iQ[®] Adjusting Instrument (IAI) trigger point therapy group and ischaemic compression (IC) group. Neck pain level was determined using a numerical pain rating scale (NRS). Degree of lateral flexion (LF) was determined by a cervical range of motion (CROM) goniometer. Pain pressure thresholds (PPT) were measured with a pain pressure algometer. The effect of neck pain on participants' activities of daily living was assessed using the Canadian Memorial Chiropractic College (CMCC) Neck Disability Index (NDI). The participants' overall perception of improvement since the initiation of treatment was assessed using the Patients Global Impression of Change (PGIC). The participants received three treatments over a two and half week period with the fourth consultation being used for the final subjective and objective measurements.

Results: Repeated measures ANOVA testing was used to examine the intra-group effect of time and the inter-group effect of treatment on the outcomes of NRS, algometer readings and CROM goniometer measurements. Profile plots were used to assess the direction and trends of the effects. An intra-group analysis revealed that, objectively and subjectively, all groups responded positively to treatment over time, with no significant time-group interaction. It was noted that there was a higher rate of improvement in IAI Group with respect to algometer readings over time; however, this difference was not statistically significant.

Conclusion: This study concluded that neither IAI nor IC is more effective than the other with respect to participants' pain perception and CROM. However, the IAI was more effective on pain pressure threshold. Based on the results collected from this study, both therapies can used in the treatment protocols of neck pain associated with MFTPs.

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LIST OF SYMBOLS AND ABBREVIATIONS

| % | Percent |
|------|---|
| ACh | Acetylcholine |
| AL | Algometer |
| CDC | Chiropractic Day Clinic |
| CI | Confidence Interval |
| CROM | Cervical Range of Motion |
| DUT | Durban University of Technology |
| ΙΑΙ | Impulse iQ [®] Adjusting Instrument |
| IC | Ischaemic Compression |
| ICC | Intra-class Correlation Coefficient |
| IREC | Institutional Research and Ethics Committee |
| LTR | Local Twitch Response |
| MFTP | Myofascial Trigger Point |
| MPS | Myofascial Pain Syndrome |
| n | Sample size |
| Ν | Newtons |
| NDI | Canadian Memorial Chiropractic College (CMCC) Neck Disability Index |
| NRS | Pain Numerical Rating Scale |
| PGIC | Patient's Global Impression of Change |
| PPT | Pain Pressure Threshold |

RA Research Assistant

- **ROM** Range of Motion
- **SMT** Spinal manipulative therapy
- **TENS** Transcutaneous Electrical Nerve Stimulation
- **TP** Trigger Point

CHAPTER 1 : INTRODUCTION

1.1 INTRODUCTION

Simons, Travell and Simons (1999) defined myofascial pain syndrome (MPS) as a sensory, motor and autonomic syndrome which results from myofascial trigger points (MFTPs) which are hyperirritable spots located within skeletal muscle that are associated with palpable nodules in taut bands. Active MFTPs can result in a significant amount of pain (Simons, 1983). MFTPs in the shoulder and neck region play an important role in the genesis of mechanical neck pain (Simons, Travell and Simons, 1999). Evidence exists to suggest that active MFTPs are frequent in patients suffering with non-specific neck pain (Fernández-de-las-Peñas et al., 2006a). This was further supported by Muñoz-Muñoz et al. (2012), who stated that active MFTPs in the neck and shoulder musculature influenced to symptoms of neck pain of mechanical origin. Several factors which include overuse, severe trauma, mechanical overload or psychological stress may result in the formation of MFTPs (Simons, Travell and Simons, 1999).

Early management of MFTPs in MPS requires identification of the trigger points (TPs), treatment of the MFTPs and corrective action to prevent recurrence (Gerwin, 1991). Treatment is aimed at relieving pain and restoring normal functioning of the affected muscle (Simons, 1999). There are various ways of treating MFTPs. Numerous non-invasive methods which include soft tissue stretching, massage, ischaemic compression (IC), laser therapy, heat, acupressure, ultrasound, transcutaneous electrical nerve stimulation (TENS), biofeedback and pharmacological treatments have been used in the treatment of MFTPs (Borg-Stein and Simons, 2002). The literature details numerous proposed treatment interventions to treat MFTPs (Rickards, 2006). However, reliable evidence for for many of these treatments appears to be lacking (Rickards, 2006). Therapies such as IC, which is one of the most commonly used therapies for the treatment of MFTPs (Montanez-Aguilera et al., 2010), was found to be relatively effective but may be uncomfortable for the patient (Hou et al., 2002).

The Impulse iQ[®] Adjusting Instrument (IAI) is a relatively new medical device for manual therapy of a variety of musculoskeletal conditions. Although basic scientific research has demonstrated biomechanical and neurophysiological responses associated with its use (Colloca et al., 2005),

little clinical research exists on its use. The intended use of the IAI is multiple-impulse thrusts; research into the effectiveness of the device can provide insights into a novel approach to treating MFTPs non-invasively.

As can be seen from the prevalence, it is thus important to treat MPS effectively as it is a frequent disorder. Schneider (1996) stated that an effective protocol is required for the treatment of MPS, irrespective of the range of different therapies available to clinicians. This was further supported by Han and Harrison (1997), who stated that more studies are required to determine the effectiveness of these treatments.

To the researcher's knowledge, there is a paucity in the literature worldwide with respect to studies comparing the IAI with traditional approaches in the effectiveness of treating neuromuscular conditions such as MPS. Therefore, this research study investigated the effectiveness of the IAI in comparison to IC for the treatment of upper trapezius muscle MFTPs in participants with non-specific neck pain.

1.2 AIMS AND OBJECTIVES

1.2.1 Aim of the Study

The aim of this study was to determine the effectiveness of the Impulse iQ[®] Adjusting Instrument compared to ischaemic compression for the treatment of upper trapezius muscle MFTPs in participants with non-specific neck pain.

1.2.2 Objectives of the Study

Objective One

1) To determine the effectiveness of the Impulse iQ[®] Adjusting Instrument compared to ischaemic compression for the treatment of upper trapezius MFTPs in terms of subjective measurements.

The subjective measurements included the Numerical Pain Rating Scale (NRS) (Appendix H) and Canadian Memorial Chiropractic College (CMCC) Neck Disability Index (NDI) questionnaire (Appendix M) which are questionnaires that described the participant's pretreatment state. Patients' Global Impression of Change (PGIC) (Appendix I) is a questionnaire that described the participant's post-treatment state with regards to change. Objective Two

 To determine the effectiveness of the Impulse iQ[®] Adjusting Instrument compared to ischaemic compression for the treatment of upper trapezius MFTPs in terms of objective measurements.

The objective measurements were taken using an algometer (to measure patient's pain threshold (PPT) over the most tender segments of the MFTP). The cervical spine range of motion (CROM) was measure using a CROM-II goniometer.

Objective Three

3) To correlate the subjective and objective findings in terms of the overall effectiveness of the Impulse iQ[®]Adjusting Instrument and ischaemic compression in the treatment of upper MFTPs i.e. to assess whether changes from baseline in subjective and objective outcomes are correlated within treatment groups.

1.3 HYPOTHESIS

1.3.1 Null Hypothesis

The null hypothesis stated that there would be no difference between the two study groups being compared in terms of subjective and objective measurements.

1.3.2 Alternative Hypothesis

The alternative hypothesis stated that the Impulse iQ[®] Adjusting Instrument for the treatment of upper trapezius muscle MFTPs will have a statistically significant difference compared to ischaemic compression in terms of subjective clinical findings (i.e. subjective pain perception) and objective clinical findings (pain threshold algometry).

1.4 LIMITATIONS

Limitations of the study include the use of a small population sample size. This was because of both time and budget constraints. The scoring of the subjective measurements was dependent on the honesty of the participants which may have affected results of the study.

1.5 RATIONALE

1.5.1 Rationale One

Myofascial pain syndrome is a frequent but often misunderstood pain disorder (Fricton et al., 1985) and has a mean prevalence amongst middle-aged adults (30–60 years) which is reported to be 37% in men and 65% in women, respectively (Drewes and Jennum, 1995). In the elderly (>65 years), the prevalence reaches 85% (Podichetty, Mazanec and Biscup, 2003). Thus, based on demographics of ageing, MPS can possibly become an increasingly significant problem affecting the general population in the years to come (Giamberardino et al., 2011). This increases the need for an effective treatment for MPS, which can be administered over a shorter period requiring fewer, amounts of visits, thereby, curbing costs incurred by patients. Furthermore, for maximum clinical outcome, multiple treatments need to be investigated to determine which renders the most effective as well as to add to the existing body of literature (Korthals-de Bos, 2003; Kohlbeck et al., 2005).

1.5.2 Rationale Two

Various non-invasive therapies which include stretching, massage, IC, laser therapy, heat, acupressure, ultrasound, TENS, biofeedback and pharmacological medications have been utilised in the treatment of MFTPs; however, no single treatment has demonstrated to be universally efficacious (Borg-Stein and Simons, 2002). In a study conducted by Hou et al. (2002), which incorporated numerous combinations of exercise, manual therapy, stretching and electromodalities, the groups which received some form of electromodality had a greater decrease in pain intensity in comparison to the control group. The combination of heat packs, ROM exercises, interferential current therapy and myofascial release therapy demonstrated the greatest decrease in pain. "However, reliable evidence for intra- and inter-effectiveness for many of these treatments appears to be lacking" (Rickards, 2006).

1.5.3 Rationale Three

Ischaemic compression can be used as a prophylactic or preventative therapy for the activation of MFTPs (Zadeh, 2006) but may be uncomfortable for the patient (Hou et al., 2002). It lends the credibility to the common impression that IC is superior when compared to other therapies like spray and stretch, heat packs and ultrasound (Mukkannavar, 2008). According to Christensen (2000), over 90 percent of chiropractors use MFTP treatment for inert adjustive care with 68 percent using acupressure, which is a form of IC. The pincer grasp which is commonly used in IC by clinicians results in an increased loading of the distal interphalangeal joint predisposing it to wear and hence, degeneration (Radin, Parker and Paul, 1971). Therefore, instrument assisted therapies would reduce the dependence of using IC for treatment of MFTPs.

1.5.4 Rationale Four

The IAI is a relatively new manual therapy device used for a variety of musculoskeletal conditions. Although basic scientific research has demonstrated biomechanical and neurophysiological responses associated with its use (Colloca et al., 2005), little clinical research exists on its use. Therefore, a study of this nature will add to the body of literature available with regards to clinical data on the IAI.

CHAPTER 2 : LITERATURE REVIEW

2.1 INTRODUCTION

Neck pain is a chief public health problem, with respect to individual health and general well-being (Fejer, Kyvik and Hartvigsen, 2006; Cote, Cassidy and Carroll, 2001). Commonly, non-specific neck pain occurs as a result of a mechanical or myofascial problem (Borghouts, Koes, and Bouter, 1998). Neck pain directly results from trigger points (TPs) located within the neck and shoulder musculature (e.g. sternocleidomastoid, scalenes, levator scapulae, trapezius, sub-occipital and posterior cervical muscles) (Gerwin, 2001). Gerwin (2001) further stated that anterior head carriage and rounded shoulders resulting from postural stresses are among the most frequent causes of TP related neck pain (Gerwin, 2001). Evidence exists to suggest that active MFTPs are common in patients presenting with non-specific neck pain (Ferna 'ndez-de-las-Pen"as, 2006b; Blikstad and Gemmell, 2008). This was further supported by Muñoz-Muñoz et al. (2012), who stated that active MFTPs in the neck and shoulder muscles contribute to symptoms of mechanical neck pain. In a study conducted by Ferna 'ndez-de-las-Pen"as (2007), almost all neck pain participants (n = 20) presented with MFTPs located within the upper trapezius muscle fibres on either side.

Simons, Travell and Simons (1999) defined MPS as a sensory, motor and autonomic syndrome which results from MFTPs, which are defined as "hyperirritable spots within skeletal muscle that are associated with palpable nodules in taut bands." Myofascial trigger points can be classified as active or latent (Munoz-Munoz, 2012). Active MFTPs can result in a significant amount of pain (Shah et al., 2008). When compressed, Myofascial trigger points reproduce pain and usually give rise to a characteristic pain referral pattern, tenderness, autonomic phenomena and restricted range of motion (ROM) (Simons, Travell and Simons, 1999). Myofascial trigger points can also be responsible for weakness of the involved muscles as well as autonomic dysfunction such as salivation, sweating, localised vasoconstriction and lacrimation (Simons, Travell, and Simons, 1999). The trapezius muscle is one of the frequently affected muscle in relation to MPS (Simons, Travell and Simons, 1999).

2.2 EPIDEMIOLOGY

The point prevalence of neck pain is approximately 13% (Ndlovu, 2006), with a lifetime prevalence between 45-54% in the overall population (Ferna ndez-de-las-Pen a, 2007). Up to 30% of men and 50% of women suffer from neck pain in their lifetime (Dziedzic et al., 2005) with 14% of the patients at risk of developing chronic neck pain (Saturno, 2003).

A study conducted by Skootsky Jaeger and Oye (1989) on 172 consecutive patients that presented at a university primary care general internal medicine practice, found that 30% of the 54 patients who were suffering with pain, were diagnosed with MPS. Myofascial pain syndrome has a mean prevalence amongst middle-aged adults (30–60 years) which is reported to be 37% in men and 65% in women, respectively (Drewes and Jennum, 1995; Giamberardino et al., 2011). In the elderly (>65 years), the prevalence reaches 85% (Podichetty, Mazanec and Biscup, 2003). This study is relevant in light of the above mentioned statistics,

2.3 MUSCLE OVERVIEW

2.3.1 Trapezius Muscle

According to Simons, Travell and Simons (1999), the trapezius muscle is divided into three sections i.e. upper, middle and lower sections; with MFTPs occurring most commonly in the upper part of the trapezius muscle (Simons, Travell and Simons, 1999). Sola (1981) and Rubin (1981) also concluded that the upper trapezius is the muscle most commonly affected by MFTPs.

The following information on the trapezius muscle regarding its anatomical attachments, innervation and function are according to Simons, Travell and Simons (1999) (Figure 2.1):

Attachments: The upper trapezius muscle fibres attach to the medial third of the superior nuchal line attaching to the midline of the ligamentum nuchae and to the spinous processes of the first to fifth cervical vertebrae. Distally, it attaches to the outer third of the clavicle by converging laterally. The middle fibres of the trapezius which are nearly horizontal attach to the spinous processes and interspinous ligaments from the sixth cervical vertebra through to the third thoracic vertebrae medially and to the medial margin of the acromion and superior lip of the spine of the scapula laterally. The fan-shaped lower trapezius fibres attach to the spinous processes and interspinous ligaments from approximately the fourth thoracic vertebra through to the twelfth thoracic vertebrae medially and they converge laterally to attach in the region of the tubercle at the medial end of the spine of the scapula slightly lateral to the lower attachment of the levator scapulae muscle.

Innervation: The spinal part of the accessory nerve (cranial nerve XI) innervates the trapezius muscle, this supplies primarily the motor fibres while the sensory fibres to the muscle are innevertaed by the second to fourth cervical nerves.

Function: The upper trapezius muscle functions to draw the clavicle rearwards and raise it by causing rotation of the clavicle at the sternoclavicular joint. The upper trapezius plays a complementary role in assisting the serratus anterior with rotation of the scapula resulting in the glenoid fossa facing superiorly. The middle trapezius adducts the scapula strongly, thereby, stabilising traction forces. The lower trapezius functions to stabilise the scapula while other muscles rotate it.



Figure 2.1: The anatomical structure of the Trapezius Muscle Source: Simons, Travell and Simons, 1999

2.3.2 Physiology of Skeletal Muscle

2.3.2.1 Introduction

Skeletal muscle provides incomparable examples of the interrelationships between structure and function in a biological tissue (Epstein, 1998). The skeletal muscles are the effector organs of the locomotor system and constitute 40% of total muscle mass (Hopkins, 2006). Hopkins (2006) stated the following regarding skeletal muscle: "it is striated due to its striped microscopic appearance which results from the orderly and regularly arranged sub-cellular contractile elements." Regardless of the type of muscle, they share the following basic properties (Gowitzke and Milner, 1988):

- Conductivity: the aptitude of the muscle to generate an action potential.
- Irritability: a muscle responds when stimulated.
- Contractility: the ability of the muscle to shorten or produce tension between its ends.
- Relaxation: After a contraction, a muscle retains its resting properties.
- Distensibility: with the presence of a peripheral force, a muscle has the ability to be stretched. However, if it stretched beyond its physiological limits muscle, the muscle may be injured.
- Elasticity: The muscle resists lengthening and returns to its original position after passive or active lengthening.

