The efficacy of phonophoresis with Traumeel® S in the treatment of upper trapezius myofasciitis.

By

Virosha Deonarain

Dissertation completed in partial compliance with the requirements for the

Master's Degree in Technology: Chiropractic

Durban University of Technology

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

_____ _____

Virosha Deonarain Date

Approved for Final Submission

_____ _____

Dr A Docrat Date

M.Tech:Chiro, M.Med.Sci (UKZN)

DEDICATION

This work is dedicated to my mum **Shama** and my late dad, **Lutchman**. It is for you that I endeavour to be the best that I can be. Your sacrifices, hardships and tribulations you have empowered me to stand firm about who I am and in what I believe.

And to

Reon, Schevek and my late brother Shaneel…every sister needs brothers like you, thank you for everything.

"All that we see or seem, it's but a dream within a dream"

Edgar Allen Poe

ACKNOWLEDGEMENTS

I would like to thank the following people:

- Dr. A.Docrat,thank you for your supervision of this research study. Your time and advice have been greatly appreciated. You have been fantastic. Thank You!

- My best friend and soul mate, Fagen. Your tremendous support and encouragement throughout my years of studying have been phenomenal. I am eternally grateful to you.

- My dear friend Kathleen, your kindness and support has been very uplifting. Our special 'tea parties' have been a good source of motivation and laughter. I am glad to have made a friend for life. Also, special thanks to Chantelle and Merissa: our journey from 1st to 6th year was an eventful one and wouldn't have been as good without you.

- A hearty thank you to my childhood friends, Melisha and Ritasha. Your support throughoutmy chiropractic journey was amazing. To a special friend, who has always been there and continues to be a great support, Trish – thank you for being awesome.

- To my cousins and friends, thank you for all the laughter, fun and good times. And to those, to whom I promised free treatment, alas it was just a joke!

- To Dr.C. Korporaal, I am very appreciative of your efficiency, advice and help throughout the years. Thank you for your enthusiasm and dedication to the profession and to the students of Chiropractic.

- To my class colleagues, thank you for making the past 6 years a memorable one!

- To all the patients who participated in this study…I cannot thank you enough.

ABSTRACT

Background: Myofascial Pain Syndrome is characterized by localized muscle pain, in which affected muscles are in a chronically-shortened state and contain trigger points.It is the single most common source of musculoskeletal pain that is encountered in clinical practice. Modalities such as electrotherapy, cryotherapy, thermal therapy, dry-needling and ultrasound are used in its management. The use of phonophoresis has generated much interest; and literature around this modality continues to accumulate. Numerous studies have demonstrated the efficacy of phonophoresis with an anti-inflammatory in the treatment of musculoskeletal disorders, attributing the efficacy to the penetration of the coupling medium by means of the ultrasonic waves. Traumeel®S, is a homeopathic anti-inflammatory, that has successfully been used in the treatment of musculoskeletal injuries.It has anti-oedematous, anti-exudative, anti-inflammatory and analgesic properties. Its efficacy as a coupling agent in phonophoresis has not been tested for myofascial pain syndrome.

Methodology: This study was designed as a prospective, double-blinded, randomized, and controlled experimental investigation. Sixty subjects were randomly allocated to three groups of 20 subjects each. Group Areceived active phonophoresis with Traumeel® S gel;Group B received sham phonophoresis with Traumeel® S gel; Group C received an application of Traumeel® S gel only.Algometer and Numerical Pain Rating Scale 101 (NRS) readings were taken immediately before treatment at visit one and thereafter at visits three and four.

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

Conclusion:The results from this study revealed that all three treatment groups responded favorably to the alleviation of pain. It was concluded that phonophoresis with Traumeel® gel had no significant additional beneficial effects.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

CHAPTER ONE

1.1 Introduction

Myofascial pain is a clinical syndrome of soft tissue pain arising from trigger points (TrPs) in a muscle (Skootsky, 1989). Trigger points, which maybe small and sensitive, usually cause pain either spontaneously or upon direct compression (Simons and Travell, 1993). According to Yap (2007) the precipitating and perpetuating factors are trauma, mechanical degeneration, nerve root compression, emotional psychological stress, endocrine and metabolic deficiencies, nutritional deficiencies and chronic infection.

Yap (2007) reported that a multifaceted approach is often required in the treatment of myofascial pain. However, the predisposing and perpetuating factors such as chronic overuse of stress injury on muscles must be eliminated, if possible (Alvarez and Rockwell, 2002).

