

The effectiveness of spinal manipulation and dry needling versus spinal manipulation and Traumeel®S injectable solution in the treatment of mechanical neck pain associated with trapezius myofascial trigger points.

By

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

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DEDICATION

To my mother Nurani, my father Aboo Bacar, my two siblings Abdul- Raheem and Shaquille. Without your sacrifices, hardships and motivation I would not have conquered this. I dedicate this dissertation to you; for you believed that I could and would achieve and make my dream come true.

“Knowledge exists potentially in the human soul like the seed in the soil; by learning the potential becomes actual”

(Al-Ghazali)

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ABSTRACT

Background: Mechanical neck pain is a common complaint characterized by pain, limited range of motion and myofascial trigger points. The most common treatments for it are manual therapy and drug therapy. The former includes massage and exercise therapy and more specific to this study spinal manipulation and dry needling. The latter includes non-steroidal anti-inflammatories (NSAIDs) and analgesics. Manipulation assists in increasing range of movement and reduces muscle spasm, while dry-needling inactivates trigger points and decreases local and referred pain. NSAIDs reduce pain and muscle spasm by inhibiting inflammatory pathways. Traumeel®S is a commonly used, safe and well tolerated homoeopathic anti-inflammatory with similar efficacy as NSAIDs but without the adverse gastrointestinal effects. It has also been shown to be highly effective in the treatment of myofascial pain.

Methodology: This study was designed as a randomized comparative clinical trial. Forty participants between ages 18-55 years of age were randomly allocated to two groups of twenty participants each. Group A received spinal manipulation and dry needling in trapezius trigger point two; while Group B received spinal manipulation and Traumeel®S solution injection in trapezius trigger point two. The study took place over a period of two weeks and involved four consultations. Subjective and objective readings were taken at every consultation. Subjective tools included the Numerical pain rating scale (NRS) and Canadian Memorial Chiropractic College (CMCC) neck disability index. Objective tools included the pressure algometer and cervical range of motion (CROM-II) goniometer. SPSS version 20.0 was used in the data analysis. A p -value of <0.05 was considered as statistically significant.

Results: The results showed that no statistically significant differences were observed between the two groups in terms of subjective and objective measurements. However, there were statistically significant improvements seen in both groups equally in terms of subjective and objective measurements i.e. both groups showed improvement.

Conclusion: The results of this study concluded that the effectiveness of spinal manipulation and dry needling versus spinal manipulation and Traumeel®S Injectable solution in the treatment of mechanical neck pain associated with trapezius myofascial trigger points is equivalent to each other. No statistically or clinically significant changes were noticed between the groups.

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LIST OF ABBREVIATIONS

SM- spinal manipulation

TP- trigger point

TP2- trigger point 2

NSAIDs- non-steroidal anti-inflammatory drugs

NRS- numerical pain rating scale

CROM- cervical range of motion

CMCC- Canadian Memorial Chiropractic College

Group A: cervical spine manipulation and dry needling group

Group B: cervical spine manipulation and Traumeel®S group

IFC: interferential current

TENS:transcutaneous electrical nerve stimulation

Kgs: kilograms

ROM: range of motion

Std: standard

%: percentage

***p*:** p-value

n: number in group

>: greater than

<: less than

DEFINITIONS

DEFINITION OF TERMS:

MECHANICAL NECK PAIN: Mechanical neck pain is a complaint of neck pain, headaches and limited range of motion. The pain is described as a dull aching discomfort in the posterior neck that sometimes radiates to the shoulder or mid back regions (Windsor, 2004).

MANIPULATION: A passive manual manoeuvre during which the three joint complex is suddenly carried beyond the normal physiological range of movement without exceeding the boundaries of anatomical integrity, with the object of restoring mobility to restricted areas. (Schafer and Faye, 1990)

FIXATION: The state whereby an articulation has become temporarily immobilized in a position that it may normally occupy during any phase of physiological movement (Haldeman, 1992).

MYOFASCIAL TRIGGER POINT: a focus of hyper-irritability in a muscle or its fascia that is symptomatic with respect to pain. It causes a pattern of referred pain at rest or in motion specific for that muscle (Travell and Simons, 1999).

CHAPTER ONE

1.1 Introduction

Mechanical neck pain is a common complaint and is associated with headaches, limited range of motion and a myofascial component (Windsor, 2004; Bennet, 2007; Hong-You Ge, 2011).

Due to its multi-factorial nature, a regimen is frequently used in its treatment. Spinal manipulation (SM) is a form of treatment, the effects of which include pain relief, reduction in disability and an increase in the range of movement (Lee *et al.*, 1995; Tsolakis, 2001; Gross *et al.*, 2007; Miller *et al.*, 2010).

A significant component in the aetiology of mechanical neck pain is the myofascial pain arising from the surrounding muscles (Penas *et al.*, 2007). The pain is frequently caused by myofascial trigger points which are areas of local irritability in a muscle that is tender at rest or when palpated, and can refer pain over a wide area (Travell and Simons, 1999). Travell and Simons (1999) have further reported that myofascial trigger points from neck and shoulder muscles play an important role in the origins of mechanical neck pain. Of the muscles involved, trigger points in the trapezius muscle are a common contributing factor of mechanical neck pain (Gross, 2002; Penas *et al.*, 2007).

The treatment of myofascial trigger points commonly includes ischaemic compression, dry needling, ultrasound therapy and trigger point injection with local anaesthetic, saline or steroids (Alvarez and Rockwell, 2002; Yap, 2007).

Dry needling of myofascial trigger points has been shown to decrease both local and referred pain (Travell and Simons, 1999). Clinical trials on dry needling alone as well as an adjunct to spinal manipulation have shown to be effective (Annaswamy *et al.*, 2011). Jones (1994) performed a study on the effectiveness of myofascial trigger point therapy on myofascial pain syndrome. Two treatments were used. The results showed that the efficacy of myofascial trigger point therapy in the form of dry needling to be significantly more improved than the placebo groups. The study by Cummings *et al.*, (2004) on the relative effectiveness of ultrasound versus dry needling of myofascial trigger points revealed dry needling to be more effective and superior in pain relief.

Traumeel®S is a homeopathic anti-inflammatory which is available in oral, injectable and topical form (Zenner and Metelmann, 1992). It is frequently used for musculoskeletal conditions (Zell, 1999; Schneider, 2011). It is an alternative to non steroidal anti-inflammatory drugs (NSAIDs) which are also commonly used to limit inflammation and to control pain (Schneider, 2011). It displays analgesic, anti-oedematous, and anti-exudative properties (Zell, 1999; Kersschot, 2004; Heel, 2009). These properties are proposed to aid the reduction in referred pain from trigger points and their inflammatory effects (Birnesser *et al.* 2004).

Dry needling is an effective treatment option individually and as an adjunct (Travell and Simons, 1999). Traumeel®S has shown comparable effectiveness to NSAIDs in terms of reducing inflammation and pain, and improving mobility, with a favourable safety profile in musculoskeletal conditions (Schneider, 2011). In conditions like neck pain and lower back pain which have multi-faceted aetiology, combination treatments need to be investigated (Haldeman and Kohlbeck, 2002; Kohlbeck *et al.*, 2005; Dagenais *et al.*, 2008).

Kohlbeck *et al.*, (2005) showed that medication-assisted manipulation appears to offer some patients increased improvement in pain and disability however further investigation of these apparent benefits in randomized clinical trials are warranted. Combinations of spinal manipulation, dry needling and Traumeel®S injectable have not been investigated. Therefore, the aim of this study was to compare the effectiveness of spinal manipulation (SM) and dry needling versus spinal manipulation (SM) and Traumeel®S injectable solution in the treatment of mechanical neck pain and trapezius two (TP2) myofascial trigger points.

1.2 Aim and Objectives

1.2.1 Aim of the study

The aim of this study was to compare spinal manipulation (SM) and dry needling versus spinal manipulation and Traumeel®S injectable solution in the treatment of mechanical neck pain and trapezius two (TP2) myofascial trigger points.

1.2.2 Objectives of the study

Objective one

- 1) To compare spinal manipulation and dry needling vs. spinal manipulation and Traumeel®S injections by means of subjective findings.

The subjective measurements included the Numerical Pain Rating Scale (NRS) (Appendix G), and Canadian Memorial Chiropractic College (CMCC) neck disability index questionnaire (Appendix H) which are questionnaires that described the participant's pre-treatment state.

Objective two

- 2) To compare spinal manipulation and dry needling vs. spinal manipulation and Traumeel®S injections by means of objective findings.

The objective measurements were taken using an algometer, (to measure patient's pain threshold over the tenderest segments of trigger point). The cervical spine range of motion was measure using a CROM-II goniometer which measures range of motion in the cervical spine.

Objective three

- 3) To compare the two groups in terms of subjective and objective data. i.e. to assess whether changes from baseline in subjective and objective outcomes are correlated within treatment groups.

1.3. Rationale

1.3.1 Rationale one: Mechanical neck disorders are common, disabling and costly (Makela *et al.*, 1991; Rajala *et al.*, 1995; Co^{te} *et al.*, 1998). Direct and indirect costs for neck disorders are substantive (Borghouts *et al.*, 1999; Hoving *et al.*, 2002, Korthal-de Bos, 2003). A large proportion of the health-care costs can be attributed to visits to health-care providers (Waalén *et al.* 1994; Linton *et al.* 1998; Skargren *et al.* 1998, Korthal-de Bos, 2003). If a combination of effective treatments can be administered over a shorter period of time, requiring fewer amounts

of visits, costs can be curbed by patients. Furthermore for maximum patient benefit, multiple treatments need to be investigated to see which renders the most effective as well as to add to the body of literature (Korthal-de Bos, 2003, Kohlbeck, 2005).

1.3.2 Rationale two: Manual therapies include spinal manipulation, passive mobilization, neuromuscular mobilization, and soft tissue therapies (Basmajian and Nyberg, 1993). These manual therapies have individually proven their effectiveness however superiority in combination and comparison needs to be investigated further (Miller *et al.*, 2010). In a systematic review by Hoving *et al.* (2001), reviewers found inconclusiveness of effects of manipulation and mobilization in combination with other conservative treatments. Investigation of combinations of therapies is necessary in multi-faceted conditions like mechanical neck pain such that maximum patient care is administered (Haldeman and Kohlbeck, 2002; Dagenais and Haldeman, 2008.)

1.3.3 Rationale three: Traumeel®S is a safe and well tolerated homoeopathic anti-inflammatory drug with similar efficacy as non-steroidal anti-inflammatory (NSAIDs) but without the adverse gastrointestinal effects (Hepburn, 2000; Arora *et al.*, 2000; Porozov *et al.*, 2004). It is indicated in musculoskeletal conditions and has been shown to be highly effective due to its analgesic, anti-oedematous and anti-inflammatory properties (Birnesser *et al.* 2004; Kersschot, 2004; Schneider, 2011). Although Traumeel®S is indicated for musculoskeletal conditions; there is a paucity of literature on the usage of Traumeel®S for myofascial trigger point treatment. Continued research and development is ongoing to broaden the clinical evidence of Traumeel®S in musculoskeletal injury and to further establish its benefits, so investigation into its maximum functionality is warranted (Schneider, 2011). Therefore a study of this nature will add to the body of literature available.

1.3.4 Rationale four: Dry needling is commonly used in the treatment of myofascial trigger points and has a side effect of post needling soreness (Travell and Simons, 1999). Using Traumeel®S which has analgesic properties may assist in the post needling soreness in addition to solving the myofascial trigger point pain. Therefore by comparing the two treatments, it will distinguish if one has superior analgesic properties to the other.

1.4 Outline of chapters

Chapter two will outlay the review of the literature including anatomy related to mechanical neck pain. Chapter three discusses the methodology of the study including consultations and interventions used. Chapter Four addresses the statistical results of the study whereas Chapters five and six will discuss the results, give recommendations and provide conclusion to the study.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 Introduction

This chapter will present the relevant literature on mechanical neck pain. It will discuss the anatomy of the cervical spine and trapezius muscle. The myofascial component to mechanical neck pain will also be reviewed. It will further discuss literature on spinal manipulation, dry needling and Traumeel®S including their roles in the treatment of mechanical neck pain.

2.2 Mechanical neck pain

Mechanical neck pain is a presentation of pain or stiffness and limited range of motion. The pain is described as a dull aching discomfort in the posterior neck that radiates to the shoulder or mid back regions (Ferrari and Russell, 2003; Gross *et al.*, 2007, Windsor *et al.*, 2011).

2.3 Epidemiology of mechanical neck pain

Neck pain is a frequent impairment that affects physical and social function (Co^{te} *et al.*, 1998, Hoving *et al.*, 2002). It is the most common musculoskeletal disorder in population surveys and primary care (Ferrari and Russell, 2003). Mechanical neck pain occurs in 80 percent of the population at any given time (Penas *et al.*, 2007). Research shows a 20 to 30 percent incidence of mechanical neck pain in population based studies (Ferrari and Russell, 2003). Co^{te} *et al.*, (1998), found that the age standardization lifetime prevalence of neck pain is approximately 67 percent, significantly disabling 4.6 percent of the adult population. Bland and Boushey (1994) stated that working individuals between the ages 25-29 years have a 25-30 percent incidence of neck pain with individuals over the age of 45 having a 50 percent incidence of neck pain. The lifetime prevalence of mechanical neck pain has been estimated to be between 67 percent and 71 percent, indicating that approximately two thirds of the general population will experience an episode of neck pain at some time during their life (Penas *et al.*, 2007). A Scandinavian study by Borenstein *et al.*, (1996), showed the prevalence of neck pain to be greater in females than in males.