According to Hopkins (2006), most skeletal myofibres are innervated at single central swellings of the fibres known as the motor endplates. Regardless of the type of innervation, the charge intensity delivered at the motor nerve terminal is ineffectual to directly excite the much larger myofibres. At the neuromuscular junction, the electrical neuronal impulse is intensified. The resulting generation of the endplate potential is the first step in muscle contraction. According to Epstein (1998), for normal muscle contraction to occur, three individual molecular machinery systems within a muscle have to interact with each other:

- 1. The sarcomere with its interdigitating arrays of protein threads that execute work by creating tension.
- The sarcoplasmic reticulum and T-tubule organisation with their particular membranes that link the electrical signals resulting from neuronal excitation with the contraction of the sarcomeres.
- 3. The membrane-cytoskeleton system that attaches the above stated systems to the plasma membrane and to the extra-cellular protein matrix.

2.3.2.2 Morphology of Skeletal Muscle

Skeletal muscles are made up of bundles of fibres parallel to one another (Zatsiorsky and Prilutsky, 2012) (Figure 2.2). Individual muscle cells or myofibres may cover the entire length of a muscle (McNally, 2006). Each myofiber encompasses threadlike myofibrils (Zatsiorsky and Prilutsky, 2012). Myofibrils are made up of contractile proteins (sarcomeres) and can be isolated from the muscle by removing the overlying plasma membrane (McNally, 2006) and are enclosed by a case of collagenous tissue known as the endomysium (Zatsiorsky and Prilutsky, 2012). Purslow (2010) stated that the endomysium is an incessant web of connective tissue, which splits individual myofibers, and is the only structure that combines myofibres together in the fascicle. Schleip et al. (2013) further stated that with the functional anatomy of the endomysium, there are three distinct structures separating the surface of an individual myofiber from its adjacent neighbouring fiber:

- 1. Attached to the surface of the myofibres is the plasmalemma (plasma membrane) which has a thickness of approximately 9nm.
- 2. Outside the plasmalemma is the endomysial basement membrane which has a thickness of approximately 50nm–70nm comprising two layers viz: the lamina lucida next to the plasma membrane and an outer lamina densa. Individually, each myofiber has its own plasma membrane and basal lamina surrounding it. A third layer is located inside the area between the basal lamina of two neighbouring myofibres.
- 3. The reticular layer, which is a complex of collagen fibrils and collagen fibres in a mucoprotein milieu. The reticular layer forms a continuous network that runs across the whole muscle fascicles.

Schleip et al. (2013) cited Trotter and Purslow (1992) who stated that due to constant changes in muscle length, the thickness of the endomysium varies, becoming thinner as the muscle is expanded and thicker as the muscle length shortens, making the endomysium very accommodating to tensile forces that act inside the plane of the network. Hence, the endomysium can readily distort to follow the length and diameter variations of myofibres during contraction and relaxation of muscles. Therefore, the functional importance of this is that the endomysium provides a shear connection of force from one muscle cell to its adjacent cells in a highly effectual way whilst still being able to distort effortlessly in the plane of the network allowing changes in length and diameter of the myofibres during contraction and relaxation phases (Schleip et al., 2013). Schleip et al. (2013) concluded that the endomysium, therefore, forms a continuous three-dimensional connecting matrix which firmly shear-links neighbouring myofibres together

organising a force transmission within a fascicle and keeping the myofibres fibres in uniform register.

Zatsiorsky and Prilutsky (2012) stated that fascicles are bound within cases of connective tissue called the perimysium. This was further supported by Schleip et al. (2013) who stated that the perimysium is an incessant network of connective tissue, dividing the muscle into myofiber bundles. The quantities and spatial distribution of the perimysium differ more between muscles in the body than those of the endomysium (Schleip et al., 2013). Schleip et al. (2013) cited Lewis and Purslow (1989), who stated that the perimysium does not display high tensile stiffness until it has been stretched to a point where the collagen fibres become orientated in the direction of the force, resulting in it being easily deformed in tension. Therefore, the perimysium can exhibit a high tensile stiffness and resulting in accommodation of higher tensile forces, but only at excessive extensions well beyond the physiological limits in living muscle.

Even though the perimysium tensile characteristics are comparable in nature to those of the endomysium, one would conclude that the perimysium might function similarly to convey the loads produced in the myofiber bundles to their neighbouring bundles via translaminar shear. Schleip et al. (2013) argued that this is unlikely as the force transmission by the perimysium by such a process can be produced in extreme conditions of muscle injury or surgical detachment of the tendinous attachments to some myofibers. Schleip et al. (2013) further argued that with the perimysium being much thicker than the endomysium, distortions which result from shear forces through its thickness would be of orders of scales greater than in the endomysium, and so the perimysium would symbolise a rather sloppy and incompetent force conduction pathway at physiologically-relevant muscle lengths.

Schleip et al. (2013) stated that each singular muscle is enveloped by the epimysium, which is a dense connective tissue layer, which is the outer most layer that is incessant with the tendons that attach the muscle to the bones (Schleip et al., 2013). The epimysium in some muscles has the form of dense fascia (Mense, Simons and Russell, 2001).



Figure 2.2: Organisation of skeletal muscle Source: Whiting and Rugg, 2006

Sarcomeres are the contractile unit of muscle. The sarcomere possesses three crucial properties which are important to its function:

- 1. Its ability to swiftly and efficiently shorten;
- 2. Its ability to be stimulated on and off in milliseconds; and
- 3. Its ability to self-assemble and structurally assimilate (Craig and Padrón, 2004)

According to Craig and Padrón (2004), the above properties are best understood in terms of the structures and interactions of the sarcomeres constituent proteins, which can be divided into three important functional classes i.e. contractile, regulatory and structural. The contractile proteins are made up of myosin and actin which accumulate creating polymeric filaments that interrelate with each other resulting in force generation and shortening. The regulatory proteins are the tropomyosin and troponin which join to the actin and control the actin-myosin interaction. During development of the sarcomere, the structure of the sarcomere is integrated and stabilised using a variety of structural proteins that create an association with the actin and myosin filaments (Craig and Padrón, 2004).

Skeletal muscle is striated due to the sarcomeres that are the physical basis of interchanging dark (A bands) and light (I bands) visible in polarised light microscopy (Epstein, 1998). Clark et al. (2002) further added that the light band is known as the I-band because of its isotropic appearance in polarised light; the dark band is known as the A-band because its anisotropic appearance. The

A-band consists of bipolar thick filaments comprising myosin and associated proteins (Clark et al., 2002). Within the myosin filament of skeletal muscle, myosin is the fundamental protein and each filament is made up of about 300 myosin molecules (Epstein, 1998), making it the motor protein of the sarcomere (Clark et al., 2002). Each individual myosin protein has two binding sites i.e. a primary nucleotide binding site which binds with adenosine triphosphate (ATP) or adenosine diphosphate (ADP) and a secondary site which binds with actin (Kostopoulos and Rizopoulos, 2001). Within the actin filament of skeletal muscle, actin is the fundamental protein (Epstein, 1998). This was further supported by Craig and Padrón (2002) who stated that in skeletal muscle, actin is the most abundant protein. Within each sarcomere, multiple myosin and actin filaments are aligned in a regular arrangement with the myosin arranged centrally and bordered on each side by actin filament arrays (Epstein, 1998). The myosin organisations are cross-linked in their innermost zone by M-structures and the actin filaments are cross-linked by Z-structures at their distal ends (Epstein, 1998). Epstein (1998) further stated that, for each of the myofibrils within the fibres and for each sarcomere unit, there is a sheath of membrane which is linked via the Ttubules to the external plasma membrane called the sarcoplasmic reticulum. This is further supported by Gatterman (1990), who stated that the sarcoplasmic reticulum is an extensive branching and anastomosing channel filling most of the space between the myofibrils. The sarcoplasmic reticulum consists of terminal cisternae, which are situated at the level of the overlapping A, and I bands. These cisternae store extra calcium which is required to initiate a muscle contraction and will reabsorb free calcium if contraction is not required (Simons, Travell and Simons, 1999). This is achieved by means of the calcium pump (Baldry Yunus and Inanici, 2001). According to Mense and Simons (2001), the signals for the filaments to shorten the sarcomere by gliding opposite one another is due to a proliferation of intercellular calcium concentration resulting in a contraction. According to Epstein (1998), the calcium pump transports calcium from the myofibril to the lumen of the sarcoplasmic reticulum. Calcium is then discharged from the sarcoplasmic reticulum that encloses each individual myofibril when a proliferated action potential reaches it from the surface of the cell through T-tubules (Simons, Travell and Simons, 1999).

2.3.2.3 The Motor Unit

Simons, Travell and Simons (1999) defined motor units as the final pathway via which the central nervous system regulates voluntary muscular activity. This was further supported by Purves (2001) who stated that a motor unit is made up of a motor neuron and the associated skeletal myofibres it innervates. Purves (2001) added that most developed skeletal myofibres are

innervated by only a single alpha motor neuron, therefore, founding an important relationship between an alpha motor neuron and the myofiber it supplies. According to Simons, Travell and Simons (1999), a motor unit is comprised of the cell body of an alpha-motor neuron found within the anterior horn of the spinal cord, its axon and the multiple end plates where each nerve branch ends on one myofiber (Figure 2.3). According to Bron and Dommerholt (2011), smaller motor units have a smaller alpha-motor neuron cell body, smaller axons and fewer muscle fibers to activate compared with larger ones.

Simons, Travell and Simons (1999) further stated that palpable taut bands are located within the motor unit, which are characteristic of how MFTPs are formed and may vary in size depending on the homogeneity of the muscle fiber density inside the motor unit.

The terminal nerve fiber of the motor-neuron is connected to a myofiber by the motor endplate. This is where the synapse is located and where the conversion of nerve fiber's electrical signal into a chemical messenger called acetylcholine (ACh) occurs. This in turn starts another electrical impulse in the myolemma of the myofiber (Simons, Travell and Simons, 1999).

Understanding the locale of the motor endplates is of great importance for the clinical diagnosis and management of MFTPs. Simons, Travell and Simons (1999) further stated that the pathophysiology of MFTPs is closely related to endplates, with MFTPs most likely to be located only where there are motor endplates. The motor endplate is most commonly located at the center of the myofiber, mid-way between its attachments (Simons, Travell and Simons, 1999). The motor endplate is a complex of the myoneural junction, which is made up of the synaptic terminal that releases ACh, the synaptic cleft and the postsynaptic muscle membrane (Simons, 2001). This is the region where the palpable muscle twitch can be elicited (Simons, Travell and Simons, 1999).



Figure 2.3: Schematic of a motor unit Source: Simons, Travell and Simons, 1999

2.3.2.4 Muscle Spindle

The muscle spindle (MS) is located within most striated skeletal muscle and is a highly specialised sensory organ, supplying mechanosensory information on muscle length. This sensory information is regulated by the gamma motor neurons which set the intrafusal muscle fibres to an appropriate length. Alpha motor neurons are the second type of lower motor neurons, which innervate the extrafusal muscle fibres (Purves, 2001). Muscle spindles respond to active and passive muscle stretch sending their excitatory impulses to the homonymous alpha motor neurons in the anterior horn resulting in a contraction of homonymous extrafusal muscle fibres, therefore, inducing a localised twitch response (FitzGerald, Gruener and Mtui, 2012).

The MS mainly comprises approximately four to eight specialised intrafusal myofibers which are enclosed within a case of connective tissue. The intrafusal myofibres assume a parallel arrangement within the skeletal muscle and are distributed among the extrafusal fibres which are responsible for the force generation required for posture and movement (Purves, 2001).

The response of the muscle spindles to length and to velocity of lengthening can to some extent be altered independently by fusimotor activity (Jansen, 1966). Intrafusal muscle shortening is probably associated with static fusimotor activation whilst dynamic fusimotor activation is responsible for the maintenance of spindle dynamic sensitivity (Allen, Ansems, and Proske, 2007). Various studies have demonstrated the effects of fusimotor activity on muscle spindle fibres (Goodwin, Hulliger and Matthews, 1975; Hulliger, Matthews and Noth, 1977). Co-activation of the skeletomotor and fusimotor neurons results in the voluntary contraction of a muscle (Vallbo, 1971).

2.3.2.5 Stimulation of Muscle contraction

Upon arrival of an action potential at the neuromuscular junction, molecules of ACh are produced by the nerve terminal. This response of the terminal neuron is due to opening of the voltage-gated channels, allowing ionised calcium to be transported from the synaptic cleft into the nerve terminal. The ionised charges reduce the negative membrane potential and instigate a large number of short-lasting postsynaptic action potentials (Mense and Simons, 2001), enough for the post-junctional membrane to reach its threshold for excitation resulting in a contraction (Simons, Travell and Simons, 1999).

2.4 MYOFASCIAL TRIGGER POINTS

Simons, Travell and Simons (1999) classically describe MFTPs as "hyperirritable spots located within skeletal muscle that are associated with palpable nodules in taut bands. The spots are tender on compression and can result in characteristic referred pain, referred tenderness, motor dysfunction and autonomic phenomena." Types of MFTPs include: active, associated, attachment, central, key, latent, primary and satellite (Simons, Travell and Simons, 1999).

Simons, Travell and Simons (1999) define an active MFTP as a clinical pain complaint that is constantly painful, preventing maximum elongation of the muscle, weakening the muscle, referring a patient-recognised pain pattern on direct compression and facilitating a local twitch response (LTR). When adequately stimulated and compressed within the patient's pain tolerance,

an active MFTP results in referred motor phenomena and frequently autonomic phenomena, generally within its pain reference zone, which results in soreness (Simons, Travell and Simons, 1999).

An associated MFTP is a TP that is located within a muscle that occurs concomitantly with a MFTP located in another muscle (Simons, Travell and Simons, 1999).

Simons, Travell and Simons (1999) described a latent MFTP as a TP that is clinically silent concerning unprompted pain; hence, it is only reproduces pain upon palpation. A latent TP may comprise of all the other clinical features of an active TP and always has a taut band which increases muscle tension and restricts ROM.

Simons, Travell and Simons (1999) defined a satellite MFTP as a central MFTP that was prompted neurogenically or mechanically by the presence of an active MFTP.

2.5 ETIOLOGY OF MFTPS

Conclusive results are still lacking with respect to the basis of MFTPs and, thus, that of MPS, however, substantial progress has been made in the classification of a number of features of these triggers. Probable theories have been raised to account for the development and tenacity of MFTPs (Srbely, 2010). Clinical and research evidence (Reitinger et al., 1996; Windisch et al., 1999; Mense, 2003; Shah et al., 2005; Kuan et al., 2007; Niddam et al., 2007) suggests that the MFTP phenomenon occurs initially as a neuromuscular dysfunction arising from muscle overexertion (Simons, 1983; Shah et al., 2008). Active MFTPs then advance at an inconsistent rate to a dystrophic phase with evident pathological changes (Bengtsson, Henriksson and Larsson, 1986).

The sensitive local tenderness of the MFTP is best explained by nerve ending sensitisation of muscle group III and group IV nociceptors (Simons, 1983). Simons (1983) cited Perl (1976) who stated that sensitisation is evidently one mechanism accounting for the tenderness and pain associated with tissue damage and the inflammatory processes. Impulsive firing within a nerve that is not impulsively active can be induced through sensitisation of an afferent nerve, for example, C-fiber polymodal nociceptor that induces the nerve to react at a lessened threshold to increase its response to a given applied stimulus (Perl, 1976).

Substances such as serotonin, potassium, prostaglandins, bradykinin, histamine, substance P and leukotrienes are known to sensitise tissues (Simons, 1983). This was further supported by

Shah et al. (2008), who found elevated noxious substance levels to be consistently and significantly greater in active MFTPs than in latent MFTPs. Frost (1986) conducted a study which associated prostaglandin as a sensitising agent in MFTPs. Awad (1973) conducted a study in which sensitive nodular areas in the trapezius, triceps brachii or quadriceps femoris muscles of 10 subjects were biopsied, electron microscopic examination revealed discharging mast cells and large clusters of blood platelets, which can be sources of seanalysisnsitising agents histamine and serotonin, respectively (Simons, 1983).

Sensitised group III and IV nociceptor muscle afferents are also capable of generating nerve action potentials that can be misinterpreted by the brain and projected as referred pain and tenderness (Simons, 1983). The nerves that facilitate local discomfort at the MFTPs may or may not be the same nerves that initiate referred phenomena with at least four physiological mechanisms possibly explaining referred pain from MFTPs:

1) Convergence projection

With pain being referred by the convergence-projection method, a solitary cell within the spinal cord accepts nociceptive information through nerves arising from a visceral organ and through other nerves arising from the skin and/or muscle (Simons, 1983). Simons (1983) went on to further state that, since the brain is unable to differentiate whether the nociceptive input arises from the somatic structures or from the visceral organs, according to this method, the brain processes this information as if it is arising from the skin or muscles instead of the actual internal organ. Thus, the MFTP activity within the affected muscle would relate to the visceral pain information and be recognized as arising from the nerves innervating the skin and the associated subcutaneous tissues located within the reference zone (Simons, 1983).

2) Convergence-facilitation

With pain being referred by the convergence-facilitation method, circumstantial signals from the reference zone on the spinothalamic tract are significantly increased by the amplified activity originating from the visceral source or from a MFTP.

3) Peripheral branching of primary afferent nociceptors

This is associated with axon bifurcation of a single sensory nerve to different areas of the body. Because of this, the brain could simply misconstrue the source of information. Therefore, impulses that originate from a nerve ending located in an area of the body can be misconstrued as arising from a different area of the body.