Pharmacological treatment includes the use of analgesics and medications that induce sleep, whilst non-pharmacological treatment modalities include acupuncture, osteopathic manual medicine techniques, massage, acupressure, ultrasonography, heat or ice application, diathermy, transcutaneous electrical nerve stimulation (TENS), spray and stretch technique, dry needling and injection into a trigger point with local anaesthetic, saline or steroid (Alvarez *et al*.,2002).

Physical therapies include ischemic compression, strain and counter-strain, muscle energy techniques, trigger point pressure release and transverse friction massage (Penas, Campo, Carnero and Page, 2003). Trigger point therapy involving the use of ischaemic compression, injection into a trigger point, dry needling and friction massage is effective but often painful and sometimes invasive (Alvarez *et al*.,2002). Physical modalities, such as heat therapy, ultrasound and electrical therapy (TENS) are generally used as supplementary adjuncts, as they aid in controlling muscle pain and spasm (Yap, 2007).

Therapeutic ultrasound (US) is a widely-used electro-modality in current clinical practice (Watson, 2002). For the past 40 years, US has been used in the treatment of musculoskeletal disorders such as tendonitis, tenosynovitis, epicondylitis, bursitis and osteoarthritis (Kozanoglu,Basaran, Guzel and Uysal, 2003). It is used by 94% of physical therapists in Canada and 65 % of physical therapists in the United States of America (van der Wind, van der Hiejden, van den Berg, TerRiet, de Winter and Bouter, 1998).

Phonophoresis, also known as sonophoresis or ultrasonophoresis, is defined as the migration of drug molecules through the skin under the influence of ultrasound (Watson, 2002). When applied topically, drugs are absorbed very slowly through the skin, however, high-frequency sonic vibration may accelerate this process (Robertson, Ward, Low and Reed, 2006). Drug delivery by phonophoresis may be advantageous if effective, as it permits substances to be delivered unchanged,unlike during ingestion. Phonophoresis may thus avoid hepatic or systemic collateral effects (Robertson *et al.,* 2006). The depth to which drugs can be made to penetrate remains a topic of interest.

According to Unlu, Orguc, Eskiimir, Aslan and Tasci (2008), phonophoresis with an anti-inflammatory is commonly used in the management of pain and inflammation in musculoskeletal conditions as it is a non-invasive technique that is well tolerated and involves minimal risk of gastric injury. In a study conducted by Unlu *et al*.,(2008) phonophoresis with ketoprofen (NSAID) was conducted on patients with anterior cervical osteophytes causing dysphagia. The result of the study revealed that the symptom of dysphagia regressed to various degrees. Cagnie, Vinck, Rimbaut(2003) reported that phonophoresis with ketoprofen resulted in higher local concentration of the substance whereas systemic exposure was considerably lower.

Traumeel® S is a homoeopathic complex containing 12 botanical substances and two mineral substances (Arora,Harris and Scherer, 2002). Traumeel® S is indicated for trauma, inflammation, soft tissue swelling, degenerative processes and arthroses (Oberbaum, 1998). According to Arora*et al., (*2002) Traumeel® S is reported to have fulfilled all criteria to successfully treat sport injuries as it is anti-oedematous, anti-exudative, has regenerative properties and promotes wound healing. It contains extracts from plants and minerals, all of them highly diluted (10^{-1} to 10^{-6} of the stem solution) (Birnesser, Oberbaum, Klein and Weiser, 2004).

Zell, Connert, Mau and Feuerstake (1989), investigated the effect of the application of Traumeel® Son acute ankle sprains, compared to a placebo. The result showed 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.

While the efficacy of Traumeel® S has been observed via topical application (Zenner and Metelmann, 1992) and ingestion (Arora *et al*., 2002), this study aims to determine the effects of

Traumeel® S gel by phonophoresis in the treatment of active myofascial trigger points in the upper trapezius.

1.2 Aim

The aim of this study is to determine the efficacy of Traumeel® S phonophoresis in the treatment of active myofascial trigger points in the upper trapezius muscle.

1.3 Objectives

1.3.1 Objective 1

To determine the relative efficacy of Traumeel® S gel with active phonophoresis in the treatment of upper trapezius myofascitis using subjective and objective measures.

1.3.2 Objective 2

To determine the relative efficacy of Traumeel® S gel with placebo phonophoresis in the treatment of upper trapezius myofascitis using subjective and objective measures.