As mechanical neck pain is so common, it results in high levels of health-care use (Makela *et al.*, 1991; Rajala *et al.*, 1995; Co^{te} *et al.*, 1998; Korthals-de Bos, 2003). It therefore accounts

for substantial costs due to disablement and absenteeism (Bland, 1987; Bovim *et al.*, 1994; Hoving *et al.*, 2002, Korthals-de Bos, 2003).

2.4 Aetiology of mechanical neck pain

Mechanical neck pain is an ill-defined condition (Ernst, 2003). It is associated with muscular, vertebral joint and neural components (McMorland and Suter, 2000; Hoving *et al.*, 2001; Irnich *et al.*, 2002; Windsor, 2004).

The multi-factorial aetiology includes factors associated with acute, chronic and psychosocial disease (Ferrari and Russell, 2003). Chronic aetiology is usually the least common and includes tumours, systemic arthropathy, fibromyalgia, infections and long standing conditions linked to the thyroid and oesophagus (Ernst, 2003; Ferrari and Russell, 2003). Additionally, the neck is also a site for referred pain from cardiac, gastric and diaphragmatic disease processes (Bogduk, 1999). More commonly linked and acute disorders include chronic whiplash, spondylosis, and myofascial pain syndromes. These benign diagnoses are non-definitive; therefore the pain is ascribed to facet joint subluxations, trigger points, or chronic musculo-ligamentous injury (Ferrari and Russell, 2003; Miller *et al.*, 2010).

Psychosocial influences form a large part in the disease manifestation and progression (Gross *et al.*, 2002). These include posture, stress and anxiety disorders, depression, personality traits and occupational factors (Ferrari and Russell, 2003; Miller *et al.*, 2010). These factors are often overlooked and therefore have a repetitive reoccurrence, which often leads to chronic pain syndromes (Côté *et al.*, 1998). Mechanical neck pain can also be caused due to degeneration associated with increase in age resulting in spondylitic change (Esenyel *et al.*, 2007).

2.5 Clinical presentation of mechanical neck pain

The clinical picture for mechanical neck pain is not always specific (Bogduk, 1999; Gross *et al.*, 2002) however, based on an analysis of the history, physical examination and investigations, a group of common signs and symptoms are found (Ferrari and Russell, 2003). Patients with mechanical neck pain present with pain or stiffness in the posterior neck, headaches, limited range of motion and myofascial pain due to trigger points in the posterior cervical and/or trapezius musculature. The pain is described as a dull aching discomfort that can sometimes

become sharp and erratic in nature with radiation to the mid-back region (McMorland and Suter, 2000; Hoving *et al.*, 2001; Ferrari and Russell, 2003).

2.6 Discussion of the related anatomy

Mechanical neck pain is generally defined as stiffness and/or pain in the posterior neck, from between the occipital condyles and the C7 vertebral prominence (Bogduk, 1999; Ferrari and Russell, 2003; Windsor, 2004). The pain is described as a dull aching discomfort and is often accompanied by a headache, pain in the upper thoracic region, and the jaws (Simons and Maitland, 1999; Windsor, 2011).

Trigger points in the posterior neck musculature, and the trapezius muscle play an important role in the origins of mechanical neck pain (Travell and Simons, 1999). According to Travell and Simons (1999), trigger points in clinical neck settings appear to be most frequently cited in the trapezius muscle even though they can arise in any muscle group. A study by Alvarez and Rockwell in (2002) on Trigger Point Management and Diagnoses showed a strong relationship between trigger point 2 (TP2) of trapezius and neck disorders. Similarly, Penas, Blanco and Miangolarra's study (2007) on Myofascial Trigger Points in patients with Mechanical Neck Pain, revealed that 90 percent of subjects had active trigger points in the upper fibres of trapezius muscles bilaterally. This study also showed a significant relationship between the presence of active trigger points in the upper trapezius muscle and the presence of intervertebral joint dysfunctions at C3 and C4 vertebrae.

2.6.1 Anatomy of the cervical spine

2.6.1.1 Bones of the cervical spine

According to Moore and Dalley (1999), the cervical spine is made up of seven small vertebral bodies, which are the smallest movable vertebra of the spine. They are divided into atypical (C1 atlas+C2 axis) and typical (C3-C7) vertebra (Bogduk, 1999; Windsor *et al.*, 2011). The atlas is ring shaped and does not have a body, with the axis having a large vertebral body, which contains the dens, that articulates with the atlas. The typical vertebrae all have vertebral bodies, raised uncinat processes and spinous processes (Gatterman, 1990; Windsor *et al.*, 2011). The spinous processes of C3-C6 are short and bifid, with the spinous process of C7 being significantly long (Moore and Dalley, 1999).

In between the vertebral bodies lie intervertebral discs (Moore and Dalley, 1999) which serve as an articulation between adjacent vertebral bodies, unite them and allow for movement to take place at that motion segment (Gatterman, 1990). The discs provide flexibility and curvatures to the vertebral column, act as shock absorbers and provide strength and weight bearing abilities (Moore and Dalley, 1999; Chaitow and Delany, 2002).

2.6.1.2 Joints of the cervical spine

Three different joint articulations exist in the cervical spine. These include zygapophyseal, uncovertebral and craniovertebral joint articulations (Moore and Dalley, 1999).

Zygapophyseal Joints: also known as facet joints are true diarthrodial joints of the vertebral arches (Moore and Dalley, 1999). They are supported by articular cartilage, supporting ligaments, synovial capsule and muscles (Gatterman, 1990).

Uncovertebral Joints: These joints are found at the posterolateral and lateral borders of the intervertebral discs, between the uncinate processes of C3-C6 vertebral bodies and the vertebral bodies above them (Moore and Dalley, 1999).

Craniovertebral Joints: There are two craniovertebral articulations namely the atlanto-occipital joint and the atlanto-axial articulation (Windsor *et al.*, 2011). Atlanto-occipital articulation is between the superior articular facets of C1 and the occipital condyles of the occiput (Moore and Dalley, 1999). The atlanto-axial joint has two articulations. The medial joint refers to the odontoid process of C2 and anterior arch of C1. The lateral joint is a gliding joint and refers to the articulation between the inferior facets of C1 and superior facets of C2 (Gatterman, 1990; Moore and Dalley, 1999; Windsor *et al.*, 2011).

2.6.1.3 Musculature of the cervical spine

The upper trapezius and posterior cervical musculature consisting of the (semispinalis capitis, longissimus capitis, semispinalis cervicis, multifidi and rotators) are muscles most commonly found to be symptomatic in mechanical neck pain (Travell and Simons, 1999; Chaitow and Delany, 2002). For the purpose of this study the anatomy of the trapezius muscle will be discussed.

2.7 Anatomy of the trapezius muscle

According to Travell and Simons (1999) the trapezius muscle is a tripartite muscle consisting of upper, middle and lower fibres, in different directions and often having different functions. For the purpose of this research, the upper fibres which includes trigger point one and trigger point two (TP2) will be discussed.

This diamond-shaped muscle extends from the occiput (in the midline) to T12. Anteriorly it includes the lateral one-third of the clavicle, laterally attaching to the acromion and posteriorly to the spine of the scapula. The motor fibres are innervated by the spinal part of the accessory nerve (cranial nerve XI), whilst the sensory fibres receives innervations from the second to the fourth cervical nerves.

Trigger point location: Trigger point one (TP1) is found in the mid-portion of the anterior border of the upper trapezius and involves the most vertical fibres that attach anteriorly to the clavicle. Trigger point two (TP2) is caudal and slightly lateral to TP1. It is located in the middle of the more nearly horizontal fibres of the upper trapezius muscle (Travell and Simons, 1999).

The function of the upper trapezius is to draw the clavicle (and indirectly the scapula) backwards and raise them by rotating the clavicle at the sternoclavicular joint. This portion of the muscle also complements the serratus anterior in rotation of the scapula so that the glenoid fossa faces upwards. It aids in lateral flexion of the neck (Travell and Simons, 1999).

2.8 Myofascial Pain Syndrome

Myofascial pain is a common form of pain arising from hyper-irritable foci in muscle, which are referred to as myofascial trigger points (Bennet, 2007). These trigger points have been found to be a common source of musculoskeletal dysfunction and one of the main causes of headache and neck pain (Friction, 1985; Skootsy *et al.*, 1989; Travell and Simons, 1999). It may exist as a primary disorder causing local or regional pain syndromes or it may occur secondarily to other existing conditions (Gerwin, 2001). It is often referred to as 'soft tissue rheumatism' and commonly develops as a result of acute muscle injury, overuse or repetitive strain (Bennet, 2007; Huguenin, 2004).

Myofascial trigger points are an area of local irritability in a muscle that is tender at rest or when palpated (Travell and Simons, 1999). The locations of a trigger point may include fascia, ligaments, skeletal muscles and tendons (Penas *et al.*, 2007). They have been described as a common cause of pain in clinical practice and constitute the largest group of unrecognized and undertreated medical presentations (Travell and Simons, 1999).

2.8.1 Epidemiology of myofascial pain syndrome

Myofascial pain is the most common single source of musculoskeletal pain (Fricton, 1985; Travell and Simons, 1999; Penas *et al.*, 2007) and is diagnosed in nearly a third of patients who have musculoskeletal pain disorders (Annaswamy *et al.*, 2011). It is the largest group of unrecognized and undertreated acute and chronic medical presentations in clinical practice (Huguenin, 2004; Rickards, 2006).

Skootsky *et al.*, (1989) study reported that the primary complaint of 30 percent of patients in a general medical clinic was attributed to myofascial pain. Alvarez and Rockwell's (2002) study on Trigger Point Management and Diagnoses, showed a strong relationship between trigger point two (TP2) of trapezius muscle and neck disorders. Penas, Blanco and Miangolarra's (2007) study on Myofascial Trigger Points in patients with Mechanical Neck Pain, revealed that 90 percent of subjects had active trigger points in the upper fibres of trapezius muscle. A similar study by Bennet (2007), on Myofascial Pain Syndromes, showed 55 percent of head and neck pain cases reported myofascial aetiology to be of primary complaint. With a fairly high prevalence, myofascial pain, which is treatable, is often under-diagnosed and under-treated (Yap, 2007).

2.8.2 Aetiology of myofascial pain syndrome

According to Yap (2007), myofascial trigger points are perpetuated by trauma, emotional/psychological stress, or metabolic deficiencies. A host of other factors also contribute to trigger point development. Mense *et al.*, (2000) study on Muscle pain: understanding its nature, diagnosis and treatment; hypothesized that the pathogenesis of trigger points results from injured or overloaded muscle fibres. This leads to involuntary shortening, loss of oxygen supply, loss of nutrient supply and increased metabolic demand on local tissues. The

development of myofascial trigger points may also be directly due to the muscle being placed in a shortened position; contracting whilst in this position; nerve compression; direct trauma; fatigue and indirectly by diseases of the visceral organs, other trigger points and arthritis (Travell and Simons, 1999).

According to Hong (2006) and Travell and Simons (1999), myofascial trigger points develop as a result of joint dysfunction such as that of the facet joints. Penas *et al.*, (2007), study on Myofascial trigger points and sensitization revealed dysfunctions in the cervical facet joints can result in the development of myofascial trigger points.

2.8.3 Clinical presentation of myofascial pain syndrome

Myofascial pain syndrome is now understood to refer to a spectrum of clinical presentations allowing its distinction from other musculoskeletal conditions, such as strains, sprains and fibromyalgia (Argoff and Smith, 2010).

According to Finley (2010), patients with myofascial pain usually complain of aching and poorly localized pain in the muscles and joints. Sensory disturbances, such as numbness in a characteristic distribution may also be reported. Acute onset may be preceded by a specific event or trauma while chronic pain may occur as a result of poor posture or overuse. Muscle weakness may also be present (Finley, 2010).

The clinical presentation of myofascial pain syndrome also depends on whether the myofascial trigger points are active or latent (Travell and Simons, 1999; Rickards, 2006). Active trigger points are hypersensitive and can be associated with two types of pain: spontaneous with muscle use or with palpation on examination (Travell and Simons, 1999). An active trigger point is characterized as a well-demarcated, sharp, localized pain or as a radiating or referred pain (Travell and Simons, 1999). A referred pain is commonly described as deep and aching in character, projecting beyond the originating trigger point and is produced on compression of the trigger point (Huguenin, 2004; Rickards, 2006; Kamanli *et al.*, 2011). Other symptoms of an active trigger point include stiffness, muscle fatigue and decreased motor function (Travell and Simons, 1999; Rickards, 2006). Active myofascial trigger points also cause decreased range of motion and limit flexibility (Rickards, 2006; Kamanli *et al.*, 2011).

By comparison, latent myofascial trigger points remain non-painful at rest, with pain only being elicited by the application of direct steady pressure (Rickards, 2006). Latent trigger points can

become active trigger points if the muscle is stressed by tension, mechanical overloading or prolonged muscle shortening (Rickards, 2006). According to Travell and Simons (1999) latent trigger points may display all clinical characteristics of an active trigger point; they also have a taut band that increases muscle tension and restricts range of motion.

2.8.4 Clinical features of trapezius muscle

For the purpose of this study the clinical features of trapezius trigger point two (TP2) will be discussed.

Trigger points within the trapezius muscle are activated and perpetuated in acute trauma, falls or whiplash. Repetitive stress and prolonged elevation or extension of the arms also contributes to activation. Muscle overloading during prolonged typing, neck tilting and instability in the shoulder-girdle axis also result in activation (Argoff and Smith, 2010).