4) Activity of sympathetic nerves (Simons, 1983)

Activation of sympathetic nerves may facilitate the occurrence of referred pain arising from TPs due to release of substances resulting in the sensitisation of principle afferent endings in the region of the referred pain.

The palpable physiognomies of the taut band are best described by contraction of the sarcomeres of the myofibres comprising the taut band (Simons and Travell, 1981). The LTR is a unique characteristic of the palpable taut band, which is frequently associated with a MFTP (Simons, 1983). The LTR causes an increase in ACh release from the presynaptic terminal bouton at the neuromuscular junction causing ACh vesicle depletion with consequent spontaneous electrical activity reduction, which causes the active MFTP (Dommerholt and Fernández-de-las-Peñas, 2013). Simons (1983) added that motor neurons innervating muscles located within the reference zone demonstrate an increase in spontaneous background activity and amplified impulsiveness throughout voluntary activity; this can however, be regarded as a form of spasm. In addition, other muscles adjacent to the affected muscle are likely to display protective splinting or spasm, which may also be quantified as electromyographic activity (Simons, 1983). To accommodate for the shortened sarcomeres at the MFTP, the sarcomeres distant from the MFTP close to the musculotendinous junction would elongate more than the regular length of sarcomeres evident in a normal myofiber (Simons, 1983) (Figure 2.4).



UNIFORM SARCOMERE LENGTH

Figure 2.4: Schematic of sarcomeres depicting changes in sarcomere length due to MFTPs Source: Simons, 1983

According to Simons (1983), McArdle's disease also known as Glycogen storage disease type V and rigor mortis are the two recognised physiological mechanisms which can clarify the shortening of sarcomeres without physiological contracture. Simons (1983) further stated with the McArdle's disease model appears to be the more likely mechanism. The following hypothesis can thus be used to clarify the clinical phenomena associated with MFTPs. Because of a forceful coordination between actin and myosin filaments, contraction of striated skeletal muscle occurs. This contraction process is normally initiated due to the presence of an action potential, which results in release of ionic calcium from the sarcoplastic reticulum. The contraction continues until the calcium returns to the sarcoplastic reticulum. This process is regulated by the calcium pump and requires the high-energy phosphate, ATP (Hoyle, 1983). There is absence of phosphorylase or phosphofructokinase 97, which is evident in McArdle's disease, causing symptoms of painful muscle contracture with exercise (Rowland, 1965). This can also occur due to rupture of the sarcoplasmic reticulum because of stress overload of the muscle resulting in release of calcium with no instant mechanism for recuperating it (Simons, 1983). Simons (1983) concluded that this method explains why prolonged voluntary contraction, particularly with the muscle in a contracted position, or recurrently repetitive contraction without appropriate intervening rest periods is the most probable mechanism to activate latent MFTPs and to perpetuate active MFTPs.

The MFTP is an area of metabolic distress that has previously lacked energy. The metabolic dysfunction could explain the local generation of sensitisation (Simons, 1983). Simons (1983) further concluded that MFTP could be viewed as an area of metabolic distress due to the amalgamation of elevated energy requirement and deficiency of oxygen and energy distribution, possibly due to limited circulation locally. This combination could result in a self-sustaining energy crisis cycle (Simons, 1983). This was further supported by Hong (2002) who stated that the resulting elevation in energy depletion by the myofibres and decreased energy supply to the myofibres results in a local energy crisis evidenced by severe localised hypoxia (Figure 2.5).

TAUT BAND FORMATION



Figure 2.5: Schematic of a cycle of events that could maintain sarcomere shortening Source: Hong, 2002

These biochemical alterations effusively clarify the local sensitivity and pain arising from MFTPs (Simons, 2008). These changes aid the previous finding by Brückle (1989), who stated that within the vicinity of a MFTP, severe hypoxia occurs as a result of a combination of the ischemia demonstrated in biopsies by Fassbender (1975) and the amplified energy stress from the sarcomere shortening of taut bands resulting in development of a local energy crisis (Simons, 2008).

Aberration of the motor endplate complex of the myoneural intersection, which is made up of the synaptic terminal that discharges ACh, the synaptic cleft and the postsynaptic muscle membrane, is likely to result in MFTP development (Figure 2.6). An excessive release of ACh is believed to be accountable for the occurrence of an abnormal endplate noise that is associated with dysfunctional motor end plates (Simons, 2001). Chen and Grinnell (1997) demonstrated that a 1% increase in muscle elongation at the motor endplate resulted in a 10% increase in ACh discharge. Dysfunctional motor endplates are found in an uneven distribution in myofascial taut bands (Simons, 1995) and may be the fundamental irregularity that affects the occurrence of taut bands by triggering principal areas of sarcolemma shortening within the myofiber (Mense, Simons and Russell, 2001).



Figure 2.6: The motor endplate – proposed site of TP dysfunction Source: McPartland and Simons, 2006

2.6 CLINICAL FEATURES

2.6.1 Symptoms

Myofascial pain syndrome classically presents as a profound somatic pain, which is tensile, constrictive or cramp-like, impartially distinguishable, variable in severity, with abrupt or continuing onset, constant or sporadic, existing at rest or arising upon movement (Gerwin, 1999). Patients presenting with MPS often describe pain or discomfort varying from a trivial ache to an agonizing pain, which is perceived either as sharp or dull in character, which is often associated with generalized fatigue, reduced ROM and reduced muscle strength (Han and Harrison, 1997). The myofascial pain is often referred to a distance from the MFTP in an outline that is typical for each individual muscle. Occasionally, the patient is conscious of unresponsiveness or paresthesia rather than the actual pain (Simons, Travell and Simons, 1999).

Concerning this study, only the upper trapezius MFTPs pain referral patterns of are of concern. These include MFTP 1 and MFTP 2. Their respective pain referral patterns are as follows:

MFTP 1 – the pain referral pattern of this MFTP is frequently one-sided and upwards along the postero-lateral area of the neck towards the mastoid process. When the pain is extreme, it extends towards the lateral aspect of the head, centring in the temple, back of
the orbit, and may incorporate the angle of the jaw; pain may also extend to the occiput depending on severity (Travell and Simons, 1983).

MFTP 2 – Its pain referral pattern of this lies marginally posterior to the principal cervical reference zone of MFTP 1, amalgamating with its distribution towards the ear posteriorly (Travell and Simons, 1983).

2.6.2 Signs

Upon examination of a patient experiencing MPS, specific physical findings are essential before an appropriate diagnosis can be made. According to Simons (1983), clinically, whenever the tautness is amplified inside the fibres of the taut band, the patient is subjected to pain. This can be accomplished in the following ways:

- 1) Application of an inert stretch beyond the slack position of the muscle
- 2) Strongly contracting the muscle voluntarily
- 3) Application of pressure to the MFTP area

Efforts to swiftly elongate the muscle inertly or aggressively to its full ROM would result in a significant amount of pain that the individual will experience as excruciating (Simons, 1983).

The most distinctive substantial sign evident in MPS is the presence of MFTPs (Simons, Travell and Simons, 1999; Hou et al., 2002).

Simons, Travell and Simons (1999) and Gatterman (1990) list the distinctive indications of active MFTPs on patient assessment:

- Results in a clinical pain complaint.
- On palpation, the muscles neighbouring the active MFTPs may also feel taut and tender.
- Arbitrates a LTR of myofibres when sufficiently stimulated.
- ✤ A jump sign is generally elicited.
- Because of the muscle being constantly tender, their ability to fully lengthen is reduced, thus weakening the muscle.
- Direct palpation refers pain that is recognised by the patient.
- Motor phenomena and often autonomic phenomena occur when the MFTP is compacted within the patient's pain lenience. This usually occurs within the MFTP's zone of pain referral.
- An autonomic phenomena provoked in the referral zone consists of amplified vasomotor activity, coryza, sudomotor activity, lacrimation and pilomotor reaction (goose flesh).

2.7 DIAGNOSIS

Myofascial trigger point diagnosis requires sufficient distinctive skill, training and clinical experience to acquire a higher degree of reliability in the examination (Gerwin, 1999). Criteria that are accessible for diagnosis of MPS are purely clinical; consequently, clinical history taking and physical assessment seem to be decisive in the classification of this syndrome (Simons, Travell and Simons, 1999).

Simons, Travell and Simons (1999) define specific criteria for the examination and diagnosis of MFTPs:

- A taut band A taut band is located either by using flat or pincer palpation on a muscle that is slightly elongated (this slight stretch must not evoke or worsen pain).
- Local twitch response A spontaneous local twitch is produced when a portion of the muscle containing the MFTP is palpated under the fingers.
- Jump sign When adequate pressure is applied to a MFTP, the behavioral response may be withdrawal or a verbal response. This is characteristic of MPS.
- Referred pain Pressure applied to an active MFTP generates local pain over the tender spot as well as referred pain in a pattern distinctive of the muscle.

Schneider (1994) recommended a set of diagnostic criteria for active MFTPs associated with MPS (Table 2.1).

| Major Criteria | Minor Criteria |
|--|--|
| Regional pain complaint. | Compression of the MFTP nodule reproduces the clinical pain complaint. |
| Pain referral pattern in the predicted distribution of muscular referred pain. | LTR reproduced by either snapping palpation or injection of the tender spot. |
| Palpable taut band in accessible muscles. | Pain that is lessened or reduced by muscular therapy e.g. stretch, IC or needle injection of the MFTP. |

Table 2.1:Diagnostic criteria for active MFTPs associated with MPS

Exquisite tenderness at one point within a taut band. Some degree of decreased ROM or trivial muscle weakness.

To effectively diagnose MPS, all of the above mentioned five major criteria should be evident and at least one of the three minor criteria should be present.

Simons, Travell and Simons (1999) and Gerwin et al. (1997) recommended that the minimum acceptable criteria for active MFTP diagnosis is the combination of the presence of spot tenderness in a palpable taut band in a skeletal muscle and patient acknowledgement of referred pain that is provoked by pressure applied to the tender spot.

The above mentioned criteria are predominantly evaluated via palpation of the involved muscles. The application of a constant profound physical pressure is the most often utilised clinical technique in the diagnosis of MFTPs. Upon palpation of MFTPs, the pain produced is localised either in the MFTP area or along the muscle's definite pain referral pattern, which is persistent, clinically reproducible and does not follow a dermatomal or nerve distribution (Han, 1997).

2.8 CONFIRMATORY DIAGNOSIS

There are generally no recognised laboratory tests or instrumental investigations that are investigative of MFTPs and thus, of MPS. To date, the diagnosis of MPS remains completely centred on clinical examination findings, though a number of changes can be detected with numerous instrumental assessments and can be considered as positive findings (Mense, Simons and Russell 2001).

Surface electromyography (EMG) recognises MFTPs by documenting the continuous low amplitude action potentials, disrupted by elevated voltage spikes of EMG activity of MFTPs within the muscles which are generally not found at other non-tender sites (Hong, 1998). Mense, Simons and Russell (2001) further supported this by stating that EMG findings suggested that the muscles harbouring active MFTPs are primarily fatigued, exhausts more quickly and earlier than healthier muscles.

Several research studies (Diakow, 1988; Diakow, 1992; Kruse and Christiansen, 1992) have recorded a thermographic hot-spot area in the skin overlying the MFTP. However, locating a hot spot on the thermogram is not decisive to the identification of an underlying MFTP because

comparable temperature variations can be expected in other pain conditions such as radiculopathy, articular dysfunction or subcutaneous inflammation (Giamberardino et al., 2011).

For the purposes of this study, the palpatory diagnosis was used as it is a pragmatic way which has been validated as a dependable and effective method of patient examination concerning MPS (Hsieh et al., 2000). Similar to Shacksnovis (2005), the application of thermography and EMG in this study was not possible based on the fact that this study was conceptualised in order to discover a time effective, cheaper and more effective treatment for MFTPs for chiropractors in the field, which would not be complemented by the use of assessment modalities that do not conform to the same criteria.

2.9 TREATMENT

Early management of MFTPs in MPS requires identification of the MFTPs, treatment of the MFTPs and remedial action to avert recurrence (Gerwin, 1991). Therapy is intended to relieve pain and to reestablish normal function of the affected muscle (Simons, Travell and Simons, 1999).

Because of a vast quantity of research, a considerable number of alternative treatment techniques have demonstrated to be clinically efficient in the treatment of MFTPs. These treatment techniques are outlined in Table 2.2.

| Table 2.2: Therapies used for the treatment of MFTPS in | I MPS | | |
|--|--|--|--|
| Invasive | Non-Invasive | | |
| Dry needling (Lewit, 1979; Hong, 1994; Alvarez and Rockwell, 2002; Edwards and Knowles, 2003). | Ischaemic compression (Mance et al., 1986; Hanten et al., 2000; Hou et al., 2002; Fernández-de-las-Peñas et al., 2006b). | | |
| Injection with anesthetic (Simons, Travell and Simons, 1999). | Myofascial manipulation (Cantu and Grodin, 2001; Schleip, 2003) | | |
| Injection with non-steroidal anti-inflammatory (Simons, Travell and Simons, 1999; Bogduk, 2003). | Spray and stretch (Han, 1997) | | |
| Injection with steroidal anti-inflammatory (Simons, Travell and Simons, 1999). | Ultrasound (Gam et al., 1998: | | |
| Injection of Botulinum A Toxin (Porta, 2000) | Transcutaneous electrical nerve stimulation (Han, 1997) | | |
| | Soft tissue massage (van den Dolder and Roberts, 2003; Hong et al., 1993) | | |
| | Laser therapy (et al., 2007; Altan et al., 2005) | | |
| | Magnet therapies (Brown et al., 2002) | | |
| | Activator instrument therapy (Gemmell and Allen, 2008) | | |
| | | | |

Table 2.2: Therapies used for the treatment of METPs in MPS

Although IC and IAI therapy have been classified as non-invasive therapies, there are discrepancies with regards to the two therapies, which include:

- Pain and discomfort experienced by the patient during application of treatment.
- The mechanism in which the therapy is applied (i.e. duration of therapy application and method).
- The suggested changes at the muscular level with regards to how the therapy is applied (Schneider, 1996).

The two therapies used have dissimilar mechanisms of actions, which will be deliberated below.

2.9.1 **Ischaemic Compression**

Ischaemic compression can be described as application of gradually increasing, non-painful force over a MFTP until a barrier of tissue resistance is encountered with contact being sustained until release of the tissue barrier and the compressive pressure is amplified to reach a new barrier to reduce the tautness and sensitivity of the MFTP (Simons, Travell and Simons, 1999). This was in contrast to Fryer and Hodgson (2005), who stated that with sustained manual pressure over the MFTP; irritation and increased MFTPs sensitivity may likely occur.

Schneider (1994) hypothesised that the therapeutic advantage of IC may be the result of the following:

- Localised stretch: IC is characterised as a type of intense, precise localised lengthening of the actin and myosin fibres of the taut band, therefore, it is hypothesized that severance of the actin and myosin cross fiber links results from the application of manual pressure over the taut band.
- Nerve block: it is proposed that short-term interruption of the reflex motor neuron activity by blocking incoming sensory input occurs as a result of application of deep pressure. It is also postulated that in the presence of oxygen, propagation of action potentials occur and that the ischaemia produced by prolonged pressure inhibits this.
- Reflex vasodilation: succeeding initial blanching and ischaemia, the involved muscle area experiences a reflex vasodilation, which conveys fresh blood, transporting oxygen and ATP to the area, which flushes away end product metabolites and substances that sustain muscle contraction.
- Hyper-stimulation analgesia: it is postulated that severe pain resulting from deep continual pressure that is associated with IC, results in discharge of endorphins by the dorsal horn.

Ischaemic compression is one of the most frequently used therapies for the treatment of MFTPs (Montanez-Aguilera et al., 2010). Various studies have tested the efficacy of IC (Hains, 2002; 2009; Hou et al., 2002; Fryer and Hodgson, 2005; Aguilera, 2009). Gemmell and Allen (2008) demonstrated in a study comparing IC to sham ultrasound that a solitary treatment of IC to an active upper trapezius MFTP was effective in patients complaining of non-specific neck pain, therefore, it was shown to be an effective treatment for MPS. In that study, the odds ratio for improvement with IC compared to sham ultrasound was 5.01 (95% CI 1.19—21.06). In a systemic review by Vernon and Schneider (2009), relatively strong evidence supported manipulation and IC for immediate pain relief of MFTPs, but inadequate evidence exists for long-term pain relief of MFTPs. A study conducted by Ferna ndez-de-las-Pen are et al., (2006b) comparing IC to transverse friction massage in 40 subjects with MFTPs in the upper trapezius muscle demonstrated significant improvement in pain pressure threshold within two minutes in both groups with no distinctions found between the groups.