1.3.3 Objective 3

To determine the relative efficacy of the topical application Traumeel® S gel in the treatment of upper trapezius myofascitis using subjective and objective measures.

1.3.4 Objective 4

To determine by means of statistical analysis of the data obtained from Objectives 1,2 and 3 which combination is more effective in the treatment of active myofascial trigger points in the upper trapezius muscle.

1.4 Rationale

1.4.1 Rationale 1

Phonophoresis has been successfully used in the treatment of various musculoskeletal conditions (Kassan, Lynch and Stiller.1996:657). Phonophoresis with an anti-inflammatory is commonly used in the management of pain and inflammation in musculoskeletal conditions as it is a non-invasive technique that is well tolerated.

1.4.2 Rationale 2

Traumeel ®S is a safe and well-tolerated homeopathic anti-inflammatory with similar efficacy as NSAIDs but without the adverse gastrointestinal effects (Hepburn, 2000 ; Arora *etal*., 2000). Traumeel ®S has been indicated for trauma, inflammation, soft tissue swelling, degenerative processes and arthroses (Oberbaum, 1998). While the efficacy of Traumeel®S has been successfully demonstrated by the topical application of the ointment in the treatment of ankle sprains, its efficacy by phonophoresis has yet to be established.

1.4.3 Rationale 3

Other effective forms of treatment of myofascial pain syndrome include dry needling, injections into a trigger point, action potential therapy or ischaemic compression all of which are either invasive or painful (Alvarez *et al*., 2002 ;Penas *et al*.,2003). Investigating other ways to treat myofascial pain is suggested in finding a less invasive and pain free modality for patients in the treatment of myofascial pain.

CHAPTER TWO

LITERATURE REVIEW

This literature review summarizes the available information regarding myofascial pain syndrome and its treatment. The following aspects will be discussed:

- Myofascial Pain Syndrome (MPS)
- The ultrasound and phonophoresisin the treatment of myofascial pain syndrome
- The use of Traumeel ® S in the treatment of myofascial pain syndrome

2.1 Myofascial Pain syndrome

Myofascial Pain Syndrome is a condition characterized by localized muscle pain, in which affected muscles are found to be in a chronically shortened state and containing trigger points within taut palpable bands of muscle (Abrams*,* 2006). It has been found to be acommon source of musculoskeletal dysfunction (Fricton,1985 ;Skootsy, Jaeger and Oye*,* 1985) and one of the main causes of headache and neck pain (Grosshandler, Stratas, Toomey and Gray, 1985). According to Gerwin (2001) it can be classified as being either acute or chronic, regional or generalized. It may exist as a primary disorder causing local or regional pain syndromes or it may occur secondarily to another existing condition (Gerwin, 2001). When chronic, it tends to generalize but does not change or progress into fibromyalgia (Gerwin, 2001).

The locations of a trigger point may include fascia, ligaments, skeletal muscles and tendons (Penas *et al.,* 2003). Although myofascial pain is the most common single source of musculoskeletal pain (Fricton*,* 1985), it constitutes the largest group of unrecognized and undertreated medical presentations (acute and chronic) in clinical practice today (Simons, 2004). Despite the belief by clinicians and scientists that musculoskeletal pain comes from trigger points, mainstream medicine has yet to accept or incorporate them as an integral part of its teaching, research and practice (Zieglgansberger, 2004).

Trigger points, which maybe small and sensitive, usually cause pain either spontaneously or upon direct compression. The diagnosis of myofascial trigger points is a clinical one typically depicted by the physical signs demonstrated (Simons *et al*., 1993).These include:

- the presence of a hypersensitive tender spot in the taut band
- palpable or visible local twitch response on snapping palpation, and/or needling of the TrPs (Hong, 1994)
- a 'jump'sign
- the presence of the typical referred pain pattern of the TrP
- restricted range of motion (ROM) of the affected tissues
- muscular fatigue and autonomic phenomena (Simons *et al*.,1993).

However, the minimal acceptable criteria recommended by Travell, Simons and Simons(1999) and Gerwin (2001), involves the presence of :

,

- a palpable taut band
- an exquisite tender spot in the taut band
- patient's recognition of pain as 'familiar'
- pain on stretching of the tissues

Trigger points may arise in virtually any muscle group, however, it has been noted that muscles of posture are most commonly involved. These muscles include the levator scapulae, upper trapezius, sternocleidomastoid, scalenes and quadratus lumborum muscles (Richards, 2006).