Pain from the trapezius muscle, is often referred to the postero-lateral neck and temple, cervico-occipital area and acromion, shoulder and midback regions (Travell and Simons, 1999). More specifically pain referral of trigger point two (TP2) is posterior to the cervical spine to the mastoid process, often to the base of occipit, shoulder and upper thoracic regions (Travell and Simons, 1999).

Other associated symptoms include decreased muscle strength and endurance (Argoff and Smith, 2010). Autonomic phenomena are often associated with trigger-point presentation and these include localized vasoconstriction, persistent hyperaemia after palpation, pilomotor activity, diaphoresis and lacrimation (Travell and Simons, 1999; Argoff and Smith, 2010).

2.8.5 Treatment modalities for myofascial trigger points

Manually, the treatment of myofascial trigger points commonly include ischaemic compression, dry needling, ultrasound, heat or ice application, muscle energy techniques, spray and stretch, and massage (Alvarez and Rockwell, 2002; Rickards, 2006; Penas *et al.*, 2007; Yap, 2007). Alternatively pharmacological treatment includes the use of analgesics and medications that induce sleep. These may include anti-depressants, neuroleptics or non-steroidal anti-inflammatory drugs (NSAIDs) (Hoving *et al.*, 2002, Penas *et al.*, 2007). Trigger point injection

with local anaesthetic, saline or steroids are also used (Travell and Simons, 1999; Hong, 2006; Yap, 2007). Spinal manipulation has also proven to aid in myofascial release (Mense *et al.*, 2000; Hong, 2006). Physical modalities and electrical modalities such as Interferential Current (IFC), ultrasound and transcutaneous electrical therapy (TENS) are generally used as supplementary adjuncts, as they aid in controlling muscle pain and spasm (Yap, 2007).

The effectiveness of treatment approaches is not fully recognised even though many different methods have been stated in the literature (Esenyel, Aldemir, Gursoy *et al.*, 2007; Annaswamy *et al.*, 2011). Furthermore there is a lot of difference in opinion when it comes to advocating the treatment of choice for myofascial trigger points, as there is little statistical evidence to support the use of one treatment over another (Annaswamy *et al.*, 2011). For the context of this study we will look at the use of dry needling and trigger point injection.

2.8.6 Dry needling

Dry needling has been advocated as the treatment of choice in aiding myofascial trigger points and appears to be an effective treatment modality (Lewit, 1979, Mense *et al.*, 2000; Kamanli *et al.*, 2005; Hong, 2006; Tough *et al.*, 2007). It is minimally invasive, inexpensive, easy to learn with appropriate training, and carries a low risk (Annaswamy *et al.*, 2011). Dry needling uses an acupuncture needle insertion into a trigger point that reproduces the pain, causes a local twitch response followed by pain relief and relaxes the tension in the muscle (Travell and Simons, 1999; Huguenin, 2004). The local twitch response is a reflex contraction and is a confirmation of trigger point localization (Travell and Simons, 1999; Chaitow and Delany, 2002; Huguenin, 2004). Dry needling effectiveness is achieved by direct stimulation or mechanical disruption by the needle which decreases or ceases the pain (Travell and Simons, 1999; Huguenin, 2004; Hong, 2006).

Many studies in the literature have proven the effectiveness of dry needling. Lewit (1979) published an article that stated “the needle effect is as distinct from the injected substance”. Hong (1998) later agreed and showed that, whether or not an injection is performed, the needling procedure is more effective as a local twitch response is obtained from the muscle. Studies undertaken by Jones (1994), to show the efficacy of myofascial trigger point therapy in the form of dry needling techniques versus placebo groups revealed dry needling to be significantly more beneficial than the placebo groups and hence myofascial trigger point therapy

via dry needling is effective. Broome (1996) performed a study on the therapeutic efficacy of invasive needling techniques in the management of myofascial pain and dysfunction syndrome. The study involved the use of dry needling and saline injection for trigger point treatment. The study hypothesized that saline would be superior form of treatment. Results of the study concluded that both treatments were effective and neither was found to be more effective than the other. Cummings and White (2001) performed a systematic review on Needling therapies in the management of myofascial trigger point pain. The study concluded that direct needling of trigger points appears to be an effective treatment, although the efficacy beyond placebo could not be supported or refuted by the literature. They further stated that any effect of needling therapies was a result of needling and found no evidence that injection of any substance elicited a superior response compared with the insertion of a needle alone.

Cummings (2004) study on the relative effectiveness of ultrasound versus dry needling of myofascial trigger points revealed treatment of pain via dry needling to be more effective. A study was conducted by Huguenin (2004) on Myofascial Trigger points: Current evidence. This study evaluated and provided an overview of the current state of knowledge regarding the history, pathophysiology, mechanisms of pain production, and proposed methods of treatment of myofascial trigger points. The study revealed dry needling to be effective in pain relief.

A later review and meta-analysis by Tough, *et al.*, (2007) on Acupuncture and dry needling in the management of myofascial trigger point pain; revealed that deep needling directly into myofascial trigger points has an overall treatment effect when compared to other standardised care.

2.8.7 Trigger point injection

Trigger point injection can effectively inactivate trigger points and provide prompt symptomatic relief (Alvarez and Rockwell, 2002; Speed, 2003; Kamanli *et al.*, 2005). The mechanism of action is similar to that of needling whereby the injection is said to cause mechanical disruption of the trigger point and desensitization of the area (Speed, 2003). It has been proposed that pain relief, increased range of motion, and improved exercise tolerance are achieved with this therapeutic approach (Speed, 2003; Kamanli *et al.*, 2005).

Several methods and treatments have been recommended and used in trigger point injection therapy (Kamanli *et al.*, 2005). Treatments with local anesthetics, saline, non-steroidal anti-

inflammatory drugs, botulinum and corticosteroids have been used and tested (Speed, 2003; Kamanli *et al.*, 2005; Bennet, 2007).

Annaswamy (2011) performed a study that reviewed emerging concepts in the treatment of myofascial pain. The study reviewed literature on medications, modalities and needle-based interventions. The literature on needle based interventions revealed that most studies compared trigger point injections to dry needling. The study's results revealed both dry needling and trigger point injection to be effective in pain relief with only one study by Kamanli *et al.*, (2005) finding trigger point injection to be more effective than dry needling.

As far as what to inject, many studies have tested many products (Speed, 2003; Kamanli *et al.*, 2005). Local anaesthetic, NSAIDs and saline are the most commonly used (Speed, 2003; Bennet, 2007). A study was conducted by Kamanli *et al.*, (2005) on the comparison of lidocaine injection, botulinum toxin injection, and dry needling to trigger points in myofascial pain syndrome. Cervical or periscapular trigger points in 30 participants were treated. The outcomes included assessment of cervical range of motion, trigger point pain pressure threshold, pain scores, and visual analogue scales for pain, fatigue, and work disability. Additionally, depression and anxiety and quality of life were assessed. The study showed varied results in the three groups. Pain pressure thresholds and pain scores significantly improved in all three groups; however the lidocaine group showed marked changes across all outcomes making it the superior choice.

Ferrante *et al.*, (2005) performed a study on trigger point injection technique for the treatment of cervico-thoracic myofascial pain with botulinum toxin type A. Results showed no significant differences occurred between placebo and botulinum group. Bennet (2007) concluded in his study that although dry needling is effective, the use of a local anaesthetic (lidocaine or procaine) helps to confirm the accuracy of the injection and provides instant gratification for patients.

2.9 Spinal manipulation

Spinal manipulation which has been described as “a passive dynamic thrust that causes an audible release (cavitation)” (Ernst, 2003), works to relieve pain, decrease stiffness and increase range of motion (Gatterman, 1990; Lee *et al.*, 1995). It resolves muscle guarding

(Gibbon and Tehan, 2001) and aids in tissue release by releasing hypertonicity and increasing extensibility (Gatterman, 1990; Travell and Simons, 1999).

McMorland and Suter's (2000) study on Chiropractic Management of Mechanical Neck and Lower Back Pain: A Retrospective and Outcome Based Analysis involved the examination of the outcome of patients undergoing chiropractic treatment. The study showed a 58.4 percent reduction in pain and disability in the mechanical neck pain group who received manipulation. Similarly, Gross *et al.*, (2002) study on Clinical practice guideline on the use of manipulation or mobilization in the treatment of adults with mechanical neck disorders, revealed varied outcomes. The study aimed to ascertain the risks and benefits for manipulation or mobilization in treating mechanical neck disorders. Results showed manipulation and mobilization alone benefited for pain relief, whilst a combination of manipulation or mobilization and exercise had a more superior outcome.

Alternatively, Ernst (2003) performed a review on chiropractic spinal manipulation for neck pain. The study involved evaluating systematically and critically the effectiveness of spinal manipulation for neck pain. Four studies were used. Two studies were on single interventions, and two included series of spinal manipulative treatments, both with a twelve month follow-up. The two short-term trials used spinal mobilization as a control intervention. The two long-term studies compared spinal manipulation with exercise therapy. The study revealed spinal manipulation to be a superior form of treatment in pain relief and increasing range of motion however its superiority over interventions like exercise still remains unclear. Miller *et al.*, (2010) study on Manual therapy and exercise for neck pain: a systematic review; also revealed that manipulation with or without exercise improves pain, function, and disability in patients with neck pain. It is evident from the above literature that manipulation alone or in combination is beneficial.

2.10 Traumeel®S

Besides manual therapies which are effective for treatment of mechanical neck pain and myofascial trigger points, non-steroidal anti-inflammatory drugs (NSAIDs), are a first line drug therapy treatment of choice (Bennet, 2007; Annaswamy *et al.*, 2011). However there is a

growing concern about the safety of NSAIDs due to gastro intestinal side effects ((Lussignoli *et al.*, 1999).

Side effects associated with NSAIDs are common. Most frequent are the effects on the gastrointestinal tract, the most common being gastritis and upper gastrointestinal ulcer and bleeding (Allison *et al.*, 1992). Moreover, it has been demonstrated that non-steroidal anti-inflammatory treatment may not promote healing in the musculoskeletal system, but rather impair the return of mechanical strength following acute injury to either, bone, ligament, or tendon (Warden, 2005).

Traumeel®S which is available in oral, injectable and topical form is a homeopathic anti-inflammatory indicated for musculoskeletal conditions. It fulfills the criteria for a locally acting therapeutic medication with analgesic action, anti-oedematous, and anti-exudative properties (Heel, 2009). These properties are proposed to aid the reduction in referred pain from trigger points and their inflammatory effects (Birnesser *et al.*, 2004). Traumeel®S (Heel GmbH, Baden-Baden, Germany) is also used to treat post traumatic oedema and swelling of soft tissues. It has been shown to modulate inflammation as well as to show a reparative effect on tissues subjected to chronic inflammatory states. It is a mixture of highly diluted (10^{-1} - 10^{-9}) extracts from medicinal plants and minerals that is sold as an over the counter remedy in pharmacies in many countries. The mixture consists of the following: Arnica montana, radix 2X, Belladonna 2X, Calendula officinalis 2X, Chamomilla 3X, Millefolium 3X, Hepar sulphuris calcareum 6X, Symphytum officinale 6X 2.2 mcl each; Aconitum napellus 2X 1.32 mcl; Bellis perennis 2X, Mercurius solubilis 6X, 1.1 mcl each; Hypericum perforatum 2X 0.66 mcl; Echinacea 2X, Echinacea purpurea 2X 0.55 mcl each; Hamamelis virginiana 1X 0.22 mcl. Inactive ingredient: Sterile isotonic sodium chloride solution. The mineral ingredients are Hepar sulphuris calcareum (calcium sulfide) Mercurius solubilis (Hahnemann's soluble mercury) (Arora *et al.*, 2002; Heel, 2009).

Its anti-inflammatory and analgesic effects have been demonstrated in clinical trials as well as in *in vivo* experimental models, including the carrageenin-induced oedema test and the adjuvant arthritis test. These tests demonstrate the anti-inflammatory effects of Traumeel® S and show that Traumeel®S reduces inflammation at a local level and not at a biochemical level like conventional drugs (Conforti *et al.*, 1997; Arora *et al.*, 2002; Cenulevicius, 2010; Schneider, 2011).

Whilst NSAIDs act by inhibiting the arachidonic acid pathway and therefore the production of prostaglandins (Lussignoli *et al.*, 1999; Porozov *et al.*, 2004), Traumeel®S mechanism of action involves and results from the various components acting on the different phases of the inflammatory response. For example, *Aconitum napellus*, *Matricariarecutita*, *Hamamelisvirginiana*, and *Hypericum* may reduce pain associated with inflammation; *Mercuriussolubilis* may be anti-inflammatory; while *Arnica montana*, *Calendula officinalis*, *Echinacea*, and *Symphytum* may accelerate wound healing (Lussignoli *et al.*, 1999). Study of single components of Traumeel®S has shown that *Arnica montana*, *Hamamelisvirginiana*, *Achilleamillefolium*, *Aconitum napellus*, *Atropa belladonna*, and *Mercuriussolubilis* exert a considerable inhibitory effect on oedema, while other components have a pro-inflammatory effect (*Calendula officinalis*, *Echinacea purpurea*, *Matricariarecutita*). However, other components are reported not to influence the development of oedema (*Symphytum*, *Hypericum*, *Heparsulfuris*) (Lussignoli *et al.*, 1999). The synergistic interaction between all components of Traumeel®S has a greater effect than any of the components acting alone (Lussignoli *et al.*, 1999).

Being a broad-spectrum anti-oedematous, anti-exudative, anti-inflammatory and analgesic, Traumeel®S indications are varied to include the stimulation of wound healing, relief of pain, blood clotting and muscle tone improvement (Arora *et al.*, 2002).