2.9.2 Impulse iQ[®] Adjusting Instrument (IAI)

The IAI is a new manual therapy device used for a variety of musculoskeletal conditions. The IAI is used for the delivery of manipulation and mobilisation to the musculoskeletal system (Colloca et al., 2005). The IAI delivers multiple thrusts and provides a wide range of forces that have been shown to improve spinal motion responses when compared to the Activator instruments (Colloca et al., 2005). The IAI is hypothesized to treat different areas of the body including joints, muscles and nerves in order to relieve pain and restore functioning (www.impulseseminars.com/impulse). The IAI has three different force settings (low [100 N], medium [200 N] and high [400 N]) for different areas of the body and to treat patients of all ages. The precise low force thrust of IAI makes the treatment to be more comfortable, thus, reducing the occurrence of post-treatment discomfort (www.impulseseminars.com/impulseiq).

The IAI exploits a microprocessor-controlled electromagnetic coil to generate a haversine-like impulse, approximately two milliseconds in duration (Colloca et al., 2005). Haversine impulse profiles result in the deliverance of uniform mechanical energy to the test structures over a comprehensive frequency range, ranging from 0 to 200Hz (Colloca et al., 2005). Implanted inside the IAI is a motion sensor and a micro-computer which monitors alterations in movement and the frequency of the movement is ascertained in real-time by the acceleration responses acquired from the spine. As the tissue ricochets during the therapy application, information is delivered into the micro-computer and the Auto-sense[®] technology adjusts the frequency of succeeding thrusts. In this manner, the acceleration response is continuously monitored during treatment and adjusting terminates automatically when motion is maximised in an effort to control treatment dosage (http://impulseseminars.com/impulseiq).

Although basic scientific research has demonstrated biomechanical and neurophysiological responses associated with its use (Colloca et al., 2005), little clinical research exists on its use and its effectiveness on MPS. A recent study by Gemmell and Allen (2008), which is the closest study to the IAI, examined the effect of activator TP therapy on upper trapezius MFTPs and found a seven-fold decrease of pain reduction in patients receiving the mechanically-assisted thrusts of an activator device when compared to myofascial band therapy or sham ultrasound (p > 0.05) (95% CI: 1.23-45.08). The number of treatments required for activator TP therapy for one patient to improve was three (Gemmell and Allen, 2008). However, in this study, the activator instrument was not used in accordance with activator method protocols by Fuhr (2008), as device usage was not limited to a single thrust. The device was used to deliver ten repetitive 170 Newton thrusts over a period of ten seconds (Gemmell and Allen, 2008).

There is a paucity in the literature and according to the researcher's knowledge, there are no studies comparing the effectiveness of the IAI device in the treatment of MFTPs. Therefore, the aim of this study is to determine the effectiveness of the IAI compared to IC in the treatment of MFTPs found in the upper trapezius muscle in patients with non-specific neck pain in terms of objective and subjective clinical findings.

CHAPTER 3 : METHODOLOGY

3.1 STUDY DESIGN

This study was designed as a prospective randomised, single-blinded clinical trial.

3.2 SAMPLING

3.2.1 Population

The study population consisted of participants residing in the eThekwini municipality who met the inclusion criteria.

3.2.2 Recruitment

Advertisements (Appendix A) were placed on the notice boards at the Durban University of Technology (DUT) (all campuses and residents); Chiropractic Day Clinic (CDC), around the DUT Berea and City campuses, Spar supermarkets (the free advertisement boards) after permission had been granted by the relevant authorities. Prospective participants were requested to contact the researcher telephonically for more information.

All prospective participants who contacted the researcher telephonically were informed that this was a preliminary selection and further inclusion/exclusion criteria were to be applied after the telephonic communication as well as after the first consultation. The prospective participants were then asked certain questions to determine qualification for the study, as listed in Table 3.1.

Table 3.1: Questions to determine qualification for the study

| QUESTIONS ASKED | EXPECTED ANSWERS |
|---|---------------------|
| "May I ask you some questions which will help me to determine if you are eligible to partake in my study?" | Yes |
| "How old are you?" | 20-50 |
| "For how long have you experienced neck pain?" | 1-12 weeks |
| "Where is your pain located?" | Lower neck region |
| "Do you have any recent history of trauma?" | No |
| "Are you currently taking any anti-inflammatory medication?" | No |
| "Are you currently taking any blood thinning medications?" | No |

If any participant answered yes to history of trauma and taking any medication for pain relief or blood thinning they were automatically excluded.

3.2.3 Sample Size

The study required 40 participants, who were then randomly allocated into two groups of 20 i.e. IC Group and IAI Group.

3.2.4 Sample Allocation

Participants were randomised using concealed allocation by a computer-generated list, which was maintained at the reception so that the researcher was blinded to the treatment allocation of any participant. The clinic receptionist allocated interventions via opaque sealed envelopes marked according to the allocation schedule (Rompe et al., 2007). Each participant, therefore, had an equal opportunity of being in either group.

3.3 RESEARCH - PARTICIPANT PROCEDURE

Participants voluntarily agreed to participate in the study. All participants had to read a letter of information and sign a letter of informed consent (Appendix B) before being allowed to partake in the study. An opportunity to ask the researcher any questions regarding the research procedure was provided for each participant.

3.3.1 Research - Participant Assessment

Prospective participants were then screened for research compliance by means of completing a consultation consisting of a case history (Appendix C), a physical examination (Appendix D) and a cervical spine orthopedic examination (Appendix E), to determine if they met the study's inclusion criteria.

3.4 INCLUSION AND EXCLUSION CRITERIA

3.4.1 Inclusion Criteria

- Participants were between 20 and 50 years of age (Berry, 2006). With respect to age, Simons, Travell and Simons (1999) indicated that individuals during their mature years (31-50) are most likely to experience MPS. However, MPS does occur in younger individuals. The above statistics supported the current age group restrictions which were set for this study.
- Fluency in verbal or written English language.
- Diagnosis of non-specific neck pain (> 4 weeks duration) of at least four on an 11-point Numerical Pain Rating Scale 101 (NRS 101) (to maintain sample homogeneity) (Gemmell and Allen, 2008) with associated MPS of the upper trapezius. This was applied during the telephonic screening and initial consultation.
- Participants were diagnosed with an active MFTP 1 or MFTP 2 in the upper trapezius muscle fibres. To diagnose an active MFTP, one looks for the following characteristics (as stated in Travell and Simons, 1983):
 - A history of abrupt onset resulting from acute overload demand, or a history of gradual onset with prolonged overload to the affected muscle.
 - Distinctive MFTPs pain referral patterns that are specific to individual muscles.
 - ✤ Affected muscles show weakness and decreased stretch ROM of the.
 - Upon palpation, a taut band is evident in affected muscles.
 - Discriminating, focal sensitivity to digital pressure (the MFTP), in the band of taut muscle fibres.
 - ✤ A LTR that is elicited by either snapping palpation or needling of the sensitive spot.

Pain referral to the referral zone specific to the muscle involved.

This was applied during the initial consultation.

3.4.2 Exclusion Criteria

- Participants who were on taking oral non-steroidal anti-inflammatory drug/s were required to
 partake in a three-day wash out period before being allowed to participate in the study
 (Bekker-Smith, 2003). Participants advised not to receive any form of treatment for MPS for
 the duration of the research to minimise bias within the study. This included allopathic,
 homeopathic or any other form of medicine and any form of manual therapy. Participants who
 that felt they could not adhere to the above, were excluded from the study. This was applied
 during the telephonic screening and again at the initial consultation.
- Participants who refused to sign the informed consent form (Appendix B).
- Participants who exhibited signs of fibromyalgia syndrome (Schneider, 1994). Patients diagnosed with fibromyalgia syndrome often present with symptoms suggestive of different diagnoses that include peripheral neuropathy, polymyalgia, spondylitis, early systemic lupus erythematosus, metabolic myopathy, early rheumatoid arthritis or chronic fatigue syndrome (Bennett, 1989). Patients with fibromyalgia syndrome often have a history of extensive pain for at least three months duration (pain present bilaterally, above and below the waist), found in at least 11 of the 18 tender sites on digital palpation (Schneider, 1994). This was assessed for during the initial consultation.
- Participants experiencing neck or shoulder pain arising from TPs other than those incorporated in the study.
- Participants who displayed any of the following contra-indications to myofascial manipulation therapy as recommended by Nook (1998):
 - Vascular compromise;
 - Use of anticoagulants and haemophiliacs;
 - Severe diabetes with associated peripheral neuropathy;
 - Sensory deficit; and
 - Infection which can either be local or systemic.

3.5 LOCATION AND DIAGNOSIS OF MFTP'S IN THE UPPER TRAPEZIUS MUSCLE

The upper trapezius is identified as an impulsive muscle and EMG studies revealed that though there is no atypical motor unit activity occurring at rest; when it harbouring MFTPs, it tended to "overreact" during voluntary contraction (Basler, Keller and Herda, 1997). There are two regions in which MFTPs are present in the upper trapezius muscle fibres viz MFTP 1 and MFTP 2 (Simons, Travell and Simons, 1999).

MFTP 1 can be located within the central part of the anterior margin of the upper trapezius and includes the majority of the vertical fibres that attach to the clavicle anteriorly and is located by pincer palpation of the free boarder of the upper trapezius muscle fibers, approximately halfway between the spinous processes and the acromion, in the anterior fibres, as depicted in Figure 3.1.



Figure 3.1: Diagram depicting the trapezius MFTP 1 location and its pain referral patterns Source: Simons, Travell and Simons, 1999

The MFTP 2 location is close to MFTP 1, but slightly postero-inferiorly, caudal to the free margin of the upper trapezius muscle fibres. The MFTP 2 region lies in the middle of the more nearly-horizontal fibres of the upper trapezius, as is depicted in Figure 3.2. Palpation of this TP is performed in a similarly as for MFTP 1, however, use of flat palpation may be required on larger patients. (Simons, Travell and Simons 1999).



Figure 3.2: Diagram depicting the trapezius MFTP 2 location and its pain referral patterns Source: Simons, Travell and Simons, 1999

The patient was required to meet all of the criteria specified by Simons, Travell and Simons (1999) as depicted in Table 3.1.

Table 3.2: Criteria for diagnosis of MFTPs

Essential criteria (minimum required)

- 1. Palpation of a taut band within the muscle being tested (if muscle accessible).
- 2. A nodule within a taut band that displays a sensitive spot tenderness upon palpation.
- 3. Weakness of the muscle being tested when compared bilaterally (if there is unilateral involvement).
- 4. Limitation of full stretch ROM accompanied by pain.

Confirmatory observations (confirmatory findings)

- 1. A LTR within the muscle identified visually or through tactile palpation.
- 2. Patient experiences pain or distorted sensation (along the reference zone of the TP in that muscle) upon manual compression of a painful nodule.

3. Recognition by the patient, their present pain complaint can be reproduced by pressure applied to the tender nodule (identifies an active TP).

Adapted from the 'Recommended Criteria for Identifying an Active or Latent MFTP' by Simons, Travell and Simons (1999)

3.6 RESEARCH ASSISTANT

A research assistant (RA) was recruited (Appendix L) for this study. The RA was a chiropractic student with a B.Tech qualification in Chiropractic. The RA was given a full written purpose of the research and the training protocol as recommended by Goulet (1998). The RA was trained by the researcher over a single day. The algometer training procedure included recommendations made

by Goulet (1998) to increase inter-rater reliability. This included applying the algometer at 90 degrees to a flat surface and applying pressure at an even and constant rate. After the training was completed, the RA's competency in using the algometer was tested. The RA was required to make five successive algometry applications at the recommended rate of 5 Newtons/second (N/s); 15 seconds apart (Chesterton et al., 2007). Each application persisted for 10 seconds and was applied at the first dorsal interosseous muscle of a volunteer participant (Chesterton et al., 2007). The test was deemed successful if all five applications were performed at a rate of 5N/s over a period of 10 seconds because the pressure pain threshold of the first dorsal interosseous muscle is generally reported well within this timescale (Chesterton et al., 2007).

The RA also received CROM device training as suggested by Norkin and White (2009). The RA was trained on how to position the participant in the testing position so that the gravity inclinometer reads zero degrees and how to place the CROM device on the participant's head so that the nosepiece was on the bridge of the nose and the bands fit snugly across the back of the participant's head (Norkin and White, 2009). The RA was then trained on how to guide the participants head into lateral flexion. At the end ROM, the RA stabilised the participant's head and recorded the dial reading at the end ROM (Norkin and White, 2009).

3.7 INTERVENTIONS

The upper trapezius muscle MFTPs 1 and 2 were marked unilaterally with a henna stain, so that the RA was able to determine the exact site for placement of the algometer at the fourth consultation. Markings made with henna are durable and do not fade with routine bathing (Mehendale et al., 2011).

For IC Group, the participant was placed in the seated position, with the involved side appropriately exposed (Nook, 2001). The location of the MFTP was determined by the researcher by means of flat or pincer palpation as depicted by Simons, Travell and Simons (1999). Once located, treatment was administered by the researcher as prescribed by Hains (2002) consisting of a steady even pressure using the thumb over a period of five to 15 seconds applied to the MFTP. This was repeated two to three times at successfully deeper levels (Schneider, 1996). Hains (2002) stated that the force applied by the physician via digital pressure, should reproduce local or referred pain that does not result in the patient attempting to protect the muscle being

treated by contracting it, therefore, making the treatment more painful but bearable. According to Hains (2002), excessive pressure or holding pressure for long periods may result in bruising.

For IAI Group, the participant was placed in the seated position, with the involved side exposed appropriately. Once the MFTP was located by the researcher, the IAI was held over the MFTP with a preload of 20 Newtons (N) and the trigger was pulled delivering a medium (200 N) force setting adjustment to the MFTP. Within the IAI is a motion sensor and a micro-computer which monitors changes in motion and the frequency of motion controlled in real-time by the acceleration response obtained from the tissue. As the tissue rebounded during the treatment application, data was fed into the micro-computer and the Auto-sense[®] technology set the frequency of subsequent thrusts. In this manner, the acceleration response was continuously monitored during treatment and adjusting ceased automatically when motion was maximised in an effort to control treatment dosage (http://impulseseminars.com/impulseiq).

3.8 INTERVENTION FREQUENCY

Participants in both groups received a series of three treatments and a follow-up consultation over a maximum period of two and a half weeks. The RA only took the algometry and CROM measurement readings per participant.

The consultation process was as follows:

Consultation One:

Participants underwent a full case history (Appendix C), a physical examination (Appendix D) and a cervical spine orthopedic examination (Appendix E). Subjective measurements i.e. Numerical Pain Rating Scale (NRS) (Appendix H) and CMCC Neck Disability Index Questionnaires (Appendix M) were completed by the researcher, describing the participant's pre-treatment state. Objective measurements were taken by the RA, which included the use of an algometer over the trapezius MFTP 2 on the respective side (this tool measured the pain threshold over the most tender segment of the TP) and Cervical Range of Motion (CROM-II goniometer) readings in lateral flexion.

Thereafter, treatment one was administered by the researcher according to group allocation.

Consultation Two:

This took place depending on participant availability, within seven days of initial consultation. Subjective (by the researcher) and objective measurements (RA) were taken and treatment was administered by the researcher as per group allocation.

Consultation Three:

This took place in week two. No measurements were taken and treatment was administered as per group allocation.

Consultation Four:

This took place in week two depending on participant availability. This consultation was purely for subjective and objective measurements.

3.9 MEASUREMENT TOOLS

3.9.1 Subjective Measurements:

3.9.1.1 Patients' Global Impression of Change (PGIC) scale

The PGIC (Appendix G) was utilized in this study because it is easy to comprehend and it provides information on activity limitations, symptoms, emotions and overall quality of life (Guy, 1976). Studenski et al. (2004) found the PGIC to have strong face validity, reliability and viability for use in clinical studies. It consists of seven descriptors of degree of change since the participant's initial treatment as follows:

- ✤ 1 = No change (or condition has got worse).
- ✤ 2 = Almost the same, hardly any change at all.
- 3 = A little better, but no noticeable change.
- ✤ 4 = somewhat better, but the change has not made any real difference.
- ✤ 5 = moderately better, and a slight but noticeable change.
- ✤ 6 =Better, and a definite improvement that has made a real and worthwhile difference.
- ✤ 7 = A great deal better, and a considerable improvement that has made all the difference.

3.9.1.2 Numerical pain rating scale (NRS)

The NRS (Appendix H) was used to ask the participant to rate their pain severity on a numerical scale of 0 - 10. Jensen, Karoly and Braver, (1986) compared six procedures of pain measurement on 75 chronic pain patients, the NRS was considered to be the most practical index to use based on its straightforwardness and easy administration. In a study with a sample of 79 conducted by Pool et al. (2007), comparing the NRS scale to the Verbal Rating Scale (VRS) and the Visual Analogue Scale (VAS), the NRS proved to be the most responsive with an effect size of 0.86. In the same study, the NRS was found to have pain sensitivity and specificity of 0.8. The NRS 101 is a scale that requests the patient to rate their pain severity out of 10, where 0 being the least severe pain perceived and 10 being the most severe pain perceived, thus making it a practical index to use, as it can be easily administered and tallied (Jensen, Karoly and Braver, 1986). Upon completion of the scale, the average score of the least and the worst pain perceived was obtained by adding them together.