2.2 Pathophysiology and Aetiology of Myofascial Pain Syndrome

According to Simons (2004) the integrated hypothesis is currently the most credible proposed aetiology of trigger points. This hypothesis identifies three essential pathophysiological features that relate to one another in a positive feedback cycle. These features are: abnormal acetylcholine release at the neuromuscular junction; increased muscle fibre tension while passing through the trigger point, producing a taut band; and the release of sensitizing substances within the muscle tissue, producing pain.

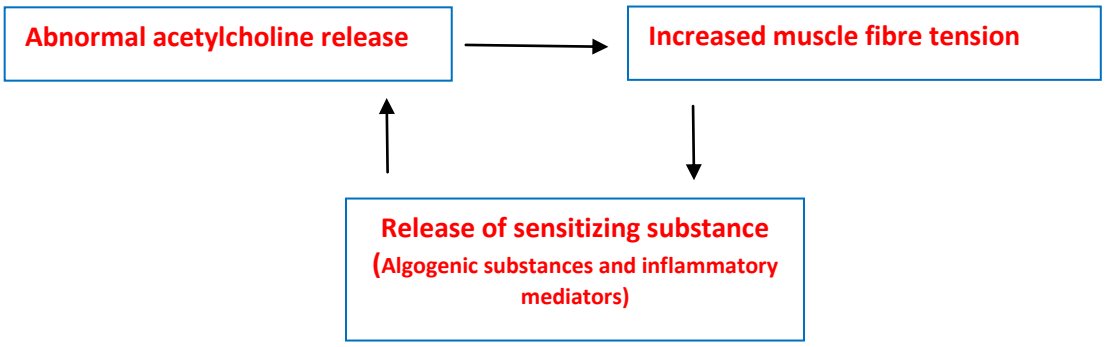


Figure 2.1. The essential pathophysiological features of myofascial trigger points and relationship in a positive feedback cycle according to the integrated hypothesis (Simons, 2004)

The integrated hypothesis proposes a high production and release of acetylcholine at affected neuromuscular junctions resulting in a prolonged post-junctional depolarization with shortening of sarcomeres. This muscle contraction inhibits adequate arterial supply, producing oxygen deprivation of the affected muscle and subsequent release of algogenic substances and inflammatory mediators that cause pain (Abrams, 2006).

Precipitating and perpetuating factors have been attributed to the development of myofascial pain. The presence of these factors may cause the facilitated release of acetylcholine (Ach) at motor end plates which then either begins or perpetuates the integrated hypothesis positive feedback cycle. A continuation of this process over a prolonged period results in local muscle fibrosis (Yap, 2007).

According to Yap (2007) the precipitating and perpetuating factors are:

- trauma
- mechanical degeneration
- nerve-root compression
- emotional psychological stress,
- endocrine and metabolic deficiencies

- nutritional deficiencies
- chronic infection

Although the mechanism of trigger point activation is not clearly understood, it has also been hypothesized that the pathophysiology of myofascial pain syndrome and the formation of myofascial TrPs commonly result from injured or overloaded muscle fibres (Hong and Simons, 1998). This leads to an involuntary shortening of muscle fibres with a consequent loss of oxygen and nutrient supply and increased metabolic demand on local tissues (Han and Harrison, 1997; Hong and Simons, 1998).

2.3 Prevalence

Myofascial pain is the most common single source of musculoskeletal pain, comparing in severity with other painful conditions that cause the patient to seek medical assistance (Fricton, 1985),constituting the largest group of unrecognized and undertreated medical presentations (acute and chronic) in clinical practice (Simons*et al*.,1993). In a study of 164 patients referred to a pain clinic with chronic head and neck pain of at least 6 months' duration, 55% were found to have a primary diagnosis of myofascial pain (Fricton, 1985). Skootsky *et al*., (1989) has reported in a general medical clinic study that the primary complaint of 30% of patients was attributed to myofascialpain. With a fairly high prevalence, myofascial pain, which is treatable, is often under-diagnosed and under-treated (Yap, 2007).

2.4 Clinical Features

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 regionalized 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 or a tendency to drop things, may occur, without the patients being

aware of the weakness (Finley, 2010).Depending on the clinical pattern and pain referral, trigger points may be either active or latent and may range from 2 – 5mm in diameter (Richards, 2006).