Zell *et al.*, (1989), determined the effect of the application of Traumeel®S solution on acute ankle sprains compared to placebo. The result concluded a significant difference between the two groups, with Traumeel®S having an advantage over the placebo group. The probability for successful therapy with Traumeel®S was shown to be significantly greater.

In a placebo-controlled, double-blind study by Bohmer and Ambrus (1992), 68 patients with a range of musculoskeletal sports injuries were treated with an occlusive dressing of either Traumeel®S ointment or a placebo, followed by a cold compression for 30 minutes after application. After 15 days of treatment, twice daily, it was found that Traumeel®S was superior to the placebo in terms of reduction of swelling, pain, and joint circumference.

In a study by Hepburn (2000), comparing the efficacy of oral Traumeel®S against NSAIDs in the treatment of cervical facet syndrome, the results showed no statistical difference between the two treatment options. This outcome therefore infers Traumeel®S may be a valid alternative in the treatment of facet syndrome. Harpham's (2005) study on cervical manipulation versus

manipulation and oral Traumeel®S; revealed the Traumeel®S group to have no significant measurable effect over the spinal manipulation group.

Schneider *et al.*, (2005) conducted a study to assess and compare the homeopathic preparation Traumeel®S ointment with diclofenac 1% gel in patients with tendinopathies of varying aetiology. Three hundred and fifty-seven patients aged 18 to 93 years with tendinopathy of varying aetiology based on excessive tendon load rather than inflammation were recruited into the study. Interventions included applying either Traumeel®S or diclofenac 1% gel over the tendon securing with a bandage. Results showed Traumeel®S was non inferior to diclofenac therapy on all variables. These results suggest that Traumeel®S ointment is an effective alternative to nonsteroidal anti-inflammatory drugs (NSAIDs) therapy for the acute symptomatic treatment of patients with tendinopathy.

Docrat's study (2008) on the effect of an anti-inflammatory homeopathic product on cytokine status in venous blood following 90 minutes of downhill running, aimed to establish whether the administration of oral Traumeel®S five days before and three days after a 90 minute downhill treadmill run at 75% VO₂ peak, would significantly change systemic markers of the inflammatory response. Full blood counts, serum creatine kinase (CK) and cortisol concentrations were determined. Plasma interleukins were also analysed. Results showed despite a faster running speed and higher post trial CK concentration in the Traumeel®S group following the 90 minute run, statistically significant differences in circulating stress hormone, and cytokine interleukin concentrations between the Traumeel®S and placebo groups were not identified.

In a recent study by Deonarain (2012) on the efficacy of Traumeel®S gel with active phonophoresis in the treatment of upper trapezius myofascitis, results revealed no difference between the Traumeel®S and placebo group. Similarly Schneider (2011) conducted a review on Traumeel®S as an emerging option to nonsteroidal anti-inflammatory drugs in the management of acute musculoskeletal injuries. The study reviewed both randomized and non-randomized clinical trials where Traumeel®S was administered. The results of the review revealed that there is a growing evidence-base supporting the effectiveness of Traumeel®S, alone and in combination with other medicines and/or therapies, in treating acute musculoskeletal injuries. Furthermore, Traumeel®S appears to be well tolerated, with no signs of severe adverse events and no evidence of gastrointestinal bleeding, therefore making it an option to NSAIDs and other conventional drugs when treating musculoskeletal conditions.

2.11 Traumeel® S Injectable

The use of the injectable form of Traumeel®S is common in musculoskeletal complaints (Zenner and Metelmann, 1992; Zell, 1999; Schneider, 2011). An advantage of using an injectable as opposed to oral or topical treatment would be direct contact, greater tissue exposure, and better absorptive capabilities for patients who experience gastric intolerance to medication (Zenner and Metelmann, 1992; Zell *et al.*, 1999; Birnesser *et al.*, 2004).

Although indicated for myofascial trigger point therapy, there is a paucity of evidence in the body of literature on Traumeel®S injectable solution and its usage for myofascial conditions. In a study by Speed (2003) on injection therapies for soft tissue lesions, Traumeel®S is mentioned as an increasingly popular choice in the treatment of soft-tissue injuries especially myofascial trigger points, however trials are lacking.

Birnesser *et al.*, (2004) compared Traumeel®S to standard NSAID therapy in the treatment of epicondylitis, and found Traumeel®S to be equivalent to NSAIDs, tending towards superiority in some aspects, such as less pain at rest, extensional and torsional joint mobility.

Cape (2005) performed a comparative study to determine the efficacy of oral and parenteral Traumeel®S in the treatment of cervical facet syndrome. Thirty participants divided into two groups of fifteen were recruited into the study. One group received oral Traumeel®S via ampoules, whilst the other group received Traumeel®S subcutaneous injections in the area of pain. The results of the study showed both oral and parenteral Traumeel®S were effective in decreasing pain and increasing range of motion in cervical facet syndrome. A comparative study to determine the effectiveness of oral and parenteral Traumeel®S versus spinal manipulative therapy in the treatment of mechanical posterior neck pain was conducted by Arrandale (2005). Forty five participants were recruited and divided equally into three groups of fifteen. One group received Traumeel®S injections subcutaneously, the other received oral Traumeel®S and the last group received spinal manipulation. Participants were treated over a two week period. Results of the study showed both oral and parenteral Traumeel®S as well as spinal manipulation were effective treatments.

Heel (2010) published research on case studies and clinical trials using Traumeel®S injectable solution for acute trochanteritis, patella tendonitis, archilles tendonitis, quadriceps aponeurosis

and post-operative pain. The results of the studies showed Traumeel®S to be the superior form of treatment for pain relief and inflammatory breakdown.

2.12 Combination treatments for mechanical neck pain

Mechanical neck pain is a common and costly clinical complaint that requires a multi-disciplinary approach (Côté *et al.*, 1998; Gross *et al.*, 2007; Ferrari and Russell, 2003; Penas, 2007). Many practitioners believe that solo-care approaches do not represent best treatment outcomes for patients and therefore combination treatments need to be used (Haldeman and Kohlbeck, 2002; Kohlbeck *et al.*, 2005; Dagenais *et al.*, 2008; Miller *et al.*, 2010). Various treatment options exist in both fields of manual and pharmacological therapy (Gross *et al.*, 2002; Ferrari and Russell, 2003). Traditional pharmacological treatment involves the use of non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics (Gross *et al.*, 2002; Ferrari and Russell, 2003). Manual therapy includes manipulation, mobilisation, massage, exercise therapy and the use of modalities (Gross *et al.*, 2002; Miller *et al.*, 2010).

Various studies have shown the effects of combination therapies in the treatment of neck pain to be superior in pain relief (Hurwitz *et al.*, 2008). More so, for neck pain, evidence suggests that manual and supervised exercise interventions, low-level laser therapy, and perhaps dry needling or acupuncture are more effective than no treatment, sham, or alternative interventions (Hurwitz *et al.*, 2008). In a study by Hoving *et al.*, (2002) on physical therapy, manual therapy and care by a general practitioner for patients with neck pain, results showed that manual therapies scored consistently in comparison to physical or medicinal treatment.

2.13 Conclusion

Manipulation, dry needling and Traumeel®S have been demonstrated individually as effective in the treatment of mechanical neck pain and myofascial trigger points (Zell *et al.*, 1999; Gross *et al.*, 2002; Ferrari and Russell, 2003), and a combination thereof are now favoured to promote quicker benefits to patients (Haldeman and Kohlbeck, 2002; Kohlbeck *et al.*, 2005; Dagenais *et al.*, 2008; Hurwitz *et al.*, 2008, Miller *et al.*, 2010).

A study on Medication assisted Spinal Manipulation by Haldeman and Kohlbeck (2002) revealed that manual therapy is increasingly being used in conjunction with anaesthetics, sedatives, and analgesics, local epidural, intra-articular and intra-muscular injections. However, evidence for the effectiveness of these protocols remains largely anecdotal, based on case series mimicking many other surgical and conservative approaches for the treatment of chronic pain syndromes of musculoskeletal origin. The study further showed that there is sufficient theoretical basis and positive results from case series to warrant further controlled trials on the use of these techniques.

At present, literature has not shown the effectiveness of Traumeel® S injectable solution in mechanical neck pain associated with myofascial trigger points, therefore this study will investigate a combination of spinal manipulation and dry needling versus spinal manipulation and Traumeel®S injectable solution in the treatment of mechanical neck pain associated with trapezius myofascial trigger points. A study of this nature maybe beneficial as a treatment option for the above condition and will add to the body of literature available.

CHAPTER THREE

METHODOLOGY

3.1 Study design

This study was designed as a randomized comparative clinical trial conducted at Durban University of Technology Chiropractic Day Clinic that was given ethics clearance (ethics clearance number 036/12) (Appendix I) through the Faculty of Health Sciences Research and Ethics Committee.

3.2 Sample

A total of 40 participants were recruited from the greater Durban area. The sample was recommended by the statistician and reflects the minimum sample required for effects to be noticeable.

3.3 Patient recruitment

Participants were recruited through convenience sampling by advertisements (Appendix A) that were placed around the Durban University of Technology (DUT) campus, in local gyms and various sporting clubs. Pamphlets and word of mouth were also methods of recruitment.

Interested participants that responded to the advertisements contacted the researcher and were recruited after being screened with the following questions:

- Are you between the ages of 18 – 55?
- Do you have neck pain?
- Do you have other associated pain e.g. pain in your lower neck passing down into your mid back? Pain on your shoulders?
- Do you feel knots in your shoulder muscles? Does it feel hard and painful? If you press on your shoulders does it increase/decrease your neck pain?
- Which shoulder do you experience more pain?

If the participant met the above criteria, an appointment was made at the Durban University of Technology Chiropractic Day Clinic. Participants were given a letter of information and consent (Appendices B1 and B2), giving a detailed explanation on what the research entailed. It was also explained to them verbally. The participants were given the opportunity to ask questions and were made aware that they may withdraw from the study at any time without prejudicing any further treatment.

Participants underwent a full case history (Appendix C), physical (Appendix D) and cervical regional examination (Appendix E) to determine whether they fitted the inclusion and exclusion criteria.

3.4 Inclusion Criteria:

- Only participants between the ages of 18-55 years were recruited into the study. This included males and females from all ethnic groups. The age group was stipulated as such to minimize pain that may be caused by degenerative disc or joint disease (Esenyal, Caglar and Aldemir, 2000).
- Only participants who displayed signs and symptoms of mechanical neck pain were recruited into this study. This according to (Schafer and Faye, 1990) includes:
 1. Pain or tenderness over osseous and soft tissue areas.
 2. Abnormal range of motion detected actively and passively through motion palpation.
 3. Positive special orthopaedic tests as per cervical regional (Appendix E).
- Participants with an active trapezius trigger point two (TP2).

The criteria for active myofascial trigger points are diagnosed and outlined as follows by (Travell and Simons, 1999):

- The patient identifies the painful area.
- The examiner then manually palpates the area for local tenderness.
- Upon manual palpation of the tender area, the patient must experience referred pain and a twitch response must be felt either by the patient or the examiner.
- Autonomic or motor phenomena maybe produced when the trigger point is palpated.

Participants on analgesics were considered after a washout period of 3 days (Schafer and Faye, 1990).

3.5 Exclusion Criteria:

- Any participant for whom spinal manipulation is contraindicated as described by Gatterman (1990) were excluded from the study. These include:
 1. Vertebral artery insufficiency syndrome.
 2. History of positional vertigo, transient ischaemic attack, or severe arteriosclerosis.
 3. Uncontrolled hyper or hypotension.
 4. Severe cardiovascular disease and diabetes.
 5. Patients on medications such as anticoagulants that could predispose to vascular insult.
 6. Rheumatoid Arthritis or other arthritides.
 7. Vertebral malignancy, spondylolisthesis or recent traumatic injuries (whiplash).
 8. Presence of neurological symptoms such as chronic headaches, visual disturbances, drop attacks, transient weakness in the legs and family history of stroke.
- Any participant who is contraindicated to dry needling as described by Hans and Harrison (1997). These include:
 1. Systemic illness.
 2. Extreme anxiety.
 3. Needle phobia or bleeding disorders.
 4. Any individual taking aspirin within three days prior to receiving dry needling.
- Any participant who is contraindicated to Traumeel®S either by hypersensitivity or anaphylactic reaction to one of the active ingredients of Traumeel®S (Heel, 2009), or in the presence of progressive systemic disease such as Tuberculosis, Leukoses, Collagen disorders, Multiple Sclerosis, Acquired immune deficiency syndrome (AIDS/ HIV) infection and other autoimmune disorders. (Heel, 2009).

- Any participant taking any analgesics or receives any other form of treatment for their neck pain or any other co-existing condition during the trial period were excluded.
- Participants receiving workers compensation, disability insurance or involved in litigation for their neck pain were excluded.

The contraindications for spinal manipulation and dry needling were assessed for by the researcher. The contraindications for Traumeel®S were assessed for by the homeopathic practitioner incorporated into the study.

3.6 Research Procedure

Once the suitability of the forty participants was determined, they were then randomly allocated to one of two groups of twenty each by means of the random allocation chart (Brink, 2006). Group A received spinal manipulation and dry needling and Group B received spinal manipulation and Traumeel®S injection. The allocation process was not blinded to the researcher.

The study took place over a period of 2 weeks involving 4 consultations. Participants received 3 treatments each. The fourth visit was for measurements only. The same trigger point was treated three times.

Each participant in Group A was needled at trapezius trigger point two (TP2) on a specific side and manipulated at their respective fixations. Each participant in group B was injected at TP2 on a specific side and manipulated at their respective fixations. Dry needling and manipulation was administered by the researcher. Traumeel®S injections were administered by a homeopathic practitioner. In order to make sure the correct and same trigger point was being treated the trigger point was marked using henna at the first consultation.