3.9.1.3 Canadian Memorial Chiropractic College (CMCC) Neck Disability Index Questionnaire (NDI)

The CMCC Neck Disability Index (NDI) (Appendix M) (Vernon and Mior, 1991) was used to establish how the participant's neck pain has influenced their ability to cope with day to day life. Ten questions covering domains of pain intensity, personal care (washing, dressing, etc.), lifting, reading, headaches, concentration, work, driving, sleeping and recreation was individually evaluated and a total score was derived. Each domain had six possible answers from no significance to major significance in the participant's life. Scores for each question were obtained in a 0-5 fashion for their severity and the total score divided by 50 provided the total NDI score. In a study conducted by Cleland et al. (2006), test-retest reliability of the NDI was moderate (intraclass correlation coefficient [ICC] = 0.68; 95% confidence interval [CI], 0.30-0.90) and high for the Patient Specific Functional Scale (PSFS) (ICC = 0.82; 95% CI, 0.54-0.93).

3.9.2 Objective Measurements

The research RA took the algometry and CROM measurement readings per participant so as to introduce the blinding.

3.9.2.1 Algometer readings

Algometer readings (Appendix F) were obtained to evaluate changes in PPT for each participant. Algometer measuments were obtained at the initial, second and fourth consultations. The algometer device is an effective and dependable instrument, which is often used in the evaluation of MFTPs sensitivity. It has been utilized effectively for the assessment of MFTPs, to substantiate the diagnosis and to quantify irritability. Therapeutic efficacy of numerous protocols on MFTPs can be quantified by algometry readings (Hong, 1998). This form of measurement was demonstrated to be useful for the evaluation of treatment findings (Corcoran and Fischer, 1987) with a p-value of (p = 0.0094) and a very high ICC = 0.91; 95 CI 0.82, 0.97 (Chesterton et al., 2007). Differences in PPT measurements of more than 1.77 kg/cm² are more likely to surpass the degree of measurement error and could be used to indicate true change (Chesterton et al., 2007). The procedure was conducted as recommended by Fischer (1987):

- The dial on the gauge was set to zero.
- The disc was placed over the point of maximum TP sensitivity.
- Pressure was then intensified gradually at 1kg/cm²/sec.
- The participant was requested to signify by saying "yes" at the point where the pain was first recognized.
- The pressure was then ceased at this point and a once-off measurement was taken

3.9.2.2 A CROM device

The CROM device (CROM-II goniometer) (Appendix F) is a cervical spine ROM device containing a magnetic yoke and gravity goniometers which measures the cervical ROM in the frontal and sagittal planes. Inter-examiner reliability of the CROM device for measuring lateral cervical flexion is good to excellent (ICC = 0.73-0.89) (Hole, Cook and Bolton, 1995). The standard error of the measurement ranged from 2.5° to 4.1° . Minimal detectable change ranged from 5.4° (Fletcher and Bandy, 2007). In this study, because of the structure of the muscle being tested, the upper trapezius (a lateral flexor of the cervical spine), only values for active Lateral ROM were recorded before the start of the first and second treatments were administered and then a final measurement was obtained during the fourth consultation; this is similar to Berry (2006).

The CROM device was placed on the participant's nasal bridge and ears and secured with Velcro straps to the back of the participant's head. Good posture was ensured while the participant was seated on a chair prior to readings and a set of three readings were captured.

3.10 MEASUREMENT FREQUENCY

Subjective measurements were obtained prior to the initial treatment with the exception of the NRS which was taken as part of the SOAPE note at each consultation (Appendix E). Objective measurements were also obtained before the initial treatment, second treatment and at the fourth consultation.

3.11 STATISTICAL ANALYSIS

Data analysis was performed using IBM SPSS version 20 (IBM Corp. Released 2010.IBM SPSS Statistics for Windows, version 19.0. Armonk, NY: IBM Corp.). Statistical significance was assumed at a p < 0.05 level. Intra-group and inter-group comparisons were measured using repeated measures ANOVA testing. Profile plots were used to assess the direction and trend of the intervention effect (Esterhuisen personal communication, 2013).

CHAPTER 4 : RESULTS

4.1 INTRODUCTION

In this chapter, data obtained from each subject was analysed in the form of subjective and objective measures, as described in Chapter Three. IBM SPSS version 22 was used to analyse the data. A *p* value < 0.05 was considered as statistically significant. Repeated measures ANOVA within and between groups analysis was used to compare the changes over time within and between treatment groups. A significant time x group interaction indicated a significant difference in treatment effect over time between the two groups.

The analysis included:

- 1. Demographic data analysis comprising age and gender.
- Subjective measurements consisting of the NRS, CMCC NDI Questionnaire and PGIC. PGIC scores were compared between the groups using a non-parametric Mann Whitney test.
- 3. Objective measurements comprising of the algometer and CROM goniometer device.

4.2 **DEMOGRAPHICS**

The sample consisted of 40 participants who were between 20 and 36 years of age with a mean age of 22.9. Participants in the IC Group had an average age of 22.3 years, whereas participants in IAI Group had an average age of 23.3 years (Table 4.1).

| Table 4.1. Demographic da | ta analysis of age and genue | 71 | |
|---------------------------|------------------------------|-----------|----------------|
| Data | IC Group | IAI Group | Combined Total |
| Age distribution (years) | 20-36 | 20-35 | 20-36 |
| Mean age (years) | 22.3 | 23.3 | 22.9 |
| Std Deviation | 3.7 | 4.2 | 4.0 |
| Gender Distribution | 3 Females | 8 Females | 11 Females |
| | 16 Males | 13 Males | 29 Males |

| Table 4.1: | Demogra | ohic data | analysis | of age | and gender |
|------------|----------|-----------|----------|--------|------------|
| 10010 4.1. | Demograp | me data | anarysis | or age | and genaer |

| | | | | | | | | Age | | | | | | |
|--------|--------|--------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| | | | 20.00 | 21.00 | 22.00 | 23.00 | 24.00 | 25.00 | 26.00 | 27.00 | 34.00 | 35.00 | 36.00 | Total |
| Gender | Female | Count | 3 | 1 | 3 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 11 |
| | | % within Gender | 27.3% | 9.1% | 27.3% | 9.1% | 9.1% | 0.0% | 0.0% | 0.0% | 9.1% | 9.1% | 0.0% | 100.0% |
| | | % within Age | 25.0% | 14.3% | 50.0% | 25.0% | 20.0% | 0.0% | 0.0% | 0.0% | 100.0% | 100.0% | 0.0% | 27.5% |
| | | % of Total | 7.5% | 2.5% | 7.5% | 2.5% | 2.5% | 0.0% | 0.0% | 0.0% | 2.5% | 2.5% | 0.0% | 27.5% |
| | Male | Count | 9 | 6 | 3 | 3 | 4 | 1 | 1 | 1 | 0 | 0 | 1 | 29 |
| | | % within Gender | 31.0% | 20.7% | 10.3% | 10.3% | 13.8% | 3.4% | 3.4% | 3.4% | 0.0% | 0.0% | 3.4% | 100.0% |
| | | % within Age | 75.0% | 85.7% | 50.0% | 75.0% | 80.0% | 100.0% | 100.0% | 100.0% | 0.0% | 0.0% | 100.0% | 72.5% |
| | | % of Total | 22.5% | 15.0% | 7.5% | 7.5% | 10.0% | 2.5% | 2.5% | 2.5% | 0.0% | 0.0% | 2.5% | 72.5% |
| Total | | Count | 12 | 7 | 6 | 4 | 5 | 1 | 1 | 1 | 1 | 1 | 1 | 40 |
| | | % within Gender | 30.0% | 17.5% | 15.0% | 10.0% | 12.5% | 2.5% | 2.5% | 2.5% | 2.5% | 2.5% | 2.5% | 100.0% |
| | | % within Age | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| | | % of Total | 30.0% | 17.5% | 15.0% | 10.0% | 12.5% | 2.5% | 2.5% | 2.5% | 2.5% | 2.5% | 2.5% | 100.0% |

Table 4.2: Gender * age cross tabulation

Pearson's chi square = 9.118 and p = 0.521.

Table 4.2 reflects that the male population comprised 72.5% of the total population whilst the female population was 27.5%. The most common age for both males and females was 20 years and accounted for 30% of the total population sample.

4.3 BASELINE MEASUREMENTS

Table 4.3 shows that there was a statistically significant difference at baseline in NRS and AL between the two groups. IC Group had higher values of both measurements at baseline. CROM values and NDI were equivalent between the groups. At baseline: NRS had a p value = 0.019; AL had a p value = 0.031; CROM left had a p value = 0.087; CROM right p value = 0.297 and NDI p value = 0.681.

| ap | ie 4.3. Comparisoi | n of the base | ine measureme | nts between the | groups | | |
|----|-----------------------------|---------------|-----------------------|-----------------|-----------------------|----------------|--|
| | | GROUP | | | | <i>p</i> value | |
| | | Ischaemic c | ompression | Impulse iQ A | Adjusting instrument | | |
| | | Mean | Standard Deviation | Mean | Standard Deviation | | |
| | NRS -1 | 5.2 | 1.1 | 4.5 | .7 | 0.019 | |
| | AL -1 (KG/CM ²) | 3.2 | 1.2 | 2.5 | .8 | 0.031 | |
| | CROM -1 Left | 46.3 | 8.5 | 40.7 | 11.2 | 0.087 | |
| | CROM -1 Right | 41.5 | 10.0 | 37.9 | 11.6 | 0.297 | |
| | NDI | 10.2 | 5.1 | 9.6 | 3.8 | 0.681 | |
| | | | | | | | |

Table 4.3: Comparison of the baseline measurements between the groups

4.4 OBJECTIVE ONE

To determine the effectiveness of the IC alone in the treatment of upper trapezius MFTPs in patients with neck pain in terms of subjective and objective measurements.

4.4.1 NRS (Subjective Measurement)

There was a steady and significant decrease in pain over the three time points (p < 0.001; repeated measures ANOVA) particularly between time=2 and time=3 in IC Group (Figure 4.1).



Figure 4.1: Mean NRS over time in IC Group

4.4.2 Algometer (Objective Measurement)

There was no significant change in algometer readings over the three time points indicating no change in pain sensitivity (p = 0.102; repeated measures ANOVA) (Figure 4.2).



Figure 4.2: Algometer Readings over time in IC Group

4.4.3 CROM Left Lateral Flexion (Objective Measurement)

There was a significant increase in CROM left measurements over the three time points. The increase was steady increase between time = 1 and time = 2 followed by a steep increase between time = 2 and time = 3 (p = 0.008; repeated measures ANOVA) (Figure 4.3).



Figure 4.3: CROM left lateral flexion measurements over time in IC Group

4.4.4 CROM Right Lateral Flexion (Objective Measurement)

There was no significant increase in CROM right measurements (p = 0.117; repeated measures ANOVA). Figure 4.4 suggests that initially there was a marginal decrease between time = 1 and time = 2 followed by a steady increase in CROM measurements between time = 2 and time = 3.



Figure 4.4: CROM right lateral flexion measurements over time in IC Group

4.5 OBJECTIVE TWO

To determine the effectiveness of the IAI alone in the treatment of upper trapezius MFTPs in terms of subjective and objective measurements.

4.5.1 NRS (Subjective Measurement)

The NRS decreased significantly in this group over time (p < 0.001; repeated measure ANOVA) which implies there was a significant decrease in pain intensity. There was a steady decrease in pain intensity over the three points (Figure 4.5).



Figure 4.5: Mean NRS over time in IAI Group

4.5.2 Algometer Readings (Objective Measurement)

There was a significant increase in algometer readings over the three time points (p = 0.009; repeated measures ANOVA). There was a steep increase in algometer readings between time = 2 and time = 3 in this group (Figure 4.6).



Figure 4.6: Algometer Readings over time in IC Group

4.5.3 CROM Left Lateral Flexion (Objective Measurement)

There was no significant change in CROM left lateral flexion over time in this group even though there was a steady increase in CROM measurements between time = 1 and time = 2 and a slight decrease in CROM measurements between time = 2 and time = 3 (p = 0.463; repeated measures ANOVA) (Figure 4.7).



Figure 4.7: CROM left lateral flexion measurements over time in IAI Group

4.5.4 CROM Right Lateral Flexion (Objective Measurement)

There was no significant change in CROM right lateral flexion over time in this group even though there was a steady increase in CROM measurements between time = 1 and time = 2 and a steep decrease in CROM measurements between time = 2 and time = 3 beyond the initial reading obtained at time = 1 (p = 0.907; repeated measures ANOVA) (Figure 4.8).



Figure 4.8: CROM right lateral flexion measurements over time in IAI Group

4.6 OBJECTIVE THREE

To correlate the subjective and objective findings in terms of the overall effectiveness of the IAI and IC in the treatment of upper MFTPs.

4.6.1 NRS (Subjective Measurement)

The effect of time was statistically significant (p < 0.001); however, there was no significant difference in treatment effect for NRS. Both groups decreased at the same rate (p = 0.140; repeated measures ANOVA) (Table 4.4).

| able 4.4: within-subjects effects for NRS in both groups | | | | |
|--|-----------------------|-----------------|--|--|
| Effect | Statistic | <i>p</i> -value | | |
| Time | Wilk's lambda = 0.211 | <0.001 | | |
| Time x group | Wilk's lambda = 0.899 | 0.140 | | |
| Group | F = 2.075 | 0.140 | | |

 bup
 F = 2.075
 0.140



Figure 4.9: NRS measurements comparisons over time between IC Group and IAI Group

Figure 4.9 shows parallel profiles of the two groups. Ischaemic compression Group had higher baseline pain scores compared to IAI Group. Both groups had significant decrease in pain intensity; therefore, both groups had an effect on NRS. All participants' pain intensity decreased at the same time.

4.6.2 Algometer (Objective Measurement)

Although the effect of time was statistically significant (p = 0.010), there is no significant timegroup interaction (p = 0.286) which implies that both treatment groups changed significantly over time in terms of algometer measurements; the change was not significantly different between the groups (repeated measures ANOVA) (Table 4.5).

| able 4.5: Within-subjects and between-subjects effects for Algometer | | | |
|--|-----------------------|-----------------|--|
| Effect | Statistic | <i>p</i> -value | |
| Time | Wilk's lambda = 0.779 | 0.010 | |
| Time x group | Wilk's lambda = 0.935 | 0.286 | |
| Group | F = 1.296 | 0.286 | |

Figure 4.10 shows profiles of the two groups. There was a slight decrease between time = 1 and time = 2 in IC Group One whereas in IAI Group, there was a steady increase over the same period. The trend in the graph suggests that the rate of increase is higher in IAI Group. Between time = 2 and time = 3, almost parallel profiles are evident. Even though there was no significant difference in treatment, the trend in the graph suggests that the overall rate of increase is higher in IAI Group.



Figure 4.10: Within-subjects and between-subjects effects for Algometer

4.6.3 CROM Left Lateral Flexion (Objective Measurement)

There was no significant difference on the effect of time between the two groups (p = 0.091) and also there was no significant difference in treatment effects (p = 0.298; repeated measures ANOVA) (Table 4.6).

| Table 4.6: within-subjects effects and between-subjects for CROM Left | | | |
|---|-----------------------|-----------------|--|
| Effect | Statistic | <i>p</i> -value | |
| Time | Wilk's lambda = 0.879 | 0.091 | |
| Time x group | Wilk's lambda = 0.937 | 0.298 | |
| Group | F = 1.253 | 0.298 | |

| Figure 4.11 shows unparalleled profiles of the two groups. There was a slight increase between |
|--|
| the three points in IC Group whereas in IAI Group there was a steady increase between time = 1 |
| and time = 2 and a slight decrease in between time = 2 and time = 3. Trend in the graph suggests |
| that the rate of increase is higher in IC Group. |



Figure 4.11: Within-subjects and between-subjects effects for CROM left

4.6.4 CROM Right Lateral Flexion (Objective Measurement)

There was no significant difference on the effect of time between the two groups (p = 0.728) and also there was no significant difference in treatment effects (p = 398; repeated measures ANOVA) (Table 4.7).

| Table 4.7: within-subjects effects and between-subjects effects for CROM Right | | | |
|--|-----------------------|-----------------|--|
| Effect | Statistic | <i>p</i> -value | |
| Time | Wilk's lambda = 0.983 | 0.728 | |
| Time x group | Wilk's lambda = 0.951 | 0.398 | |
| Group | F = 0.944 | 0.398 | |

Figure 4.12 shows unparalleled profiles of the two groups. There was an initial decrease between time = 3 and time = 2 followed by a slight increase between time = 2 and time = 3 in IC Group whereas in IAI Group, there was a steady increase between time = 1 and time = 2 and a slight decrease between time = 2 and time = 3. The trend in the graph suggests that the rate of increase

is higher in IC Group even though there was no significant difference in treatment effects between the two groups overall.



Figure 4.12: Within-subjects and between-subjects effects for CROM Right

4.6.5 Patients Global Impression Of Change Scale

The PGIC scale was obtained after the final treatment between the groups. The scores were compared between the groups using a non-parametric Mann Whitney test.