Active trigger points are hypersensitive and can be associated with two types of pain that may occur spontaneously with muscle use or with palpation on examination. An active trigger point is characterized as a well-demarcated, sharp, localized pain or as a radiating or referred pain (Simons *et al*., 1993). A referred pain is commonly described as deep and aching in character, projecting beyond the originating trigger point. The distal area of referred pain is called the zone of reference, which does not follow any dermatomal or myotomal patterns (Fricton*,* 1985). By comparison, latent myofascial trigger points remain non-painful at rest, with pain only being elicited by the application of direct, steady pressure (Richards, 2006).

Trigger points are often a coincidental finding on palpation, but have been attributed to cause movement restriction or muscle weakness. Latent trigger points may progress into active trigger points if the muscle is stressed by tension, mechanical overloading or prolonged muscle shortening, demonstrating a local twitch response and lowered pain threshold (Wreje and Brorsson, 1995).According to Travell*et al.,* (1999) latent trigger points may display all clinical characteristics of an active trigger point; they always have a taut band that increases muscle tension and restricts range of motion.

In the trapezius muscle, pain is commonly referred to the postero-lateral neck and temple, cervico-occipital area and acromion. Trigger points within the Trapezius muscle maybe activated and perpetuated inacute trauma, as with falls or whiplash, repetitive stress from prolonged elevation and extension of the arms for example typing; or overloading during its key role in neck stabilization with tilt of the shoulder-girdle axis (Argoff and Smith, 2010).

Other associated symptoms include decreased muscle strength and endurance (Argoff and Smith, 2010). Autonomic phenomena include localized vasoconstriction, persistent hyperaemia after palpation, pilomotor activity, diaphoresis and lacrimation. These are often associated with trigger-point presentation (Argoff and Smith, 2010). Identification of myofascial TrPs is essential for the diagnosis and treatment of myofascial pain syndrome, because persistence of TrPs results in chronicity and propagation to other muscles as secondary and satellite TrPs (Argoffand Smith, 2010).

2.5 Diagnostic Criteria for Myofascial Trigger Points

According to Schneider (1996), the diagnosis of myofascial pain syndrome requires that all five major criteria and at least one of the minor criteria be present.

Major Criteria

1. Regional pain complaint
2. Pain pattern follows a known distribution of muscular referred pain
3. Palpable taut band (in accessible muscles)
4. Exquisite focal tenderness at one point or nodule within a taut band
5. Some restricted range of motion or muscle weakness (when measurable)

Minor Criteria

1. Manual pressure on the MFTP nodule reproduces the chief pain complaint
2. Snapping palpation of the taut band at the MFTP elicits a local twitch response
3. Pain is diminished or eliminated by muscular treatment, e.g. therapeutic stretch, ischaemic compression or needle injection of the MFTP.

The principal assessment of these criteria is by palpation of the affected muscles, which is usually obtained by a pincer or flat palpation. This requires a sustained deep pressure to be applied on the affected muscle. The pain elicited may be either concentrated in the trigger-point area or along that muscle's distinct referral pattern, which is constant, reproducible or does not follow a dermatomal or nerve distribution pattern (Han and Harrison, 1997).

2.6 Treatment of Myofascial Trigger Points

According to Yap (2007) a multifaceted approach is often required in the treatment of myofascial pain. However, the predisposing and perpetuating factors in chronic overuse of stress injury on muscles must be identified and eliminated, if possible (Alvarez *et al*, 2002). The treatment of myofascial pain syndrome ranges from analgesics and medications that induce sleep, which may include anti-depressants, neuroleptics or non-steroidal anti-inflammatory drugs, to treatment modalities which may be used as an adjunct to treatment with medication or alone. These modalities include acupuncture, osteopathic manual medicine techniques, massage, acupressure, ultrasonography, heat or ice application, diathermy, transcutaneous electrical nerve stimulation (TENS), spray and stretch technique, dry needling and trigger-point injection with local anaesthetic, saline or steroid (Alvarez *et al*, 2002).

Following acute musculoskeletal injuries, tissue processes involve an acute inflammatory response at the injury site. Although inflammation is a homeostatic mechanism and part of the body's response to injury, excessive inflammation can slow the healing process and cause tissue damage (Schneider, 2011), therefore conventional management aims to control pain, restore range of motion and voluntary muscle control and delay or minimize secondary tissue injury (Denegar, Saliba and Saliba, 2006). Additional medication is often required to achieve symptomatic relief for which NSAIDs have become synonymous with the management of acute musculoskeletal injuries (Warden, 2005). Although effective in reducing pain and inflammation, NSAIDs may not be appropriate, particularly for those frequently participating in sports, because masking pain may enable an individual to continue his sport or daily activities in the short term, but may lead to a worsening of the injury without the patient realizing the extent of damage that has been inflicted (Schneider, 2011).