The consultation process was as follows:

- **Consultation 1:** Participants underwent a full case history (Appendix C), physical (Appendix D) and cervical spine regional exam (Appendix E). Subjective measurements i.e. Numerical Pain Rating Scale (NRS) (Appendix G) and CMCC Neck Disability Index Questionnaires (Appendix H) were completed, describing their pre-treatment state. Objective measurements were taken. These included the use of an algometer over the trapezius trigger point 2 on a respective side (this tool measures the pain threshold over the most tender segment of the trigger point), and Cervical Range of Motion (CROM-II)

goniometer readings in lateral flexion (measure range of motion in the cervical spine). Thereafter, treatment 1 was administered according to group allocation.

- **Consultation 2:** This took place two days after consultation one. Subjective and objective measurements were taken and treatment was administered as per group allocation.
- **Consultation 3:** This took place in week two on the same day as consultation one. Subjective and Objective measurements were taken and treatment was administered as per group allocation.
- **Consultation 4:** This took place in week two on the same day as consultation two. No treatment was administered. This consultation was purely for subjective and objective measurements.

There was strict uniformity in treatment days and spaces in between treatment for each participant.

3.7 Interventions

3.7.1 Spinal Manipulation (SM)

Spinal manipulation was administered to participants in both Group A and Group B in accordance with the techniques outlined by Bergmann and Peterson (2002). Motion palpation and orthopaedic testing were performed to find fixations as per cervical regional (Appendix E), and spinal manipulation was carried out in the cervical spine according to fixations found.

3.7.2 Dry Needling

Dry Needling in the form of sterile disposable acupuncture needles were administered to participants in Group A.

3.7.3 Traumeel® S Injections

Traumeel®S injectable was administered to those participants in Group B.

3.8 Needling and Injection Procedure

Needle insertion via dry needling or Traumeel®S injection was administered into the participant's trapezius trigger point two on a respective side. Both the researcher and a qualified homeopathic practitioner were trained in their respective fields, therefore safety was optimal. A

qualified Chiropractic practitioner at the clinic was always present too supervise the proceedings.

- The aseptic technique was used. The skin was cleaned with alcohol before any needle penetration took place to minimize infection.
- Dry needles in the form of sterile disposable acupuncture needles were used on participants in Group A. The needles were opened in front of the participant and used for penetration into the trigger point using the direct insertion technique (Travell and Simons, 1999). No fanning or stimulation of the needle took place.
- The needles used for Traumeel®S injection were very small and fine. The quantity of Traumeel ®S injected was 1ml. A 1cm needle and 26 gauge were used. The injection was given into the specific trigger point using the direct insertion technique (Keresschot, 2004). No fanning or stimulation of the needle took place.
- All interventions were performed in the seated position.
- Once the treatment was over, the area was cleaned with alcohol and the needles were disposed of in the sharps container.

3.9 Measurement Tools

Participants were monitored and assessed in the form of objective and subjective data. Objective tools included the Algometer and CROM-II goniometer. Subjective tools included NRS and the CMCC Neck Disability Index Questionnaire.

3.9.1 Objective Tools

3.9.1.1 Algometer

Pressure Algometer – (manufactured by Wagner instruments: P.O Box 1217, Greenwich T 06836 USA). This is a measurement tool that measures pain threshold in an area of tenderness (Fischer, 1987). Trigger point two of the trapezius muscle on a respective side was assessed and treated. This pressure gauge was placed on the active trigger point, on the most tender side at consultation one before treatment. The trigger point was then marked with henna, and the same trigger point was assessed and treated at consultation two and three. Assessment took place before treatment. At consultation four, the same trigger point was assessed. At all consults the assessment involved applying pressure over the trigger point until the participant's threshold for pain was met. This value was recorded and monitored throughout the study.

Fischer (1987) stated in his study that pressure threshold measurements with an algometer to have good reliability and reproducibility. This is supported by Potter, McCarthy and Oldham (2006) who in their study found the algometer to be reliable and valid in measuring a patient's pressure pain threshold to determine myofascial tenderness scores in response to myofascial treatments.

3.9.1.2 CROM-II Goniometer

Cervical range of motion (CROM-II) Goniometer – this instrument measures cervical range of motion in degrees in right and left rotation, right and left lateral flexion and extension and flexion. For the purpose of the study, only lateral flexion was measured because the trapezius muscle primarily controls the movement of lateral flexion of the neck.

The CROM-II goniometer (3600 Labore Rd, suite 6, St Paul, MN 55110-41144) is a tool that was placed on the participant's nasal bridge and ears and fastened with valcro straps to the back of the participant's head. It was used to measure the active bilateral lateral flexion movement that occurred until the participant could not move their head anymore or pain prevented movement. Good posture was ensured while the patient was seated on a chair prior to readings. Readings were taken at all four consultations prior to treatment.

According to a comparative study on goniometers by Youdas, Carey and Garret (1991), it was found that the CROM-II goniometer showed a higher level of reliability, and they reported good inter and intra-examiner reliability. Similarly, Tousignant, Duclos and Laflecche (2002) reported CROM-II goniometer to have good validity with respect to measuring flexion, extension, bilateral lateral flexion and rotation.

3.9.2 Subjective Tools

3.9.2.1 Numerical Pain Rating Scale (NRS)

NRS is a questionnaire consisting of a numerical scale from 0 -10, with 0 representing one extreme (no pain) and 10 representing the other extreme (pain at its worst). Pain is indicated by means of a percentage, both at its worst and least. The average of these two scores is the level of pain intensity experienced by the patient. This scale was found to be the most practical index as it can be administered in a written or verbal score and is also simple to score (Jensen, Karoly

and Braver, 1986). At every consult prior to treatment each participant was allocated an NRS sheet to score. Their progress was monitored over the period of the study.

3.9.2.2 Canadian Memorial Chiropractic College (CMCC) Neck Disability Index Questionnaire

CMCC neck disability index is a questionnaire designed to assess disability in activities of daily living as a result of neck pain (Vernon and Mior, 1991). This is a useful source of information in assessing the consequences of the progression or regression of neck pain.

At every consult prior to treatment each participant was allocated a questionnaire to complete. Their progress was monitored over the period of the study and the questionnaire was scored out of 50.

In a study by Pool *et al.*, (2007), to assess the minimal clinically important change (MCIC) on the Neck Disability Index (NDI) and the Numerical Rating Scale (NRS) for pain in patients with neck pain, the results showed a minimal detectable change of 10.5 points for the NDI (scale range, 0–50) and 4.3 points for the NRS (scale range 0–10). This indicates the estimated MCIC should be used as an indication for relevant changes in clinical practice.

3.10. Statistical Analysis

IBM SPSS version 20.0 was used to analyse the data. A *p* value of <0.05 was considered as statistically significant. Treatment groups were compared to ensure effective randomisation had taken place using Pearson's chi square tests in the case of categorical variables and t-tests for continuous variables. Repeated measures ANOVA testing was used to examine the intra-group effect of time and the inter-group effect of the intervention in the analysis of results. Profile plots were used to visually assess the direction and trend of the effects. Intra-group correlations between changes from baseline of the subjective and objective outcome measures were assessed using Pearson's correlation coefficient.

Analysis of variance (ANOVA): ANOVA determines an overall *p* value and not the differences between specific groups. This statistical technique is used for analysing data that tests for a difference between two or more means, by comparing the variances within and between groups (www.isixsigma.com, 2003).

CHAPTER FOUR

STATISTICAL RESULTS

4.1 Introduction

The following chapter presents the results obtained from the statistical analysis of the objective and subjective data that was collected during the study. The demographic, inter-group and intra-group data are presented in the form of tables and figures.

4.2 Demographics

These data tables represent the baseline comparison between groups. In order to ensure that randomisation had taken place effectively, demographics were compared between the two groups. Demographics included gender, occupation, age, height and weight.

4.2.1 Gender

Table 4.2.1 : Gender distribution of the sample group participants.

Group	Male		Female		Total in each group
	n	%	n	%	n
A	10	50	10	50	20
B	7	35	13	65	20
Total	17	42.5	23	57.5	40

* p=0.337*

Table 4.2.1 depicts that in the spinal manipulation and dry needling group (Group A); there were 10 males and 10 females. In the spinal manipulation and Traumeel®S group (Group B), there were 7 males and 13 females. There was no statistically significant difference in the gender distribution between the two groups ($p=0.337$).

4.2.2 Occupation

Table 4.2.2 : Occupation distribution of the sample group participants.

		Occupation					Total
		unemployed	housewife	teacher	student	other	
Group A	n	0	3	2	4	11	20
Group B	n	1	3	3	5	8	20
Total % In groups combined		2.5	15	12.5	22.5	47.5	100

*** $p=0.775$ ***

Table 4.2.2 represents the occupation variation amongst the participants. A common trend is seen amongst the participants and the occupation distribution did not differ significantly between the groups. The highest percentage came from the group labelled 'other'. This group included multiple different professions. The student grouping was also a high percentage. Even so results showed there were no statistically significant difference in the occupation distribution between the two groups ($p=0.775$).

4.2.3 Age, Height, Weight

Table 4.2.3: Age, height and weight distribution of sample group participants.

	Group	n	Mean	Std Deviation	Std Error Mean
Age	A	20	31.60	11.445	2.559
	B	20	36.65	12.942	2.894
Height	A	20	1.6620	0.10288	0.2301
	B	20	1.6280	0.06902	0.01543
Weight	A	20	72.15	15.594	3.487
	B	20	77.50	18.813	4.207

Table 4.2.3 depicts the forty participants who were randomly placed into two equal groups (n=20). The table reflects the mean age, height and weight of each group. The mean age was highest in the spinal manipulation and Traumeel®S group i.e. Group B. The mean height was highest in the spinal manipulation and dry needling group i.e. Group A, with the mean weight being highest in Group B. This was a random event as subjects were allocated to their groups according to the randomization process (Brink, 2006). There were no statistical differences between the groups in terms of age, height or weight.

4.3 Statistics of the affected side

Table 4.3.1: Affected side treated of the sample group participants.

Group	Side		Total
	Right	Left	
A	13 (65%)	7 (35%)	20 (100%)
B	13 (65%)	7 (35%)	20 (100%)

Total	26 (65%)	14(35%)	40 (100%)
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*** $p=1.000$ ***

Table 4.3.1 depicts the side treated in the study. Only one specific side was treated per participant. Results show that the right side had a higher percentage with a total of 65% i.e. 26 participants treated with either dry needling or Traumeel®S injection on the right trapezius trigger point two. Statistics show there was no difference in terms of affected side ($p=1.000$).

The groups were randomized effectively and any differences detected after randomisation were due to the treatment intervention.

4.4. Subjective Measurements

Objective One

To compare spinal manipulation and dry needling vs. spinal manipulation and Traumeel®S injections by means of subjective findings. Subjective Measurements included the Numerical Pain Rating Scale (NRS) (Appendix G), and Canadian Memorial Chiropractic College (CMCC) neck disability index questionnaire (Appendix H).

4.4.1 Statistical Analysis on Numerical Pain Rating Scale (NRS)

Table 4.4.1: Statistics between and within group effects for NRS

Effect	Statistic	<i>P</i> value
Time	Wilk's lambda = 0.131	<0.001
Time*group	Wilk's lambda =0.969	0.769
Group	F=3.478	0.070

*** $p=0.769$ ***

Table 4.4.1 shows there was no significant time*group treatment effect for NRS ($p=0.769$). However, there was a highly statistically significant effect of time on NRS meaning that the NRS values changed over the study period ($p < 0.001$), indicating a reduction of pain in both groups

A and B. This means that both groups improved equally with respect to NRS scores over the period of the study.

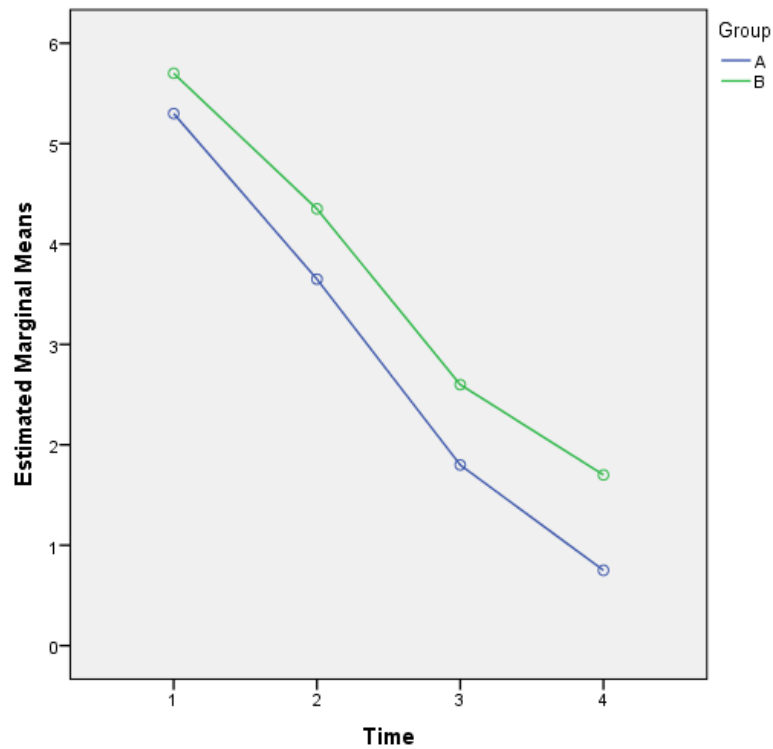


Figure 1: Profile plot of NRS by time and group

Figure 1 shows that the rate of decrease in pain was similar in both groups A and B throughout the study time period. The profile plots are parallel and both groups pain rating according to NRS scores decreased at approximately the same rate.