Figure 4.13 suggests that the mean rank for Group One (n = 19) was 16.68 whereas for Group Two (n = 21) it was 23.95. Ischaemic compression Group had the highest frequency of six and the lowest frequency of two, with six being the most common frequency. With the IAI Group, the highest frequency was seven and the lowest frequency was three, with seven being the most common frequency. There was a borderline statistically significant difference in score between the groups (p = < 0.05). The scores of IAI Group were higher.


Independent-Samples Mann-Whitney U Test GROUP

0 4.0 2.0 0.0 2.0 4.0 6. quency Frequency Total N 40 Mann-Whitney U 272.000 Willaswan W 502.000

| Mann-Winney 0 | 212.000 |
|--------------------------------|---------|
| Wilcoxon W | 503.000 |
| Test Statistic | 272.000 |
| Standard Error | 35.618 |
| Standardized Test Statistic | 2.036 |
| Asymptotic Sig. (2-sided test) | .042 |
| Exact Sig. (2-sided test) | .050 |

Figure 4.13: Within-subjects and between-subjects effects for PGIC

CHAPTER 5 : DISCUSSION

5.1 INTRODUCTION

The aim of this study was to determine the effectiveness of the IAI compared to IC for the treatment of upper trapezius muscle MFTPs in participants with non-specific neck pain.

This chapter will discuss the results in detail and possibly explain the subjective and objective data obtained during this study. References will be made to relevant sections in Chapter Four in addition to the studies discussed in Chapter Two.

The statistical and clinical significance of the data obtained from the inter-group analysis with respect to subjective and objective measurements at the initial, second and fourth visit will be discussed in relation to possible indications relevant theories.

The results were obtained from statistical analysis of the NRS, CMCC NDI, PGIC, pressure pain algometry readings and CROM goniometer readings.

5.2 DEMOGRAPHIC DATA ANALYSIS

5.2.1 Age and gender Distribution

Age was an inclusion criterion for this study and participants were required to be between 20 and 50 years of age. With respect to age, Simons, Travell and Simons (1999) indicated that individuals most likely suffer from MPS in their mature years (31-50). However, the condition does occur in younger individuals, therefore the minimum age of 20 years was chosen.

Table 4.1 indicates that the the participants were between 20 and 36 years of age with a mean age of 22.9 and Participants in IC Group had an average age of 22.3 years, whereas participants in Group Two had an average of 23.3 years. The above results indicate that IC Group and IAI Group were comparable due to their almost similar mean age values. Most of the participants were students thus the mean age between both groups was between 22 and 24 years of age. The high number of student participants might have been due to the location of the adverts, which

were placed around all DUT campuses. Thus, this study had an age group significantly younger than the average age of studies previously completed, but it is similar to Trampas et al (2010), who noted an age range of 20.9 ± 1.2 ; 21.0 ± 1.6 ; 20.8 ± 1.4 for the three treatment groups respectively. This coincides with the longitudinal study conducted by Siivola et al. (2004), which investigated the occurrence of neck pain in 826 young people when they were 15 to 18 years old and again at 22 to 25 years of age and the occurrence of weekly neck and shoulder pain increased from 17% to 28%.

Despite the randomised allocation conducted between the two groups, there were more male participants who took part in the study than female participants. The total number of male participants was 29 (72.5%) and female was 11 (27.5%). This was similar to a study conducted by Ferna ndez-de-las-Pen a et al., (2006b) (n = 40) which also had more male participants (57.5%) compared to female participants (42.5%). This was in contrast to the epidemiological study conducted by Drewes and Jennum (1995), which reported the prevalence of MPS to be 37% in men and 65% in women, respectively.

5.3 SUBJECTIVE DATA ANALYSIS

5.3.1 Numerical Pain Rating Scale

The NRS was used at three time variables (pre-initial treatment, pre-second treatment and fourth visit) to subjectively measure the participants' neck pain status. The participants were asked to rate the perceived pain at that current moment on a scale that ranged from zero to ten with zero equal to no pain and ten equal to worst pain possible.

5.3.1.1 Intragroup Analysis

Both IC Group and IAI Group (p = 0.001) had a statistically significant reduction in pain intensity over the three time points as shown in Figure 4.9, with IAI Group having a general positive effect in the reduction of pain perceived by the participant.

Interpretation of the data obtained from IC Group revealed that the mean NRS on visit one was 5.2, on visit two was 4.3 and on final visit was 2.6. The average improvement between visit one and the final visit for this group was 2.6. This improvement was statistically significant (p = 0.001).

As for IAI Group data, NRS on visit one was 4.5; on visit two was 3.1 and on final visit was 0.8. The average improvement between visit one and the final visit for this group was 3.7. This improvement was statistically significant (p = 0.001).

5.3.1.2 Intergroup Analysis

When comparing the mean NRS value between IC Group and IAI Group, IAI Group had a more clinically significant decrease in NRS values when compared to mean NRS value in the IC Group. However, no statistically significant changes were found between the groups at the final consultation.

5.3.2 CMCC Neck Disability Index

The CMCC NDI was used to establish how the participant's neck pain had affected their ability to manage in everyday life. This was applied prior to the initial treatment.

5.3.2.1 Intragroup Analysis

Both groups had almost similar mean values at baseline measurements and had a *p*-value of 0.681 indicating that there were no statistically significant differences between the two groups. IC Group had a mean value of 10.2 and IAI Group had a mean value of 9.6. The groups were comparable at the start of the study. Cleland, Childs and Whitman (2008) proposed that the minimal detectable change (MDC) for the NDI was 19-percentage points (mean value of 9.5). In a study conducted by Dundar et al. (2007), the NDI had a mean value of 13.2 with a standard deviation of \pm 6.5 which was similar to the NDI values obtained in this study. However, since the baseline measurements were low in this study, it can thus be concluded that the participants were moderately functional at the time of the first visit. It can be hypothesized that this may have been due to the younger mean age of 22.9 \pm 3.6.

5.3.3 Patients Global Impression of Change

The PGIC was used at the fourth consultation to evaluate the overall sensitivities of improvement perceived since the beginning of treatment.

5.3.3.1 Intragroup Analysis

For IC Group, the highest score achieved was six whereas for IAI Group, the highest score achieved was seven. In contrast, the lowest score achieved in IC Group was two and it was three in IAI Group, therefore, showing that both groups had improvement with regards to the PGIC. According to Young et al. (2009), patients who achieved a mean PGIC rating value of three or more were considered to have improved. Patients who achieved a mean of one or two rating were considered to have remained stable. As reported by Cleland, Childs and Whitman (2008), choosing different cut-offs in a rating scale can affect the receptiveness values of a patient outcome measure. Similar to Young et al. (2009), a PGIC value of three or more was chosen as the cut off to depict improved participants versus unimproved participants. From this, it can thus be speculated that both groups showed significant improvement since the initial treatment.

5.3.3.2 Intergroup Analysis

There was a marginal statistically significant difference (p = 0.042) in score between the groups. The scores of IAI Group were higher when compared to those of Group One showing that IAI Group had greater improvement with regards to activity limitations, symptoms, emotions, and overall quality of life. However, there are restrictions that should be considered when interpreting these results, as the PGIC may not always be an appropriate measure (Farrar et al., 2000), especially in the evaluation of pain disorders with a substantial psychiatric overlap (Just et al., 1999).

5.4 OBJECTIVE MEASUREMENTS

5.4.1 Algometer Readings

The algometer was used during the initial, second and fourth consultations to measure the amount of force that the patient could tolerate on the MFTP before perceiving pain. An increase in readings indicates an increase in pain threshold resulting from decreased MFTP sensitivity.

5.4.1.1 Intragroup Analysis

5.4.1.1.1 IC Group

There was no significant change over time in algometer in this group (p = 0.102). Figure 4.2 indicates that there was no change in algometer readings obtained over the three time points indicating no overall change in pain sensitivity. IC Group had a decrease in pain threshold during the second visit showing that the MFTP was more sensitised following the initial treatment. Regardless of the second consultation occurring between day three and day seven, this was in contrast to Fryer and Hodgson (2005), who stated that it is possible that sustained manual pressure on a MFTP could result in irritation and increased sensitivity to post-treatment algometry measurement, although this was not the case in their study. This was similar to Ferna ndez-delas-Pen^as et al. (2006b) who compared IC to transverse friction massage in 40 subjects with MFTPs in the upper trapezius muscle who demonstrated significant improvement in pain pressure threshold within two minutes in both groups with no differences found between the groups. Other studies (Hou et al., 2002; Aguilera, 2009) had similar results to Ferna ndez-de-las-Pen as et al. (2006b) with respect to the immediate effect of IC. This may have been due to difference in technique with which the IC was applied with respect to time. For this study, a steady even pressure using the pincer grip over a period of 10 seconds was applied to the MFTP, similar to Hains (2002; 2009). This was repeated three times at successfully deeper levels. Whereas in the study by Ferna ndez-de-las-Pen as et al. (2006b), the pressure was applied until discomfort or pain decreased by about 50%, at which time the pressure was elevated until irritation was felt once again. This process was repeated for 90 seconds.

According to Hou et al. (2002), high pressure, which is an average of PPT and pain tolerance applied over a period of 90 seconds, produced the most substantial pain relief; however, substantial improvement was also achieved with lower pressure at the PPT level for each individual patient. Some authors (Simons, Travell and Simons, 1999; Lewit, 1979) have argued that application of excessive force provoking ischemia is pointless (Ferna ndez-de-las-Pen a et al, 2006b). Hains (2002) stated that it is beneficial to maintain pressure for a longer period on TPs that are more subtle to digital pressure.

On the fourth visit, Figure 4.2 shows that there was an average increase in PPT between the second and fourth consultation. The PPT by the fourth visit was slightly higher than the initial measurement showing a slight improvement in general. According to Gemmell and Allen (2008), the number of treatments required for an individual patient to improve with IC therapy compared

to sham ultrasound was 2.5. This was supported by Fryer and Hodgson (2005) who suggested that prospective studies should incorporate symptomatic participants with a longer treatment and evaluation period of at least four weeks, thus enabling the duration of treatment effect to be thoroughly investigated. In this study, the participants were treated three times before the final measurement was taken. From this, it can thus be speculated that the improvement depicted on Figure 4.2 was as a result of the number of treatments.

Comparison with NRS Values

Comparing the NRS values (Figure 4.1) for this group to the algometer values (Figure 4.2) the following were noted:

The initial mean NRS values were moderately high and mean algometer readings were low, indicating that the participants had significant pain and sensitised MFTPs respectively. This correlation between a high NRS and a low algometer reading was explained by Simons (1983) (citing Perl, 1976) who stated that sensitisation is one of the mechanisms accountable for the tenderness and pain related to the tissue damage and the inflammatory processes.

For the second measurements (time = 2); the NRS values decreased, indicating a decrease in pain sensation. However, the algometer readings also decreased, indicating a decrease in PPT which suggests that the MFTPs were more sensitizied. A decrease in NRS would normally be expected to be associated with an increase in PPT, indicating a decrease in pain intensity and MFTP sensitivity. However, this was not the case and may have been due to the NRS being applied initially as a homogeneity screen which did not specify sides to be tested. Therefore, it can be hypothesized that the change in the NRS during this specified time might be an increase in generalised neck pain rather than the affected side.

For the final measurements (between time = 2 and time = 3), there was an inversely proportional relationship between the NRS and algometer readings, indicating that as the pain intensity decreased, the PPT was increasing. This was supported by Hou et al. (2002), who found that manual pressure release therapy (which is a form of IC) resulted in a decrease in MFTPs sensitivity. This was similar to Fryer and Hodgson (2005) who concluded that their study demonstrated that the pressure sensitivity of MFTPs was reduced during the application of myofascial pressure release.

From this, one can conclude that subjectively, the participant's pain intensity decreased as observed in the NRS data but objectively, the overall improvement with regards to PPT was marginal as observed in the algometer data.

5.4.1.1.2 IAI Group

There was a significant change in algometer readings in this group (p = 0.009). Figure 4.6 indicates that there was a positive change in algometer readings over the three time points indicating that there was an overall change in MFTP sensitivity. The decrease in MFTP sensitivity can be linked with the mechanism in which the IAI (which was the used for IAI Group) works.

As discussed in Chapter Two, MFTPs center upon dysregulated motor endplates, sustained by a neural loop of sensory afferents and autonomic efferents (McPartland and Simons, 2006). The IAI utilises a microprocessor-controlled electromagnetic coil to produce a haversine-like impulse, approximately two milliseconds in duration (Colloca et al., 2005). Haversine impulse profiles result in a uniform mechanical energy delivery to the test structure over a broad frequency range, ranging from 0 to 200Hz (Colloca et al., 2005).

It can thus be hypothesized that the mechanical energy delivered by the IAI will result in a manual stretch of extrafusal muscle fibres eliciting an involuntary reflex arc, therefore, activating muscle spindle type Ia and IIa afferents (FitzGerald, Gruener and Mtui, 2012). Muscle spindles respond to active and passive muscle stretch, sending their excitatory impulses to the homonymous alpha motor neurons in the anterior horn resulting in a contraction of homonymous extrafusal muscle fibres, inducing a localised twitch response (FitzGerald, Gruener and Mtui, 2012). The LTR causes an increase in ACh release from presynaptic terminal bouton at neuromuscular junction causing ACh vesicle depletion with consequent spontaneous electrical activity reduction which caused the active MFTP (Dommerholt and Fernández-de-las-Peñas, 2013). The IAI therefore can be hypothesised to cause disruption of the endplate dysfunction and desensitise the active MFTP with restoration of the normal gamma loop (FitzGerald, Gruener and Mtui, 2012).

The response of the muscle spindles to lengthen and the velocity of lengthening can to some extent be altered independently by fusimotor activity (Jansen, 1966). In a comprehensive study conducted by Goodwin Hulliger and Matthews, (1975) on fusimotor effects, the researcher found that with small-amplitude sine stretches, both static and dynamic fusimotor fibre stimulation reduced the sensitivity of primary endings (Goodwin, Hulliger and Matthews, 1975). However, with larger amplitudes (0.5-1 mm) and low frequencies (typically 1Hz), dynamic fusimotor stimulation

caused substantial increases in sensitivity and static stimulation caused decreases associated with increased mean frequencies of afferent firing (Hulliger, Matthews and Noth, 1977). This may further explain the changes in MFTP sensivitity due to administration of IAI in the IAI Group.

Due to lack of similar studies, the closest study to the IAI was conducted by Gemmell and Allen (2008), who examined the effect of Activator Trigger Point therapy on upper trapezius MFTPs and found a seven-fold decrease of pain in patients receiving the mechanically-assisted thrusts of an activator device when compared to myofascial band therapy or sham ultrasound (p > 0.05).

Comparison with NRS values

Comparing the NRS values (Figure 4.5) for this group to the algometer values (Figure 4.6) the following were noted:

The initial mean NRS value for IAI Group was also moderately high and the mean algometer reading was low, indicating that the participants had significant pain and sensitised MFTPs respectively, similar to IC Group.

For the second measurements (time = 2); the NRS values decreased, indicating a decrease in pain sensation, whilst the algometer readings increased gradually indicating an increase in PPT which suggests that the MFTPs were less sensitised and had responded positively to the therapy.

For the final measurements (between time = 2 and time = 3), there was a steep increase in the algometer readings and a steep decrease in NRS values indicating that as the PPT was increasing, the participants' pain intensity perception decreased. This was supported by the study conducted by Gemmel (2008), regarding the effect of mechanically-assisted thrusts on pain intensity reduction on MFTPs.

From this, one can conclude that subjectively the participant's pain intensity decreased as observed in the NRS data at almost a similar rate when compared to the objective algometer readings. The overall improvement with regards to PPT was greater.

5.4.1.2 Intergroup Analysis

Both groups had an increase in final pain threshold when compared to initial measurement, as depicted by Figure 4.10. Even though there was no significant difference in treatment, the trend

in the graph suggests that the overall rate of increase is higher in IAI Group. It can thus be concluded that even though it was statistically insignificant, participants in IAI Group experienced a gradual and faster rate of improvement, with a steady decrease in pain over the three time points when compared to IC Group.

5.4.2 CROM

For IC Group, CROM left lateral flexion increased significantly over time in this group (p = 0.008) and CROM right lateral flexion did not increase significantly in this group (p = 0.117). The improvement in IC Group on the left side may be explained by the mechanism of IC. As discussed in Chapter Two, IC can result in a specific localised stretch of the contractile fibres of the taunt band (Schneider, 1994). Schneider (1994) hypothesized that applying manual pressure over the taut band actually separates the actin-myosin cross fiber links. Considering that a pincer grip was used to execute IC therapy in IC Group, there was application of pressure over a broader area. The pressure applied to the MFTPs is continued until the MFTP tension is relieved (Raj and Paradise, 2004). The changes in muscle tension generally occur before changes in muscle length (Frank et al., 1975).

For IAI Group, there was no significant change in CROM left lateral flexion over time (p = 0.483) and CROM right lateral flexion did not change significantly either (p = 0.907). This was similar to the study conducted by Gemmell and Allen (2008); Activator Trigger Point therapy was not significantly effective on cervical left lateral flexion.