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, Howatson, Torrance, Lee and Russell, 1992). Moreover, it has been demonstrated that anti-inflammatory treatment may not promote healing but rather impair the return of mechanical strength following acute injury to bone, ligament, and tendon (Warden, 2005).

Birnesser *et al*., (2004) compared Traumeel® S remedy to standard NSAID therapy in the treatment of epicondylitis. 184 patients were recruited, of these 106 received Traumeel ®S and 78 NSAIDs. The method of administration was by injections. NSAIDs were applied

systematically, via intramuscular injections whilst Traumeel ® S was given as a local infiltration. As the study was non-randomized, patients chose the type of treatments. Evaluation of treatments was conducted at week one and week two. Traumeel® S was found to be equivalent to NSAIDs, tending towards superiority in some aspects, such as pain at rest, extensional joint mobility and torsional joint mobility. A limitation of this study was that treatments were administered at different centres, allowing room for error as more than one researcher was involved in the research procedure. A conflict of interest was in noted that this study was supported by a grant from BiologischeHeilmittelGeel, GmbH.

2.6.1 Ultrasound (US) and Phonophoresis in the treatment of myofascial pain syndrome

In the treatment of musculoskeletal disorders, therapeutic ultrasound (US) has been frequently used by therapists in Canada, the United States of America and the United Kingdom (van der Windt*et al*., 1998). The mechanism of action of US is the conversion of electrical energy into an acoustic waveform (Kozanoglu *et al*., 2003) This waveform then passes through tissues of varying resistance as it is converted into heat by causing a mechanical disturbance in an absorbing medium (Kozanoglu *et al*., 2003). Healing of injured tissue requires a sufficient increase in blood supply for the delivery of oxygen, nutrients and white blood cells to the site of the injury (Cunha, Parizotto, and Vidal*,* 2001). Therapeutic US is used to promote healing by reducing oedema, accelerating tissue repair, decreasing pain and modifying the formation of scar tissue (Cunha *et al*., 2001). US may also be used to enhance the penetration of anti-inflammatory agents applied topically on the skin, a technique called phonophoresis (Cunha *et al*., 2001).

According to Kozanoglu *et al*., (2003) there are two different techniques for the administration of therapeutic US: continuous US and pulsed US. Continuous US uses an unmodulated continuous wave US beam and is typically responsible for the heating effect. It uses intensities limited to 0.5 – 2.5 W/cm^3. Pulsed US uses a modulated beam to deliver brief pulses of high-intensity ultrasound separated by longer pauses of no power. This approach emphasises the non-thermal properties of ultrasound. Continuous US is recommended for treatment of restricted movement, whilst pulsed is recommended for acute pain and inflammation (Kozanoglu *et al*., 2003)

The advantages of the transdermal route of anti-inflammatory agents when compared with oral administration, is that topical delivery allows for direct interaction on the inflamed area, avoiding hepatic or systemic collateral effects (Muller, Mascher, Kikuta, Chafer, Brunner and Dorner,1997). However, transdermal delivery of a substance is limited by the low permeability of the stratum corneum of the skin (Mitragoti, 2000). Mitragotri and Kost (2004) showed how phonophoresis enhanced small-molecule penetration through the skin by using US at therapeutic frequencies (1 – 3 MHz). However this has only been observedby the administration of certain drugs like hydrocortisone and indomethacin, which are allopathic NSAIDs.

The variation, in terms of physical-chemical properties between drugs, creates controversy about the efficacy of phonophoresis in enhancing percutaneous drug delivery. These variations include lipophilicity and molecular weight. It has been shown that phonophoresis of small-molecule lipophilic drugs with high-passive skin permeability did not enhance drug transport (Mitragotri and Kost, 2004).

Phonophoresis is defined as the migration of drug molecules, contained in a coupling agent, through the skin, under the influence of ultrasound (Tyle and Agrawala, 1989). According to Tyle and Agrawala (1989), drug penetration is enhanced by ultrasonic waves which alter biological tissues thermally, mechanically and chemically. Although the exact mechanism of the action is unknown, the heating effect is said to be most important (Basford, 1998). This occurs when US converts electrical energy into an acoustic waveform, which is then converted to heat as it passes through tissues of varying resistance (Klaiman, Shrader, Danoff, Hicks, Pesce and Ferland, 1998). The ultrasonic waves in phonophoresis may penetrate the skin up to 5cm below and the usual treatment time is ten minutes, thus offering an alternative to injection with minimal trauma and damage to the site (Tyle and Agrawala, 1989). It is important to note, however, that the length of the treatment, output frequency and power level required for phonophoretic drug delivery varies with different drugs, sites and with the individual person (Tyle and Agrawala, 1989).