4.4.2 Statistical Analysis on Canadian Memorial Chiropractic College (CMCC) Neck Disability Index Questionnaire

Table 4.4.2: Statistics between and within-group effects for CMCC

Effect	Statistic	P value
Time	Wilk's lambda =0.254	<0.001
Time*group	Wilk's lambda =0.871	0.170
Group	F=0.130	0.720

* $p=0.170$ *

Table 4.4.2 shows there was no statistically significant time*group treatment effect for CMCC ($p=0.170$). However with time it is evident that CMCC scores decreased and showed a highly statistically significant improvement $p < 0.001$.

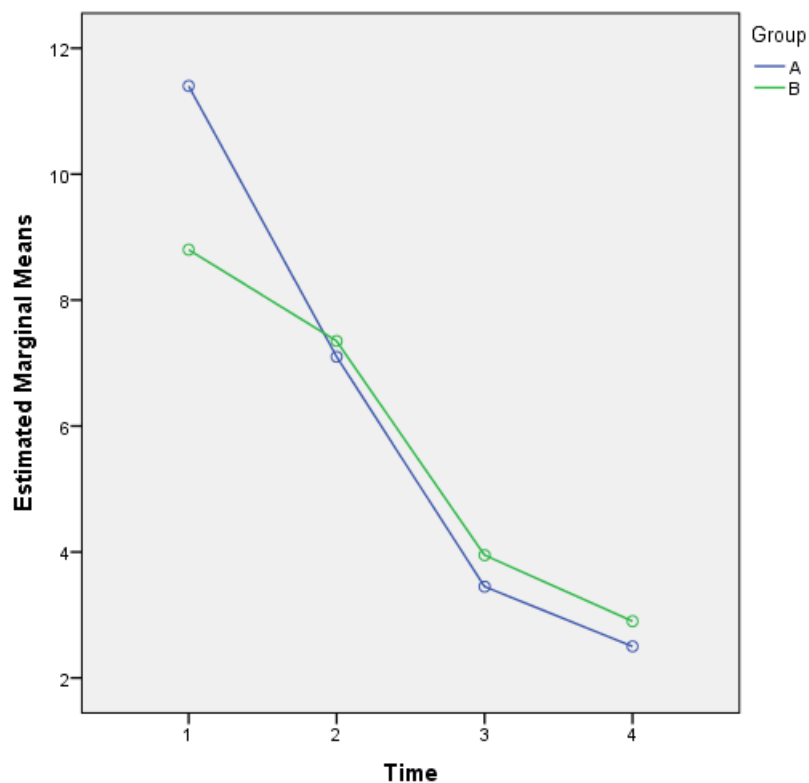


Figure 2: Profile plot of CMCC by time and group

Figure 2 depicts that Group A showed higher CMCC scores at baseline, meaning their neck disability pain scores were higher at initial consultation than Group B. However, over the study duration, the rate of decrease in CMCC scores was similar in both groups with parallel profile plots seen from consultation 2 onwards.

4.5. Objective Measurements

Objective Two

To compare spinal manipulation and dry needling vs. spinal manipulation and Traumeel® S injections via objective findings. Objective measurements were taken using an algometer, (to measure patient's pain threshold over the tenderest segments of a trigger point), and a cervical range of motion (CROM-II) goniometer (to measure range of motion in the cervical spine).

4.5.1. Statistical analysis of Algometer findings in the study

Table 4.5.1: Statistics between and within-group effects for Algometer

Effect	Statistic	P value
Time	Wilk's lambda =0.233	<0.001
Time*group	Wilk's lambda =0.910	0.331
Group	F=4.015	0.052

p=0.331

Table 4.5.1 reflects that there were no significant time*group treatment effect for algometer ($p=0.331$). The effect of time was highly statistically significant $p < 0.001$. This means that both treatment groups changed significantly over time in algometer measurements. This further indicates that algometer readings progressively increased through the study period. An increase in algometer readings reflects a decrease in tenderness.

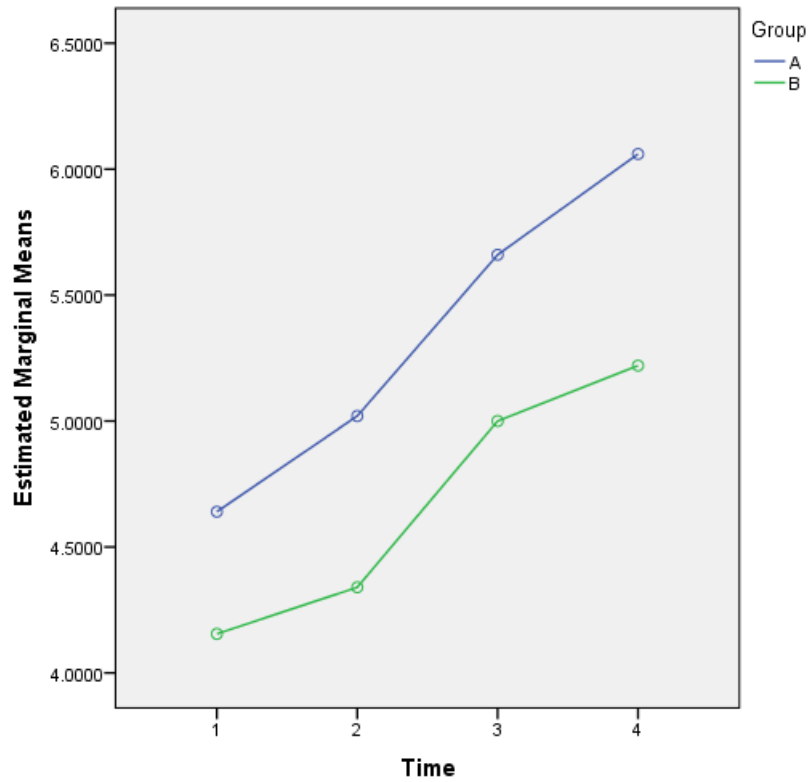


Figure 3: Profile plot of algometer by time and group

Figure 3 shows that the rate of increase in the algometer scores was similar in both groups. The profile plots are roughly parallel. Both groups' measurements increased at a similar rate. This means that the tenderness of the affected area decreased equally between the groups over time.

4.5.2. Statistical Analysis of the Cervical Range of Motion (CROM-II) goniometer findings in the study

4.5.2.1 CROM-II findings for right lateral flexion

Table 4.5.2: Statistics between and within-group effects for CROM right lateral flexion

Effect	Statistic	P value
Time	Wilk's lambda =0.647	0.001
Time*group	Wilk's lambda =0.945	0.559
Group	F=2.188	0.147

* $p=0.559$ *

Table 4.5.2 depicts that there was no significant time*group treatment effect for CROM right lateral flexion ($p=0.559$). However, a statistically significant change over time in right lateral flexion is seen ($p=0.001$). This means that over time range of motion in right lateral flexion improved in both groups.

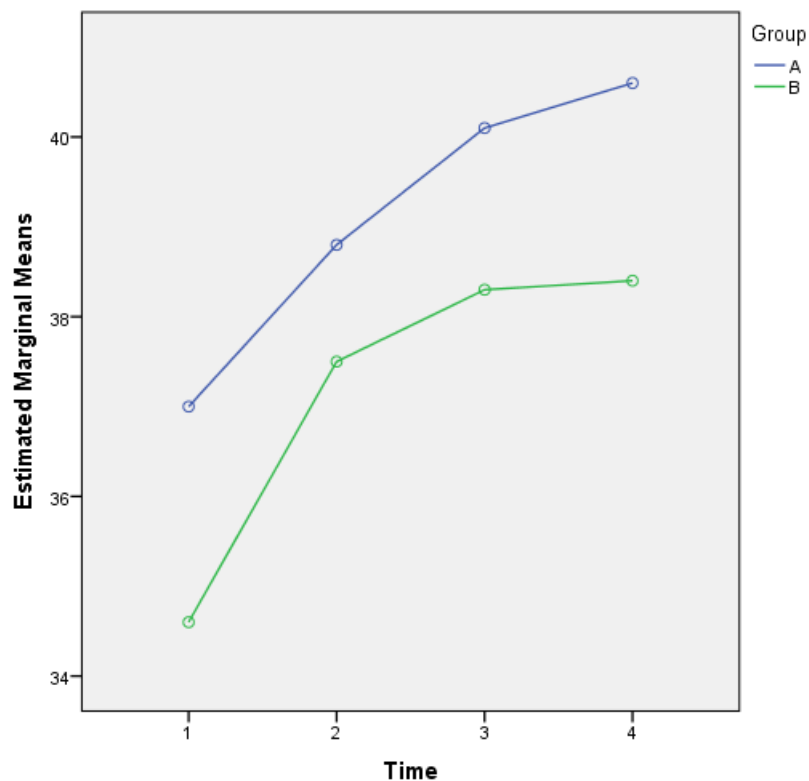


Figure 4: Profile plot of CROM right by time and group

Figure 4 shows that the rate of increase in CROM right lateral flexion measurement was similar in both groups. The profile plots are parallel. Group B showed a marked sharp increase in range of motion from consultation one to two, whereas Group A's range of motion increased consistently and uniformly throughout the period of study.

4.5.2.2. CROM findings for left lateral flexion

Table 4.5.3: Statistics between and within-subjects effects for CROM left lateral flexion

Effect	Statistic	P value
Time	Wilk's lambda =0.481	<0.001
Time*group	Wilk's lambda =0.870	0.167
Group	F=0.087	0.770

*** $p=0.167$ ***

Table 4.5.3 depicts that there was no significant time*group treatment effect for CROM left lateral flexion ($p=0.167$). However, a highly statistically significant change over time in left lateral flexion range of motion is seen ($p < 0.001$).

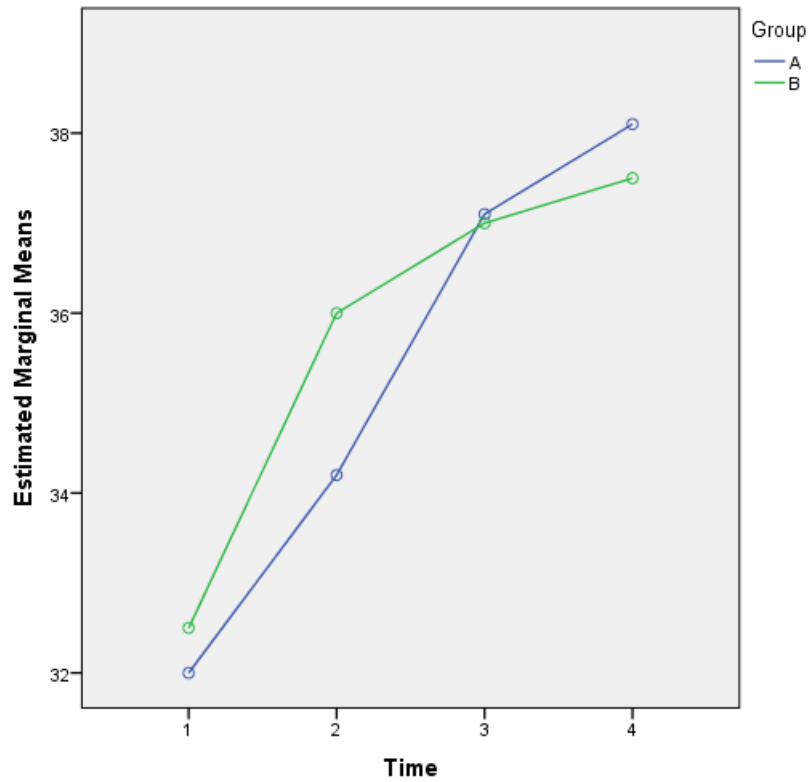


Figure 5: Profile plot of CROM left by time and group

Figure 5 showed that the rate of increase in CROM left lateral flexion measurements were similar in both groups. The profile plots are parallel; Group A showed uniform increasing spikes throughout the study. This further indicates that in both Groups A and B, participant's left lateral flexion range of motion increased.

4.6 Correlation within treatment groups

Objective Three

To compare the two groups in terms of subjective and objective data .i.e. to assess whether changes from baseline in subjective and objective outcomes are correlated within treatment groups.

4.6.1 Group A: cervical spine manipulation and dry needling group

The change in CMCC and NRS were positively correlated in this group ($r=0.719$, $p<0.001$). This means that as one value increased so did the other. This reflects that the participant's disability index scores improved as their pain reduced.