The limited changes in lateral flexion can be explained by McNair, Lapidos and Wheeler (2006), who stated that the greatest amount of positive change in cervical ROM after one treatment with joint mobilisation therapy was obtained in flexion and extension movements. Lateral flexion ROM demonstrated marginal noticeable amount of improvement. Similar to this study, Gemmel (2008) concluded that, with lateral flexion being the only movement measured, the differences in lateral flexion were generally marginal and were not as easily detected when compared to changes in flexion and extension movements.

There was no significant difference on the effect of time between the two groups (p = 0.091) and also there was no significant difference in treatment effects (p = 0.298). The trend in the graph (Figure 4.11) suggests that the rate of increase was higher in the IC Group.

CHAPTER 6 : CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

At the onset of this study, it was known that IC was effective and efficient in the treatment of MPS. By contrast, it was also known that basic scientific research has demonstrated biomechanical and neurophysiological responses associated with the use of the IAI (Colloca et al., 2005); however, little clinical research existed on its use and its effectiveness on MPS. Therefore, the aim of this study was to determine the effectiveness of the IAI compared to IC for the treatment of upper trapezius muscle MFTPs in non-specific neck pain patients.

This study demonstrated an investigation that was obtained through a randomised, single-blinded clinical trial. The study was permitted through the Institutional Research and Ethics Committee (IREC) the DUT. The study consisted of 40 participants who underwent three treatments and a follow-up consultation over a period of two and a half weeks. NRS, CMCC NDI questionnaire, Algometer and CROM measurements were obtained at the initial consultation, at the second consultation and the follow-up consultation. Data was captured and then analysed using the IBM SPSS version 20, using repeated measures ANOVA testing, in order to determine the effectiveness of the treatments over time and between each other.

IC Group received IC therapy to MFTPs, and IAI Group received treatment using the IAI.

There were clinically significant improvements for subjective measures i.e. CMCC NDI, NRS and the PGIC. IAI Group improved more than the IC Group in terms of NRS values. IAI Group had higher PGIC values compared to IC Group, therefore, suggesting that Group Two had better improvement with regards to activity limitations, symptoms, emotions and overall quality of life. NDI values were similar at baseline measurements between the two groups.

Intragroup analysis revealed statistically significant differences in both groups for the NRS over the treatment period.

Intergroup analysis revealed there was no significant difference in treatment effect for NRS over the treatment period.

Both groups showed clinically significant improvement with regards to objective measurements, i.e. algometer readings and CROM goniometer measurements. With regards to algometer readings, IAI Group improved more than IC Group. For CROM measurements, IC Group clinically improved more bilaterally in comparison to IAI Group, although only left lateral flexion was statistically significant.

Intergroup analysis did not reveal any statistically significant differences in algometer readings between both groups. However, the overall rate of increase in pain threshold was higher in IAI Group. With CROM measurements, there were no statistical significant differences between the two groups over the treatment period.

It can thus be concluded that neither IC nor IAI is more effective than the other with respect to participants' pain perception and cervical ROM. However, the IAI was more effective on PPT Based on the results collected from this study, both therapies can be used in treatment protocols of neck pain associated with MFTPs.

In terms of the associated hypotheses that were set at the onset of the study:

The Null Hypothesis which stated there would be no significant difference between the two groups with respect to subjective pain perception was rejected.

The Hypothesis which stated there would be significant difference between the two groups with respect to pain threshold algometry was accepted.

6.2 **RECOMMENDATIONS**

The following recommendations are made to aid future studies to further improve the data obtained from this study allowing for more statistically significant results:

- A larger sample size of participants should be included into the study, which may provide more statistically and clinically significant results.
- A one-month follow-up consultation after the final treatment should be included so as to compare the long-term effects of the treatment therapies.
- Possible use of an electronic or digital CROM goniometer device as reading the analogue device is operator dependent and leaves room for inaccurate measurements. The use of a digital CROM for accurate measurements would yield better results.
- Even though it is irrelevant for this study, it was noted that individuals who were right hand dominant commonly presented with MFTPs on the right and the same is true for

participants who were left hand dominant, therefore, a possible follow on study should consider plotting MFTPs related to the dominant hand.

- Exclusion of participants with structural abnormalities such as leg length discrepancies and MFTPs in other muscles which form a close relationship with the trapezius muscle.
- Due to numerous methods of application of IC on MFTPS, a clear and precise method with regards to time allocation is required. Therefore, future researchers are required to clearly define the therapeutic mechanism of IC treatment.
- An age specific study would decrease the number of variables that would affect the study as participants of different age groups react differently to any treatment protocol.
- There should be equal distribution of males and females in treatment groups so as to eliminate gender pain perception.
- Use of EMG to localize trigger points may reduce clinician error when locating MFTPs.

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APPENDICES

Appendix A: Advert

DO YOU SUFFER FROM NECK AND SHOULDER PAIN?



ARE YOU BETWEEN THE AGES OF 20 and 50?

Research is currently being conducted at the Durban University of Technology Chiropractic Day Clinic

TREATMENT MAY BE PROVIDED

To those who qualify to take part in this study

Contact Alistair Makowe on 071 725 6353

Or the Chiropractic Day Clinic on 031 373 2205

to see if you qualify for this study.

Appendix B



Letter of information and informed consent

TitleoftheResearchStudy:The effectiveness of the Impulse iQ® Adjusting Instrument compared to Ischaemic Compressionin the treatment of upper trapezius myofascial trigger points in participants with non-specific neckpain.

Principle Investigator: Alistair Makowe

Supervisor: Dr. D. Varatharajullu [MTech: Chiropractic]

Brief Introduction and Purpose of the Study:

This research study aims to investigate the effect of the Impulse iQ® Adjusting Instrument and Ischaemic compression on the treatment of upper trapezius myofascial trigger points in participants presenting with non-specific neck pain. 40 people will be required to complete this study.

Outline of the Procedures:

At the first consultation at the Chiropractic Day Clinic you will read this information sheet and ask any questions about the research. If you agree to take part in this research, you will have to sign an informed consent form. Then, the hour long appointment will commence. The researcher will take a case history and a physical examination will be done and a cervical spine regional examination will be conducted. You will then be assigned to one of the two myofascial trigger point treatment groups. Please do not take any form of medication or receive any other treatment for the upper trapezius myofascial trigger points for at least 24 hours before your initial appointment and the duration of the research. Please arrive at least 10 minutes before your second appointment.

You will meet the researcher at the DUT Chiropractic Day Clinic for their appointment. The researcher will then ask the participant if they have had any form of treatment in the last 24 hours, if the answer is no then the research may proceed.

You will then be asked to remove any clothing covering the area around the upper trapezius muscle and appropriate clothes (clinic gown for females) will be provided). A record of initial algometer and CROM device readings will be obtained by a research assistant. Your name or code will then be checked on the list to see which group you were allocated to, if you are in the Impulse iQ® Adjusting Instrument (IAI) group, then you will receive an IAI adjustment; if the you

are in the group of the ischaemic compression (IC), then a treatment will be administered over the myofascial trigger point (MFTP) for a period of 7-10 seconds, and this will be repeated two to three times at successfully deeper levels.

Participants in both groups will receive a series of three treatments and a follow-up consultation over a maximum period of two and half weeks. The research assistant will only take the algometry and CROM measurement readings per participant. A set of three CROM measurements will be obtained and an average reading will be calculated. At the first consultation, baseline measurements will be taken followed by the initial treatment. A second set of readings will be taken before the second treatment. At the fourth consultation, a final set of readings (third set) will be taken for subjective and objective clinical findings and treatment will be given. You will be treated twice in a one-week period with a one week follow-up treatment.

Risks or **Discomforts** to the **Subject:** There are no risks. You may feel a localized discomfort over the area being treated. If the sensation becomes intolerable, you may request to have the treatment stopped and withdraw from the study.

Benefits:

This study will help to determine if the Impulse iQ® Adjusting Instrument is effective in treating myofascial trigger points.

Reason/s why the Subject May withdraw from the study: You are free to withdraw from this study at any stage without any negative repercussions.

Remuneration:

You will not be offered any form of remuneration for taking part in the study.Study:CostsoftheThe initial consultation and the MFTP treatment are free of charge.Study:

Confidentiality:

All your medical records will be kept confidential and will be stored in the Chiropractic Day Clinic for 15 years, after which it will be shredded. Your name will not appear on any of the data sheets or thesis.

Please don't hesitate to ask questions on any aspect of this study. Should you have any complaints or queries, please do not hesitate to contact my research supervisor at the above details or the Constitutional Research Ethics Committee Administration: 031 373 2900

Research-related

injury:

There will be no compensation in the event of an injury.

Persons to contact in the Event of Any Problems or Queries:

Head of Department: Dr. A. Docrat Contact number: 031 373 2589

Supervisor: Dr. D. Varatharajullu Contact number: 0313732533

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, _____ (name of researcher), about the nature, conduct, benefits and risks of this study Research Ethics Clearance Number: ______,
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report. In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

| Full Name of Participant Thumbprint | Date | Time | Signature / Right | |
|---|--|--|----------------------------|--|
| I, (name of refully informed about the nature, of | searcher) herewith conduct and risks o | n confirm that the a f the above study. | above participant has been | |
| Full Name of Researcher | Date | Si | gnature | |
| | cable) Date | | Signature | |
| | If applicable) Date | | gnature | |

Appendix C

| DURBAN UNIVERSITY OF DURBAN | TMENT OF PRACTIC CHIROPRACTIC DA MATOLOGY | |
|--|---|---------|
| TECHNOLOGY | CASE Rationt: | HISTOR) |
| | | Dale |
| ile # | Age: | |
| ex: | Occupation: | |
| Student: | Signature: | |
| OR CLINICIANS | USE ONLY: | |
| nitial visit | | |
| Clinician: | Signature: | |
| | | |
| Examination: | | |
| Examination: Previous: | Current: | |
| Examination: Previous: K-Ray Studies: | Current: | |
| Examination: Previous: <-Ray Studies: Previous: | Current: Current: | |
| Examination: Previous: K-Ray Studies: Previous: Clinical Path. lab: | Current: Current: | |
| Examination: Previous: K-Ray Studies: Previous: Clinical Path. lab: Previous: | Current: Current: | |
| Examination: Previous: K-Ray Studies: Previous: Clinical Path. lab: Previous: | Current: Current: | |

| 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 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 Addiction | | | Thyroid Disease | | |
| Epilepsy | | | ТВ | | |
| Other (list) | | 1 | 1 | | 1 |
| | | | | | |

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 D



CHIROPRACTIC PROGRAMME

PHYSICAL EXAMINATION: SENIOR

| Patient Name: | | | | | File r | no: | Date: |
|------------------|--------------------|--------------------------------------|-----|-----------------------------|-------------------|------------------|-------|
| Student: | | | Sig | nature: | | | |
| VITALS: | | | | | | | |
| Pulse rate: | | | | | Respiratory rate: | | |
| Blood pressure: | R L | | | Medication if hypertensive: | | | |
| Temperature: | | | | | Height: | | |
| Weight: | Any rec change? | Any recent Y / N If Yes: How change? | | w much gain/loss Over wł | | Over what period | |
| GENERAL EXA | MINATION: | | | | | | |
| General Impress | ion | | | | | | |
| Skin | | | | | | | |
| Jaundice | | | | | | | |
| Pallor | | | | | | | |
| Clubbing | | | | | | | |
| Cyanosis (Centra | al/Peripheral) | | | | | | |
| Oedema | | | | | | | |
| | Head and neck | | | | |
|---------------|-------------------|-------------|------------|--|--|
| Lymph nodes | Axillary | | | | |
| | Epitrochlear | | | | |
| | Inguinal | | | | |
| Pulses | | | | | |
| Urinalysis | | | | | |
| 6.2.1.1.1.1 S | YSTEM SPECIFIC | EXAMINATION | : | | |
| CARDIOVASC | ULAR EXAMINATI | ON | | | |
| RESPIRATOR | Y EXAMINATION | | | | |
| 6.3 ABDOMIN | NAL EXAMINATION | | | | |
| 6.4 NEUROLO | OGICAL EXAMINATIO | N | | | |
| 6.4.1 COMM | IENTS | | | | |
| | | | | | |
| Clinician: | | | Signature: | | |



Appendix E CHIROPRACTIC PROGRAMME REGIONAL EXAMINATION – CERVICAL SPINE

| Patient: | | File No: | | | |
|---|--|---|--|--|--|
| Date: | Student: | | | | |
| Clinician: | Siį | gn: | | | |
| OBSERVATION: Posture Swellings Scars, discolouration Hair line Body and soft tissue contours | Shou Shou Facia | Ider position Left: Right: Ider dominance I expression: Flex | (hand): | | |
| RANGE OF MOTION: Extension (70°): L/R Rotation (70°): L/R Lat flex (45°): Flexion (45°): | Left rotation Left lat flex Left | Kemp's | Right rotation Right lat flex Right Kemp's | | |
| PALPATION: | | Exte | nsion | | |

Lymph nodes Thyroid Gland

Thyroid Glan 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:

| Dermatones | Left | Right | Myotomes | Left | Right | Reflexes | Left | Right |
|----------------|-------|-------|----------|------|-------|----------|------|-------|
| C2 | | | CI | | | C5 | | |
| C3 | | | C2 | | | C6 | | |
| C4 | | | C3 | | | C7 | | |
| C5 | | | C4 | | | | | |
| C6 | | | C5 | | | | | |
| C7 | | | C6 | | | | | |
| C8 | | | C7 | | | | | |
| TI | | | C8 | | | | | |
| | | | TI | | | | | |
| Cerebellar te | sts: | | Left | Rig | ght | - | | |
| Dysdiadochokir | nesis | | | | | | | |

| 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:

BASIC EXAM: SHOULDER:

Case History:

BASIC EXAM: THORACIC SPINE:

Case History:

ROM: Active: Passive:

> RIM: Orthopaedic: Neuro: Vascular:

right



Extension

| Motion Palpation: | |
|----------------------|---|
| Motion | |
| Palp: | |
| Orthopaedic: | |
| Neuro: | |
| Vascular: | |
| Observ/Palpation: | |
| Joint Play: | |
| | 1 |





Appendix F DURBAN UNIVERSITY OF TECHNOLOGY

| Patient Name: | | File #: | Page: |
|--|-----------------------------|-------------------|-------|
| Date: Visit: Attending Clinician: | Intern: | Signature: | |
| S: Numerical Pain Rating Scale (Pa Least 012345678910 | tient) Intern Rating Worst | <i>A:</i> | |
| 0: | | Р: | |
| | | <i>E:</i> | |
| Special attention to: | | Next appointment: | |
| Date: Visit: Attending Clinician: | Intern: | Signature: | |

| S: Numerical Pain Rating Scale (Patient) Least 012345678910 Worst | Intern Rating | <i>A:</i> |
|--|---------------|-------------------|
| 0: | | Р: |
| | | <i>E:</i> |
| Special attention to: | | Next appointment: |
| Date: Visit: Attending Clinician: | Intern: | Signature |
| S: Numerical Pain Rating Scale (Patient) Least 012345678910 Worst | Intern Rating | A: |
| | | |
| 0: | | Р: |
| | | <i>E:</i> |
| Special attention to: | | Next appointment: |

APPENDIX G

ALGOMETER and CROM DEVICE READINGS

Participant's Name:

Participant's

Code:

File number:

| Visit | Date | Trigger | Algometer | Final CROM Device Reading | |
|----------|---------|---------|-----------|---------------------------|--|
| affected | Reading | Left | Right | | |
| 1st | | | | | |
| 2nd | | | | | |
| 3rd | | | | | |
| 4th | | | | | |

Appendix G

CROM DEVICE MEASUREMENTS FOR LATERAL RANGE OF MOTION

Participant's Name...... File Number.....

Participant's Code:

CROM MEASUREMENTS IN DEGREES

•

| Visit | Date | Left La | Left Lateral Flexion Readings | | Right Lateral Flexion Readings | | |
|-----------------|------|-----------------|-------------------------------|-----------------|--------------------------------|-----------------|-----------------|
| | | 1 st | 2 nd | 3 rd | 1 st | 2 nd | 3 rd |
| 1 st | | | | | | | |
| 2 nd | | | | | | | |
| 4 th | | | | | | | |

Appendix H

Numerical Rating Scale - (NRS-11) Questionnaire

Date:

File no:

Visit no:

Patient name:

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 write only **one** number.



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 write only **one** number.