Cagnie *et al*., (2003) examined the transdermal delivery of ketoprofen in humans and compared the concentrations found after continuous and pulsed applications. In this study 26 patients with knee disorders requiring arthroscopy were randomly assigned to one of three groups. Patients in group A were given phonophoresis of a ketoprofen gel, using continuous ultrasound (1MHz, 1.5 W/cm^2 for five minutes), patients in Group B received the same treatment but with pulsed ultrasound (100 Hz, 20% duty cycle) and patients in Group C received 5 minutes of sham ultrasound with the ketoprofen gel. All treatments were given just before surgery. During surgery, biopsies of adipose tissue and synovial tissue were taken to evaluate local penetration of the drug. Blood samples were taken to determine whether ketoprofen entered the systemic circulation. Results showed that whilst the concentration of ketoprofen was negligible in plasma, the concentration of ketoprofen in adipose tissue and synovial tissue was consistently higher in group B than in group A and C.

This study confirmed that phonophoresis of ketoprofen allows for a higher local concentration whereas systemic exposure is lower. The results were an indication that in contrast to sham phonophoresis, ultrasound can increase the transdermal delivery of ketoprofen. However the limitations of this study must be taken into consideration when viewing the results. Although biopsy sites had been thoroughly discussed prior to surgery, biopsies were taken by different orthopaedic surgeons. Also, the time from treatment to biopsy varied due to unexpected changes in the schedule of the arthroscopies. These factors may be attributed to the high inter-individual variability in ketoprofen concentration and may have influenced the results.

The effect of indomethacin phonophoresis on temperomandibular (TMJ) joint pain was evaluated in a double-blind, placebo-controlled clinical trial by Shin and Choi (1997). In this study twenty subjects with TMJ pain were randomly assigned to either an experimental group or a control group. Each treatment consisted of the application of ultrasound massage (1.0 MHz, 0.8 to 1.5 W/cm^2 continuous output) for 15 minutes to the painful TMJ. As a conducting medium, 1% indomethacin cream was used for the experimental group and placebo cream for the control group respectively. Pre- and post-treatment pain levels and pain sensitivity were assessed with visual analogue scales (VAS) and pressure pain threshold (PPT). Mean data indicated that post-treatment VAS was significantly decreased and post-treatment PPT was significantly increased in the experimental group, not in the control group. The results of this study suggest that indomethacin phonophoresis provides significant pain relieving effect over the TMJ pain.

The aforementioned studies confirm that phonophoresis with an anti-inflammatory allows for a higher local concentration of the anti-inflammatory (Cagnie *et al.,* 2003) and produces significant pain relief (Shin and Choi, 1997). By contrast a study by Darrow, Schulties, Draper, Richard and Meason (1999) failed to show the efficacy of phonophoresis over ultrasound. Darrow *et al*., (1999) evaluated serum levels of dexamethasone, with blood draws at several intervals, after administration of Decadron (dexamethasone sodium phosphate) phonophoresis. Forty subjects with no known drug allergies or current medication were randomly assigned to one of four treatment groups (Group A - gel/sham, Group B - gel/ultrasound, Group C - dexamethasone/sham, Group D- dexamethasone/ultrasound). The treatment site was the left forearm. After the pretreatment blood draw, a 10minute ultrasound treatment was administered, followed by a post-treatment blood draw. Two additional blood draws followed at 15-minute intervals. A total of 4 serum samples (five cubic centimeter (cc) each) from each subject was centrifuged, and the pipetted serum was frozen for later analysis by double antibody radio-immunoassay. The results showed that, no significant amount of serum dexamethasone was detected in 12 consecutive samples. Testing of additional samples was, therefore, discontinued.

However the researchers indicate possibilities as to why serum dexamethasone was not detected. It is possible that, after the drug is absorbed through the skin, it is sequestered in the subcutaneous tissue. Therefore, it would not be present in serum until a later time, since it is slowly released. The inclusion of a later blood draw, perhaps 12 to 24 hours after the treatment, might have been appropriate to investigate the possibility of slow release of the drug from the subcutaneous tissue. Another possibility could have been that the injectable form of Decadron administered did not show up in the assays used. After an extensive review of available assays, there was no assay found to be specific to Decadron. Although the analysis of pilot data appeared to demonstrate the effectiveness of the testing procedure and the accuracy of the assay when used with Decadron, analysis of subsequent samples showed no presence of serum dexamethasone.