Table 4.6.1: Correlation in treatment in Group A

		Change in NRS	Change in CROM right	Change in CROM left	Change in algometer	Change in CMCC
Change in NRS	Pearson Correlation	1	.100	- .074	- .160	0.719
	Sig(2- tailed)		.675	.756	.500	.000
	N	20	20	20	20	20
Change in CROM right	Pearson Correlation	0.100	1	0.064	.041	0.093
	Sig(2- tailed)	0.675		0.790	0.865	0.697
	N	20	20	20	20	20
Change in CROM left	Pearson Correlation	-.074	0.674	1	0.235	0.070
	Sig(2- tailed)	0.756	0.790		0.319	0.771
	N	20	20	20	20	20
Change in algometer	Pearson Correlation	-.160	0.041	0.235	1	-.142
	Sig(2- tailed)	.500	0.865	0.319		0.550
	N	20	20	20	20	20
Change in CMCC	Pearson Correlation	0.719	0.093	-.070	-.142	1
	Sig(2- tailed)	.000	0.697	0.771	0.550	
	N	20	20	20	20	20

****correlations is significant at the 0.01 level (2-tailed)**

4.6.2 Group B: cervical spine manipulation and Traumeel®S group

Table 4.6.2: Correlation in treatment in Group B

		Change in NRS	Change in CROM right	Change in CROM left	Change in algometer	Change in CMCC
Change in NRS	Pearson Correlation	1	-.144	-.345	-.354	0.533
	Sig(2- tailed)		0.543	0.136	0.126	0.016
	N	20	20	20	20	20
Change in CROM right	Pearson Correlation	-.144	1	0.472	-.097	-.212
	Sig(2- tailed)	0.543		0.036	0.685	0.370
	N	20	20	20	20	20
Change in CROM left	Pearson Correlation	-.345	0.472	1	0.014	-.260
	Sig(2- tailed)	0.136	0.036		0.954	0.269
	N	20	20	20	20	20
Change in algometer	Pearson Correlation	-.354	-.097	.014	1	-.157
	Sig(2- tailed)	0.126	0.685	0.954	20	0.509
	N	20	20	20	20	20
Change in CMCC	Pearson Correlation	0.533	-.212	-.260	-.157	1
	Sig(2- tailed)	0.016	0.370	0.269	0.509	
	N	20	20	20	20	20

**correlation is significant at the 0.05 level (2-tailed)

There were positive correlations between changes in CMCC and NRS ($r=0.533$), and CROM right and CROM left ($r=0.472$). There were negative correlations between most of the other variables. However, these correlations were not clinically or statistically significant.

4.7 Conclusion

The results of this study conclude that spinal manipulation and dry needling versus spinal manipulation and Traumeel®S Injectable solution in the treatment of mechanical neck pain associated with trapezius myofascial trigger points is equivalent to each other. No statistically or clinically significant changes were noticed between the groups. The results will be discussed in detail in the following chapter.

CHAPTER FIVE

Discussion of the Results

5.1 Introduction

This chapter will discuss the results presented in Chapter Four.

5.2 Demographics

5.2.1 Gender

The total sample size consisted of 40 participants. There was a total female percentage of 57.5% across both groups showing a higher female participation (this was illustrated in Table 4.2.1). Factors that need consideration when assessing the greater female participation include higher female to male ratio of the population in which the study was conducted, and a greater interest by females with regards to advertisements and participation in the study. Results of this study is keeping in accordance to a Scandinavian study by Borenstein *et al*, (1996), that showed the prevalence of neck pain to be greater in females than in males. Furthermore Mennel, (1992) stated that the wearing of high heels by females increases their cervical lordosis, predisposing them to cervical joint dysfunction and strain resulting in neck pain.

5.2.2 Occupation

Various occupations presented in the study as per Table 4.2.2. Occupations were categorised as unemployed, students, housewives, teachers and other. The group categorised 'other' displayed the highest percentage. This group included a host of varied professions with most participants indicating they are either accountants or office workers. There were a percentage of 22.5 of students who participated in the study. This is due to the fact that the study took place at a university clinic making it easier for students to respond to the advertisements. Despite a host of occupations being present in the study, results showed there were no statistically significant difference in the occupation distribution between the two groups ($p=0.775$). The results of this study were similar to the study by Harpham (2005), where majority of participants were female office workers or administrators.

5.2.3 Age, Height, Weight

The age range for the study was 18-55 years of age. The age group was restricted to a relatively young population such that pain caused by degenerative disc or joint disease was kept to a minimum (Esenyal *et al.*, 2000). According to Borenstein *et al.*, (1996), neck pain increases with age. Bland and Boushey (1994) stated that working individuals between the ages 25-29 years have a 25-30 percent incidence of neck pain with individuals over the age of 45 having a 50 percent incidence of neck pain. This study showed similar means in age. Group A's mean was 31.60 with Group B having a higher mean age of 36.65.

Table 4.2.3 illustrates that participants had a similar means for both height and weight, with the mean height being highest in Group A (1.66m), and the mean weight being highest in Group B (77.50kg). The similarity in means across both groups in age, height and weight was a random event as subjects were allocated to their groups according to a randomization process (Brink, 2006).

5.2.4 Affected Side

Only one specific side was treated per participant. Results showed that the right side had a higher percentage with a total of 65% i.e. 26 participants treated with either dry needling or Traumeel®S injection on the right trapezius trigger point 2. Statistics show there was no difference in terms of affected side ($p=1.000$).

5.2.5 Conclusion for demographic factors

There were no statistically significant differences observed between the two groups in respect to the demographics of gender, occupation, age, height and weight. Therefore, the impact of these demographics on the results of the study was insignificant.

5.3 Subjective Measurements

5.3.1 Numerical Pain Rating Scale (NRS)

This scale is used to monitor levels of pain perception experienced by patients. A reduction in the mean score indicates a reduction in their pain experience. In this study, participants were scoring pain at the initial consultation to determine a baseline. Further scoring was done at

every consultation prior to treatment. This was done to establish conclusive evidence about the participant's pain in response to treatment.

Chiropractic treatment in the form of spinal manipulation is effective in reducing pain in patients suffering from neck pain (Giles and Muller 1999; Cassidy *et al.* 1992; Windsor, 2004). Traumeel®S is also effective in treating painful syndromes (Zenner and Metelmann 1992; Lussignoli, 1999; Heel 2009; Schnider, 2011). Dry needling aids in pain relief and relaxes the tension in muscles (Travell and Simons, 1999; Huguenin, 2004). Table 4.4.1 shows that there was no statistically significant time*group interaction treatment effect for NRS ($p=0.769$). However, there was a highly significant effect on time on NRS, meaning that the NRS values changed over the study period ($p< 0.001$). This indicates a reduction of pain in both Groups A and B. According to Figure 1 profile plot, the rate of decrease of pain was similar in both groups thereby further indicating that pain reduced at the same rate in both groups for the duration of the study. These results are in keeping with the above literature. However participants were responsible for scoring themselves at every consultation. Besides treatment intervention, other reasons for decrease in pain are possible, such as participants self-scoring in front of the researcher. It is possible time spent by the researcher with participants could have contributed to decrease in pain and therefore influenced scoring.

5.3.2 Canadian Chiropractic Memorial College (CMCC) Neck Disability Index

CMCC is a questionnaire used to assess neck pain levels experienced by patients. The questionnaire is scored out of 50 and involves questions that investigate pain levels with regards to aggravating factors, relieving factors and day to day activity. Participants answered the questionnaire at initial consultation for a baseline reading and at every consultation before treatment to monitor progression and regression of pain (Vernon and Mior, 1991).

Table 4.4.2 shows there was no statistically significant time*group treatment effect for CMCC ($p=0.170$). However, with time it is evident that CMCC scores decreased and showed a highly statistically significant improvement in scores $p<0.001$. Figure 2 shows that Group A i.e. manipulation and dry needling group displayed higher scores at baseline; however over the study duration the rate of decrease in CMCC scores was similar in both groups. Literature

discussed in this study revealed that spinal manipulation, Traumeel®S and dry needling are all effective in pain relief. This could account for the decrease in CMCC scores in the study.

5.4 Objective Measurements

5.4.1 Algometer

The algometer was used to measure the amount of force that the patient could tolerate on the trigger point two of trapezius. An increase in readings indicated an increase in pain threshold resulting from decreased trigger point sensitivity.

The results stated in Table 4.5.1 reflects there was no significant time*group treatment effect for the algometer readings ($p=0.331$). The effect of time was highly significant $p<0.001$, meaning that both treatment groups changed markedly over time in the algometer measurements i.e. algometer readings increased over the duration of the study.

Dry needling directly into myofascial trigger points has an overall treatment effect (Tough *et al.* 2007). Dry needling procedure is most effective in pain relief as a local twitch response is obtained from the muscle (Annaswamy *et al.*, 2011), thereby breaking down adhesions and lengthening the muscle (Travell and Simons, 1999). The use of trigger point injections is becoming increasingly popular (Speed, 2003). Traumeel®S has analgesic and anti-inflammatory properties (Heel, 2009). The use of the injection would therefore be rapid in pain relief and anti-inflammatory effects due to direct local application (Birnesser *et al.*, 2004).

In terms of pain pressure threshold, statistically significant results have been seen by Travell and Simons (1999) and Huguenin (2004) indicating dry needling improves pain threshold. Similar results were also seen by Kamanli *et al.*, (2005) who used dry needling for pain relief of trigger points in the cervical and shoulder regions. Manipulative procedures resolve muscle guarding (Gibbon and Tehan, 2001; Hong, 2006) and aid in tissue release by releasing hypertonicity and increasing extensibility (Gatterman, 1990; Travell and Simons, 1999, Gross *et al.*, 2002). It is proposed that Traumeel®S will also improve pain pressure threshold due to its anti-inflammatory and analgesic properties (Zenner and Metelman, 1992; Birnesser *et al.*, 2004).

5.4.2 Cervical Range of Motion CROM-II Goniometer

CROM-II goniometer measures range of motion of the cervical spine. In this study lateral flexion was assessed. Readings were taken at baseline and at every consultation before treatment to monitor changes in response to treatment (Youdas, Carey and Garret, 1991).

In this study, Table 4.5.2 depicts that there was no significant time*group treatment effect for CROM right lateral flexion ($p=0.559$), however a statistically significant change over time was observed ($p=0.001$). Left lateral flexion showed a highly statistically significant change over time ($p<0.001$). Both groups showed marked improvements which were seen in terms of range of motion. However, Group A i.e manipulation group and dry needling showed uniform increasing spikes throughout the study.

According to Gatterman (1990), manipulative procedures correct abnormal joint movement, alignment and muscle imbalances. Manipulation also relieves pain by correcting joint restrictions and allowing free movement by relaxing hypertonic muscles (Gatterman, 1990). Kamanli *et al* (2005) and Rickards (2006) found that CROM measurements improved after dry needling. Releasing muscle tension by dry needling increases cervical range of motion (Huguenin, 2004; Hong, 2006). To this researcher's knowledge, no study has investigated the combination of spinal manipulation and Traumeel®S injectable in the treatment of mechanical neck pain. Therefore, a paucity of literature exists with which to compare the CROM results. However it is proposed that due to Traumeel®S analgesic and anti-inflammatory properties it could have aided pain relief as well as act as a supportive adjunct to manipulation.

5.5 Correlation within treatment groups

In Group A, the change in CMCC and NRS were positively correlated ($r=0.719$, $p<0.001$). This means that as one value increased so did the other. In Group B i.e. the manipulation and Traumeel®S group, there were positive correlations between changes in CMCC and NRS ($r=0.533$), and CROM right and CROM left ($r=0.472$). There were negative correlations between most of the other variables. However, the correlations were not clinically or statistically significant. Algometer and CROM readings improved in both groups. Therefore, the results of this study have shown that the effectiveness of spinal manipulation and dry needling versus spinal manipulation and Traumeel®S injectable solution in the treatment of mechanical neck pain associated with trapezius myofascial trigger points is equivalent.

6. Conclusion

This study investigated two combination treatment modalities; spinal manipulation and dry needling versus spinal manipulation and Traumeel®S injectable solution. This was carried out in terms of subjective and objective measurements. Although no statistically significant differences were observed between the two groups in terms of these subjective and objective measurements, there were statistically significant improvements seen in both groups equally.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The aim and purpose of this study was to compare spinal manipulation (SM) and dry needling versus spinal manipulation and Traumeel®S injectable solution in the treatment of mechanical neck pain and trapezius two (TP2) myofascial trigger points in terms of objective and subjective findings.

Fourty participants were recruited and divided in two groups of twenty each. Group A received spinal manipulation and dry needling and Group B received spinal manipulation and Traumeel®S injectable. Data was gathered using the Numerical Pain Rating Scale (NRS), Canadian Memorial Chiropractic College (CMCC) neck disability index, algometer and CROM-II goniometer respectively. All participants received four treatments over a period of two weeks.

Results revealed that for pain measured by NRS, CMCC and algometer there was a significant decrease over time in all the groups, however, this change was not significantly related to which treatment group the participant was in. CROM-II measurements increased in both groups over the duration of the study.

There is no current literature on Traumeel®S injectable's usage for myofascial trigger point therapy but results of this study shows that it is effective as no statistically significant differences to algometer findings were found in comparison to dry needling. All treatments received in both groups demonstrated to be effective with no statistically significant difference between them. This could be due to the small sample size making it difficult to see a marginal statistical difference.

This study therefore concludes that the trend in outcomes indicates that both treatment approaches have a beneficial effect but don't imply effectiveness and the degree of anti-inflammatory effect of Traumeel®S is challenged since it does not seem to have any additional benefit over dry needling.

6.2 Limitations of the study

Limitation of the study includes the use of a small sample size. This was due to both time and budget constraints. Absence of blinding of group allocation and readings may have limited the study in terms of treatment outcomes. The scoring was dependant on the honesty of the participants which may have affected results.

6.3 Recommendations

It is recommended that in future studies, a larger sample size should be used so to allow for a more representative slice of the population so more statistically significant results could be achieved.

Age and gender distribution should be homogenous to avoid gender pain perception.

With regard to the treatment of mechanical neck pain, due to its multi-aetiological origin more follow-up consultations, over a shorter period of time is recommended. This will be helpful in obtaining more accurate results with respect to efficacy of each treatment within an exact time period.

The effects of perpetuating factors, occupational factors and psychological aspects like depression and anxiety should be considered in further studies, as these factors are not clinically quantifiable, yet they do contribute to the progression or regression of mechanical neck pain.

A placebo group would have helped to provide more accurate results.

It is also recommended that a study be conducted to determine if the treatment of trigger points with Traumeel®S injections results in post-needling soreness similar to that which is similarly found after dry needling.