Appendix I

Patients' Global Impression of Change (PGIC) Scale

| Date: | | |
|-------|------|--|
| Name: | DOB: | |

Chief Complaint (Presenting Problem):

Since beginning treatment at this clinic how would you describe the change (if any) in ACTIVITY LIMITATIONS, SYMPTOMS, EMOTIONS, and OVERALL QUALITY OF LIFE, related to your painful condition? Please circle the number below that matches your degree of change since beginning care at this clinic for the above stated chief complaint.

| No change | Almost same | the Alittle better | Somewhat better | Moderately better | Better | A great deal better |
|-----------|----------------|-----------------------|--------------------|-------------------|--------|---------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Explanation:

1= No change (or condition has got worse)

2= Almost the same, hardly any change at all

3= A little better, but no noticeable change

4= somewhat better, but the change has not made any real difference

5 = moderately better, and a slight but noticeable change

6 =Better, and a definite improvement that has made a real and worthwhile difference

7 = A great deal better, and a considerable improvement that has made all the difference

Appendix J



Memorandum of understanding between:

The RESEARCH INSTITUTION'-Durban University of Technology (this includes the respective research student and research supervisor, Department of Chiropractic. The Faculty of Health Sciences Research Committee, The Institutional Research Committee and any other related DUT employees.

AND

The 'MANUFACTURER'- <u>Neuromechanical Innovations</u> (including all members, employees, associates)

This Memorandum of Understanding pertains to the following research project and must be read in conjunction with:

APPENDIX A-Detailed Research Proposal (PG4a)

APPENDIX B-Durban University of Technology Research Committee Research Ethics Policy and Guidelines

Title of the study:

The effectiveness of the Impulse iQ® Adjusting Instrument compared to ischaemic compression in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain.

Research Supervisor: Dr. D. Varatharajullu (Dept. Chiropractic and Somatology-Durban University of Technology)

This study is a Master's Mini Dissertation conducted in partial compliance with the Master's Degree in Technology in the Department of Chiropractic-Faculty of Health Sciences-Durban

University of Technology. This study will obtain ethical approval from the Faculty of Health Sciences Research & Ethics Committee (IREC) of Durban University of Technology.

Please be aware the brand name will not be divulged to the participants and not included in any of the letters of information as well as the dissertation.

Section 1-Funding of the study and financial commitment

- 1.1 A research allowance of R5000.00 has been awarded by the Dept. Post-graduate Development & Support –The details of the funds approved are described in Section A of the Research Proposal (PG4a) attached.
- 1.2 The 'MANUFACTURER'- acknowledges that THE RESEARCH INSTITUTION' will have no financial obligations or commitments to the 'MANUFACTURER' what so ever as a result of conducting this study.
- 1.3 The 'MANUFACTURER'- may not award or incentivize the study or its related parties in any manner what so ever, nor remunerate, award or offer any financial or other donation or gift to any of those involved with the study.

Section 2-Academic processes and outcome

2.1 The RHDC has approved the above mentioned Research Supervisor who in conjunction with the Research Student are the sole contributors to the academic content, procedures, results and findings of the study based on the prescribed data analysis in the research proposal, barring amendments required by the approved research examiners appointed by the RESEARCH INSTITUTION.

2.2 The 'MANUFACTURER' acknowledges that the findings upon completion of the study (as determined by the Research Student and Research Supervisors and according to the protocol stated in the attached research proposal) will be final and non-negotiable.

The 'MANUFACTURER'-acknowledges further that it has no authority over the outcome of this study and may not influence the findings or the reporting thereof in any matter.

2.3 Any modification or deviation from the approved research proposal, must be applied for in writing, endorsed by both the Research Student & Supervisors and Head of Department before serving before the RHDC/IREC, the final say therein will be determined by the RHDC/IREC.

2.4 The 'MANUFACTURER'-acknowledges that it may not influence or make any change to the approved research protocol/proposal.

Section 3-Publication of findings

3.1 The findings and outcome of the above mentioned study remain the intellectual property of the 'RESEARCH INSTITITION' indefinitely. The study will be published in the format of a hard bound dissertation which will be placed in the DUT library.

3.2 Publication of the findings of this study in a journal or other scholarly medium will be at the discretion of the Research student and /or Research Supervisors who will determine the appropriate medium and place of publication as well as content of the publication. Authorship of any scholarly output originating from this study of the Research Student and Research Supervisors and other collaborators appointed by the Research Student and/or the Research Supervisors. Such scholarly publication must include the names of the Researcher and the

Research Supervisor as well as the 'RESEARCH INSTITUTION'.

3.3 Any reference what so ever to the findings of this study if quoted or mentioned in any format must make formal reference to the respective dissertation its official title and its author(s) and the owners of the intellectual property thereof i.e. the 'RESEARCH INSTITITION'.

3.4 Any reference what so ever to any secondary publication arising from this original study must make formal reference to the respective dissertation its official title and its author(s) and the owners of the intellectual property thereof i.e. the 'RESEARCH INSTITUTION'

3.5 The 'MANUFACTURER'-may make reference to the outcome of this study in the prescribed manner mentioned in section 3.3 and 3.4 undertaking 3.1 and 3.2.

Section 4-Indemnity

4.1 The Research Student, the Research Supervisor and the research facilities and its staff are duly covered by the 'RESEARCH INSTITUTION' insurance policy pertaining to public liability, injury or harm which may occur as a result of conducting this study.

4.2 The 'MANUFACTURER'-undertakes to indemnify the 'RESEARCH INSTITUTION' with regard to any outcome, incidents, injury or harm which occurs as a result of the conduction of this study including the results of the study and publication thereof.

Section 5

5.1 Ethical clearance of the proposed study will be granted by the DUT IREC (such ethical clearance become invalid should there be any deviation from the approved research methodology described in the research proposal attached).

5.2 The 'MANUFACTURER' undertakes to abide by the DUT Research Committee Research Ethics Policy and Guidelines (APPENDIX B).

5.3 In addition to 5.2 the 'MANUFACTURER should note and refer to **Section 1.4,2 & 3** of this document.

I ______ (name of representative of the 'RESEARCH INSTITUTION') hereby in my official capacity as representative of DUT hereby agree to abide by the regulations stated in this memorandum of understanding between the 'RESEARCH INSTITUTION' and the 'MANUFACTURER'.

Signature of official representative of the 'RESEARCH INSTITUTION' Date

I ______ (name of representative of the 'MANUFACTURER') hereby in my official capacity as representative of the Neuromechanical Innorvations hereby agree to abide by the regulations stated in this memorandum of understanding between the 'MANUFACTURER' and the 'RESEARCH INSTITUTION'

| Signature of official | representative | of the | 'MANUFACTURER' | Date |
|-----------------------|----------------|--------|----------------|------|
| olghatalo ol olhola | roprocontativo | | | Duto |

I **Mr. Alistair Makowe** hereby in my capacity as **the research student** hereby agree to abide by the regulations in this memorandum of understanding between the 'MANUFACTURER' and the 'RESEARCH INSTITUTION'

Date

Signature of research Student

Appendix K

MEMORANDUM

To : Prof Puckree

Chair : RHDC

Prof Adam

Chair : IREC

From : Dr Charmaine Korporaal

Clinic Director : Chiropractic Day Clinic : Chiropractic and Somatology

Date : 11.09.2013

Re : Request for permission to use the Chiropractic Day Clinic for research purposes

Permission is hereby granted to :

Mr Alistair Makowe (Student Number: 21020469)

Research title : The effectiveness of the Impulse iQ Adjusting Instrument compared to ischaemic compression in the treatment of myofascial trigger points.

It is noted that Mr Makowe is currently a B.Tech: Chiropractic student, therefore he would require registration as an M.Tech: Chiropractic student to access and therefore conduct his research. Therefore it is requested that Mr Makowe submit a copy of his RHDC / IREC approved proposal along with proof of his M.tech: Chiropractic registration to the Clinic Administrators before he starts with his research in order that any special procedures with regards to his research can be implemented prior to the commencement of him seeing patients.

Thank you for your time.

Kind regards

Dr Charmaine Korporaal

Clinic Director : Chiropractic Day Clinic : Chiropractic and Somatology

Cc: Mrs Pat van den Berg : Chiropractic Day Clinic

Dr L O'Connor : Research co-ordinator and research supervisor

Dr D Varatharajullu : Research supervisor

Appendix L

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

I, ID number..... voluntarily agree to participate in this study: "The relative effectiveness of the Impulse iQ Adjusting Instrument compared to Ischaemic Compression in the treatment of upper trapezius myofascial trigger points" 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 Signature | name | (print |) | |

Appendix M

Neck Disability Index

Date:

THIS QUESTIONNAIRE IS DESIGNED TO HELP US BETTER UNDERSTAND HOW YOUR NECK PAINAFFECTS

YOUR ABILITY TO MANAGE EVERYDAY -LIFE ACTIVITIES. PLEASE MARK IN EACH SECTION THE ONE BOX

THAT APPLIES TO YOU.

ALTHOUGH YOU MAY CONSIDER THAT TWO OF THE STATEMENTS IN ANY ONE SECTION RELATE TO YOU,

PLEASE MARK THE BOX THAT MOST CLOSELYDESCRIBES YOUR PRESENT -DAY SITUATION.

‰

SECTION 1 - PAIN INTENSITY

‰ I have no neck pain at the moment.

‰ The pain is very mild at the moment.

‰ The pain is moderate at the moment.

‰ The pain is fairly severe at the moment.

‰ The pain is very severe at the moment.

‰ The pain is the worst imaginable at the moment.

SECTION 2 - PERSONAL CARE

% I can look after myself normally without causing

extra neck pain.

‰ I can look after myself normally, but it causes

extra neck pain.

% It is painful to look after myself, and I am slow and careful

‰ I need some help but manage most of my personal care.

‰ I need help every day in most aspects of self -care.

‰ I do not get dressed. I wash with difficulty and

stay in bed.

SECTION 3 - LIFTING

% I can lift heavy weights without causing extra neck pain.

‰ I can lift heavy weights, but it gives me extra neck pain.

% Neck pain prevents me from lifting heavy weights off the floor but I can manage if items are conveniently positioned, ie. on a table.
% Neck pain prevents me from lifting heavy weights, but I

can manage light weights if they are conveniently

positioned

% I can lift only very light weights.

% I cannot lift or carry anything at all.

SECTION 4 - READING

‰ I can read as much as I want with no neck pain.

% I can read as much as I want with slight neck pain.

% I can read as much as I want with moderate neck pain.

% I can't read as much as I want because of moderate

neck pain.

% I can't read as much as I want because of severe

neck pain.

% I can't read at all.

SECTION 5 – HEADACHES

% I have no headaches at all.

‰ I have slight headaches that come infrequently.

% I have moderate headaches that come infrequently.

% I have moderate headaches that come frequently.

‰ I have severe headaches that come frequently.

% I have headaches almost all the time.

SECTION 6 - CONCENTRATION

% I can concentrate fully without difficulty.

‰ I can concentrate fully with slight difficulty.

‰ I have a fair degree of difficulty concentrating.

‰ I have a lot of difficulty concentrating.

‰ I have a great deal of difficulty concentrating.

% I can't concentrate at all.

SECTION 9 - SLEEPING

‰ I have no trouble sleeping.

‰ My sleep is slightly disturbed for less than 1 hour.

‰ My sleep is mildly disturbed for up to 1-2 hours.

‰ My sleep is moderately disturbed for up to 2-3 hours.

‰ My sleep is greatly disturbed for up to 3-5 hours.

‰ My sleep is completely disturbed for up to 5-7 hours.

SECTION 7 - WORK

% I can do as much work as I want.

‰ I can only do my usual work, but no more.

‰ I can do most of my usual work, but no more.

‰ I can't do my usual work.

‰ I can hardly do any work at all.

‰ I can't do any work at all.

SECTION 8 – DRIVING

‰ I can drive my car without neck pain.

‰ I can drive my car with only slight neck pain.

‰ I can drive as long as I want with moderate neck pain.

% I can't drive as long as I want because of moderate

neck pain.

% I can hardly drive at all because of severe neck pain.

‰ I can't drive my care at all because of neck pain.

SECTION 10 - RECREATION

‰ I am able to engage in all my recreational activities with no neck pain at all.

‰ I am able to engage in all my recreational activities with some neck pain.

| ‰ I am able to engage in most, but not all of my recreational | | | | |
|---|--|--|--|--|
| activities because of pain in my neck. | | | | |
| ‰ I am able to engage in a few of my recreational activities | | | | |
| because of neck pain. | | | | |
| ‰ I can hardly do recreational activities due to neck pain. | | | | |
| % I can't do any recreational activities due to neck pain. | | | | |
| PATIENT NAME DATE | | | | |
| SCORE [50] COPYRIGHT: VERNON H & HAGINO C, 1991 | | | | |

HVERNON@CMCC.CA

Appendix N



LETTER OF PERMISSION

To Whom It May Concern:

My name is Alistair Makowe and I am currently doing my Master's Degree in Chiropractic at the Durban University of Technology, South Africa.

<u>The title of my research project is</u>: The effectiveness of the Impulse iQ Adjusting Instrument compared to Ischaemic Compression in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain.

| Name of supervisor: | Dr. D. Varatharajullu +27 (31) 204 2533 |
|---------------------------|---|
| - | M.Tech: Chiropractic |
| Name of Research Student: | Alistair Makowe +2771 725 6353 |
| | B.Tech: Chiropractic |
| Name of Institution: | Durban University of Technology, South Africa |

The purpose of the study:

The aim of this study is to determine the effectiveness of the Impulse iQ Adjusting Instrument compared to ischaemic compression for the treatment of upper trapezius muscle MFTPs in participants with non-specific neck pain.

Procedures:

The participants will be required to undergo non-invasive treatment (either trigger point ischaemic compression therapy or Impulse iQ Adjusting Instrument therapy of the trapezius muscle myofascial trigger points); which will have no adverse side effects.

Benefits:

This study will help to determine if the Impulse iQ Adjusting Instrument is effective in treating

myofascial trigger points.

Based on the nature of this study, I am required to seek your permission to utilize the CMCC Neck Disability Index as a means of obtaining data from a participant in terms of neck pain improvement following the treatment intervention.

Yours sincerely,

Alistair Makowe (Chiropractic Intern) (Supervisor) Dr D. Varatharajullu

I ______ (name) hereby give Alistair Makowe consent to conduct the abovementioned research using the CMCC Neck Disability Index.

Signature: _____ Date: _____

Appendix O LETTER OF PERMISSION



To Whom It May Concern:

My name is Alistair Makowe and I am currently doing my Master's Degree in Chiropractic at the Durban University of Technology, South Africa.

<u>The title of my research project is</u>: The effectiveness of the Impulse iQ® Adjusting Instrument compared to Ischaemic Compression in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain.

| Name of supervisor: | Dr. D. Varatharajullu +27 (31) 204 2533 |
|---------------------------|---|
| | M.Tech: Chiropractic |
| Name of Research Student: | Alistair Makowe +2771 725 6353 |
| | B.Tech: Chiropractic |
| Name of Institution: | Durban University of Technology, South Africa |

The purpose of the study:

The aim of this study is to determine the effectiveness of the Impulse iQ® Adjusting Instrument compared to ischaemic compression for the treatment of upper trapezius muscle MFTPs in patients with non-specific neck pain.

Procedures:

The participants will be required to undergo non-invasive treatment (either trigger point ischaemic compression therapy or Impulse iQ® Adjusting Instrument therapy of the trapezius muscle myofascial trigger points); which will have no adverse side effects.

Benefits:

This study will help to determine if the Impulse iQ® Adjusting Instrument is effective in treating myofascial trigger points.

Based on the nature of this study, I am required to seek your permission to utilize the CMCC Neck Disability Index as a means of obtaining data from a participant in terms of neck pain improvement following the treatment intervention.

Yours sincerely,

Alistair Makowe (Chiropractic Intern) (Supervisor) Dr D. Varatharajullu

I _Dr. Howard Vernon_____ (name) hereby give Alistair Makowe consent to conduct the above-mentioned research using the CMCC Neck Disability Index.

Signature:



Date: ___February 27, 2014_

TELEPHONIC SCREEN

APPENDIX P

Title: The effectiveness of the Impulse iQ® Adjusting Instrument compared to ischaemic compression in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain.

Name of prospective participants

Date

Time.....

| QUESTIONS ASKED | EXPECTED ANSWER | PARTICIPANT'S ANSWER |
|--|-------------------------|-------------------------|
| "Would you mind answering a few questions to gauge your eligibility to participate in the study?" | Yes | |
| "How old are you?" | 20-50 | |
| "For how long have you had the pain?" | >4 weeks | |
| "Where is your pain?" | Lower neck region | |
| "Do you have a recent history of trauma?" | No | |
| "Are you currently taking any anti-inflammatory medication?" | No | |
| "Are you currently taking any blood thinning medications?" | No | |

Researcher Signature.....

Witness Signature.....



Institutional Research Ethics Committee Facility 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

Erreit:lavishad@dut.ac.za http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

16 October 2014

IREC Reference Number: REC 62/14

Mr A Makowe 61 Hyde Park 69 Peter Makoba Ridge Berea Durban

Dear Mr Makowe

The effectiveness of the Impulse iQ® Adjusting Instrument compared to ischaemic compression in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain

I am pleased to inform you that Full Approval has been granted to your proposal REC 62/14.

The Proposal has been allocated the following Ethical Clearance number IREC 073/14. Please use this number in all communication with this office.

Approval has been granted for a period of one year, 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. In addition, you will be responsible to ensure gatekeeper permission.

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

Yours Sincerely



Deputy Chairperson: IREC