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APPENDIX A

ARE SUFFERING FROM

NECK PAIN?

DO YOU FEEL PAIN ON YOUR SHOULDERS??

AND ARE BETWEEN THE AGES OF 18-45?

HELP IS AVAILABLE!!!!

**RESEARCH IS CURRENTLY BEING CARRIED
OUT AT THE**

**DURBAN UNIVERSITY OF TECHNOLOGY
CHIROPRACTIC CLINIC.**

**FREE TREATMENT IS AVAILABLE TO THOSE
WHO QUALIFY.**

PLEASE CONTACT: ASHURA A.RASHEED

031 3732511

0739461916

FOR MORE INFORMATION.

APPENDIX B1



INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC) LETTER OF INFORMATION AND CONSENT

Title of the Research Study: The effectiveness of spinal manipulation and dry needling versus spinal manipulation and Traumeel® S Injectable solution in the treatment of mechanical neck pain associated with trapezius myofascial trigger points.

Principle Investigator/s/researcher: Ashura Abdul-Rasheed

Co-Investigator/s/supervisor/s: Dr A. Docrat (supervisor)

Welcome and thank you for taking part in this research study. You have been chosen to take part in a study comparing two forms of treatment for your neck pain. Neck pain is a common condition treated by Chiropractors, and therefore different types of treatments need to be tested to help the profession get more knowledge for better treatment outcomes for the patient.

This study will involve two groups. One group will receive chiropractic treatment which is spinal manipulation and dry needling and the other group will receive spinal manipulation and also a homeopathic product Traumeel® S (injectable form). You will be randomly allocated to a group. You shall receive three treatments over a period of a week, with a follow up treatment for measurements the next week. Initial visit will be an hour and half at maximum, and the follow up visits will be half an hour.

During the study you will not be able to receive any other form of treatment for your condition and you are also advised to refrain from any activity which will make your pain worse or even any new activity or exercise. If you feel anything unusual or uncomfortable about anything during the study, please report it to me immediately. Although homeopathic treatments have no serious side effects, some people may be sensitive to it. You might feel some pain after dry-needling or injection. This is normal. The benefit of being part of this study is that you will possibly gain pain relief for your neck pain. You are not forced to partake in the study and you may have to be taken off the study if you do not follow the instructions carefully, or become ill or have adverse reactions. You will not have to pay for taking part in the study and you will not receive any money for taking part also.

Your help by taking part in this study will be appreciated. It will help chiropractors and homeopaths to give other more beneficial treatments to their patients. We would like it if you will please follow all the instructions carefully and completely.

Thank You

Ashura Abdul-Rasheed (Researcher) Dr A. Docrat (Supervisor) Ms.L. Deonarain (IREC Administrator)

0761144203

(031) 3732589

(031) 3732900

Statement of Agreement to Participate in the Research Study:

(I,.....subject's full name...., ID number....., have read this document in its entirety and understand its contents. Where I have had any questions or queries, these have been explained to me byto my satisfaction. Furthermore, I fully understand that I may withdraw from this study at any stage without any adverse consequences and my future health care will not be compromised. I, therefore, voluntarily agree to participate in this study.

Subject's name (print) Subject's signature:.....
Date:.....

Researcher's name (print) signature:

Researcher's signature:.....Date:.....

Witness name (print)

Witness signature:Date:.....

APPENDIX B2



INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC) LETTER OF INFORMATION AND CONSENT

Title of the Research Study: The effectiveness of spinal manipulation and dry needling versus spinal manipulation and Traumeel® S Injectable solution in the treatment of mechanical neck pain associated with trapezius myofascial trigger points.

Igama Lami: Ashura Abdul-Rasheed

(Igama lowengamele lolucwaningo): Dr A. Docrat

Siyanamukela futhi siyabonga ukuba yingxenye yaldu cwaningo. Ukhetiwe ukuba ubambe iqhaza kulemizamo yezezempilo ukuqhathatahanise izindlela ezimbili zokwelapha izinhlungu zomqala. Izinhlungu zomqala zelashwa ngendlela ejayeelekile ebizwa ngokuthi iChiropractors, ngakho-ke ezinye zezindlela zokulapha zisadinga ukuthi zihlaziye futhi zihloliswe ukunikikeza ongonti ulwazi oluthethe xaxa olungasisiza ekhutoleni imiphumela egcono yokhulapha iziguli.

Lesi sifundo simayelana nezinhlungu zomqala. Zimbili izindlela zokwelapha ezizonikezwa. Enye yayo yileyo yokulapha umqala nokuthi kujove umsipha womqala. Enye yayo yileyo yokwelapha ngokhuthi unikezwe umkhiqizo obizwa nge Traumeel® S. Umuntu ngamunye uyofakwa eqenjini lokuqala noma eqenjini lesibili (akekho oyaoba semaqenjini womabili). Umuntu uyokwelashwa kathathu esontweni ikuzomele ufike izikhathi ezine ukuzhlolwa. Okokuqala kuyoba ihora elilodwa, ngemuvakwalokho kuyoba isigamu sehora.

Ngesikhathi useyinxenye yalolu cwaningo awuvumelekile ukuthola noma nabe iyiphi enye indlela yokwelapha izinhlungu zomqala. Ungazami futhi ukusebenzisa ezinye izindlela zokulula (ukuzivocavoca) umqala.

Umakukhona into engajwayelekile eyenzekhayo ngalesi sikhathi socwanino kumele ubike ngokushesha. Umakujovwe umsipha kuzobakhona ukugine lokho kujwayelekile. Awuphoqelekile ukuthi ukuhlala kulolu cwaningo, ungashiya/ungayeka noma inini.

Ongabathinta uma kuba nenkinga noma imibuzo:

Ashura Abdul- Rasheed

0739461916

Dr A. Docrat (Igama lowengamele lolucwaningo)

(031) 373 2589

Ngiyabonga

Statement of Agreement to Participate in the Research Study:

Incwadi yesivumelwanosokuzibandakanyakulolucwaningo:

Mina.....(igama eliphelele lombandakanyi),
.....(inombolo yepasi), ngiyifundile lencwadi ngayiqeda. Lapho benginemibuzo khona, ngichazeliwe uAshura Abdul-Rasheed nganeliseka. Ngiyayizwisa eyokuthi ngingayeka noma kunin kulolucwaningo ngale kokucwaseka, noma ukuhlukumezeka kwempilo yami. Ngakho ke ngivuma ngokuthanda ukuzibandakanya kulolucwaningo.

Igama lozibandakanya kulolucwaningo

Isiginisha yozibandakanya kulolucwaningo.....

Usuku.....

Igama lomucwaningi

Isiginisha yomcwaningi

Usuku.....

Igama lafakazi

Isiginisha kafakazi.....

Usuku.....

APPENDIX C



D U R B A N
UNIVERSITY of
TECHNOLOGY

DURBAN UNIVERSITY OF TECHNOLOGY **CHIROPRACTIC DAY CLINIC** **CASE HISTORY**



D U R B A N
UNIVERSITY of
TECHNOLOGY

Patient: _____ Date: _____

File # : _____ Age: _____

Sex : _____ Occupation: _____

Intern : _____ Signature _____

FOR CLINICIANS USE ONLY:

Initial visit
Clinician: _____ Signature : _____

Case History:

Examination: _____
Previous: _____ Current: _____

X-Ray Studies: _____
Previous: _____ Current: _____

Clinical Path. lab: _____
Previous: _____ Current: _____

CASE STATUS:

PTT: _____	Signature: _____	Date: _____
------------	------------------	-------------

CONDITIONAL:

Reason for Conditional:

.....

.....

.....

Signature: _____ Date: _____

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

Case Summary signed off: _____	Date: _____
--------------------------------	-------------

Intern's Case History:**1. Source of History:****2. Chief Complaint : (patient's own words):****3. Present Illness:**

	Complaint 1	Complaint 2
< 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:
- < Tobacco
- < Alcohol
- < Social Drugs

7. Immediate Family Medical History:

- < Age
- < Health
- < Cause of Death
- < DM
- < Heart Disease
- < TB
- < Stroke
- < Kidney Disease
- < CA
- < Arthritis
- < Anaemia
- < Headaches
- < Thyroid Disease
- < Epilepsy
- < Mental Illness
- < Alcoholism
- < Drug Addiction
- < Other

8. Psychosocial history:

- < Home Situation and daily life
- < Important experiences
- < Religious Beliefs

9. Review of Systems

- < General
- < Skin
- < Head
- < Eyes
- < Ears
- < Nose/Sinuses
- < Mouth/Throat
- < Neck
- < Breasts
- < Respiratory
- < Cardiac
- < Gastro-intestinal
- < Urinary
- < Genital
- < Vascular
- < Musculoskeletal
- < Neurologic
- < Haematologic
- < Endocrine
- < Psvchiatric

APPENDIX D

Durban University of Technology PHYSICAL EXAMINATION: SENIOR				
Patient Name : _____		File no : _____		Date : _____
Student : _____		Signature : _____		
VITALS:				
Pulse rate:			Respiratory rate:	
Blood pressure:	R	L	Medication if hypertensive:	
Temperature:			Height:	
Weight:	Any recent change? Y / N		If Yes: How much gain/loss	Over what period
GENERAL EXAMINATION:				
General Impression				
Skin				
Jaundice				
Pallor				
Clubbing				
Cyanosis (Central/Peripheral)				
Oedema				
Lymph nodes	Head and neck			
	Axillary			
	Epitrochlear			
	Inguinal			
Pulses				
Urinalysis				
SYSTEM SPECIFIC EXAMINATION:				
CARDIOVASCULAR EXAMINATION				
RESPIRATORY EXAMINATION				
ABDOMINAL EXAMINATION				
NEUROLOGICAL EXAMINATION				
COMMENTS				
Clinician: _____		Signature : _____		

APPENDIX E

DURBAN UNIVERSITY OF TECHNOLOGY REGIONAL EXAMINATION - CERVICAL SPINE

Patient: _____ File No: _____

Date: _____ Student: _____

Clinician: _____ Sign: _____

OBSERVATION:

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

Shoulder position

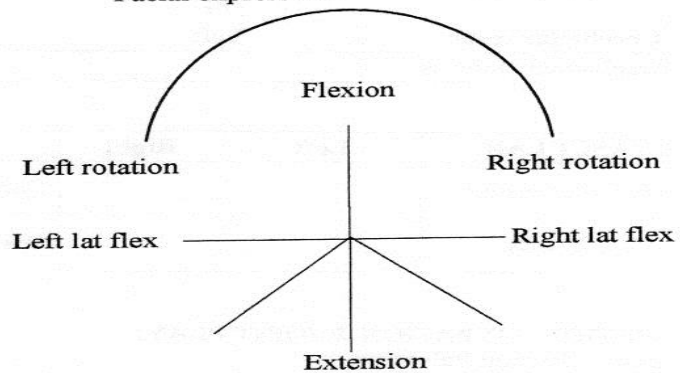
Left :
Right :

Shoulder dominance (hand):

Facial expression:

RANGE OF MOTION:

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



PALPATION:

Lymph nodes
Thyroid Gland
Trachea

ORTHOPAEDIC EXAMINATION:

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

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

NEUROLOGICAL EXAMINATION:

Dermatomes	Left	Right	Myotomes	Left	Right	Reflexes	Left	Right
C2			C1			C5		
C3			C2			C6		
C4			C3			C7		
C5			C4					
C6			C5					
C7			C6					
C8			C7					
T1			C8					
Cerebellar tests:			T1					
Disidiadochokinesis			Left		Right			

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:

ROM: Active:

Passive:

RIM:

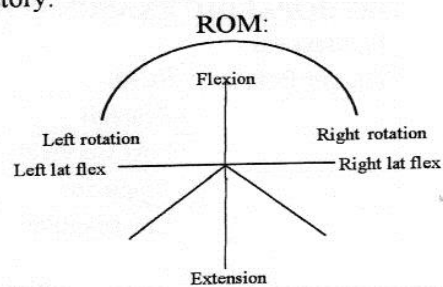
Orthopaedic:

Neuro:

Vascular:

BASIC EXAM: THORACIC SPINE:

Case History:



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

APPENDIX F

OBJECTIVE DATA COLLECTION SHEET

	VISIT ONE	VISIT TWO	VISIT THREE	VISIT FOUR
NRS RATING				
CROM READING- LATERAL FLEXION ON THE RIGHT				
CROM READING- LATERAL FLEXION ON THE LEFT				
ALGOMETER READING TP 2				
CMCC SCORE				

APPENDIX G

NRS SCORE SHEET

Kindly circle your current pain rating with 0 being the least and 10 the worst

0 1 2 3 4 5 6 7 8 9 10

APPENDIX H

CMCC Neck Disability Index

THIS QUESTIONNAIRE IS DESIGNED TO HELP US BETTER UNDERSTAND HOW YOUR **NECK PAIN** AFFECTS

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 CLOSELY** DESCRIBES 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 car 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 I



INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

2 October 2012

IREC Reference Number: REC 39/12

Ms A Abdul-Rasheed
15 Sandown Road
908 Key West
North Beach
Durban

Dear Ms Abdul-Rasheed

The effectiveness of spinal manipulation and dry needling versus spinal manipulation and Traumeel® S Injectable solution in the treatment of mechanical neck pain associated with trapezius myofascial trigger points

I am pleased to inform you that Full Approval has been granted to your proposal REC 39/12.

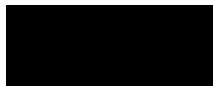
The Proposal has been allocated the following Ethical Clearance number IREC 036/12. Please use this number in all communication with this office.

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



Dr D F Naude
Chairperson: IREC