Thus these considerations must be taken into account and the researchers deem the need for future research imperative, using an appropriate medium and appropriate ultrasound parameters before a conclusion can be drawn concerning the efficacy of phonophoresis.

It can then be concluded that future studies involving the use of phonophoresis is required to ascertain if this modality can be incorporated as part of a treatment regime for the successful treatment of musculo-skeletal conditions.

2.6.2 Traumeel S® in the treatment of Myofascial Pain Syndrome

Traumeel S® is an over-the-counter homeopathic preparation composed of extracts from a combination of plants and minerals that has been highlydiluted, though not beyond Avogadro's number. It contains 12 botanical substances and two mineral substances: *Arnica Montana, radix (mountain arnica), Calendula officinalis (calendula), Hamamelisvirginiana (witch hazel), Millefolium (milfoil), Belladonna (deadly nightshade), Aconitum napellus (monkshood), Chamomilla (chamomile), Symphytumofficinale (comfrey), Bellisperennis (daisy), Echinacea angustifolia (narrow-leafed coneflower), Echinacea purpurea (purple coneflower), Hypericumperforatum* (St John's wort), *Heparsulphuriscalcareum (calcium sulphide)* and *Mercuriussolubilis*(quicksilver)(Arora *et al.,* 2002).

It has been widely sold in Germany, Switzerland and Austria for over 50 years, and is one of the most popular alternative medications in these countries(Oberbaum, Yaniv, Ben-Gal, Stein, Ben-Zvi, Freedman and Branski*,* 2001). Self-care is becoming increasingly popular with more patients wanting the opportunity for shared decision-making (Jacobs, 1998). In addition to standard medical care, the use of complementary and alternative medical care as an adjunctive treatment is fast on the rise, with many having a holistic perception of health (McCaffey, Pugh and O'Connor, 2007)

The mechanism of action of Traumeel ®S results from activity of 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 act as an anti-inflammatory; while *Arnica montana, Calendula officinalis, Echinacea*, and *Symphytum* may accelerate wound healing (Lussignoli, Bertani, Metelmann, Bellavite and Conforti*,* 1999). Study of single components of Traumeel has shown that *Arnica montana, Hamamelisvirginiana, Achilleamillefolium, Aconitum napellus, Belladonna,* and *Mercuriussolubilus* exert a considerable inhibitory effect on oedema, while other components have a pro-inflammatory effect *(Calendula officinalis, Echinacea purpurea, Matricariarecutita);* yet others are reported not to influence the development of oedema (*Symphytum, Hypericum, Heparsulphuris*) (Lussignoli*et al.,* 1999). However, the synergistic

interaction between all components of Traumeel® S has a greater effect than any of the components acting alone (Lussignoli*et al.,* 1999). Thus, being a broad-spectrum anti-oedematous,anti-exudative, anti-inflammatory analgesic, its indications are varied to include the stimulation of wound healing, providing pain relief, stopping bleeding and improvement of muscle tone (Arora *et al.,* 2002).

Despite its long history of use as an anti-inflammatory, little was known until recently, regarding the effect of Traumeel® on immune cell function (Schneider, 2011). Research byPorozov, Cahalon, Weiser, Branskis, Lider and Oberbaum (2004) has shown that Traumeel® reduces secretion of pro-inflammatory cytokines from various human immune cells in vitro, both at rest and when activated by PHA-, PMA-, or Tumour necrosis factor alpha (TNF) - (α). Interleukin 1 beta(IL 1 β) secretion was reduced by 70%, TNF-α by 65% and 54% (resting and activated), and IL-8 by 50% (Porozov*et al*.*,* 2004). This indicates that Traumeel® acts on cells of blood-borne leukocytes (the mobile arm of the immune system) and also on gut epithelial cells (the 'non-mobile' gut-associated immune system). It has been suggested that whilst Traumeel® reduces acute local inflammation, the preparation did not affect granulocyte function or human platelet adhesion, allowing for preservation of the homeostatic functions of these cells (Confort*iet al.,* 1997). It appears that Traumeel® regulates the entire process of acute local inflammation rather than by interaction with a specific cell type and promotes the healing process instead of preventing the initial development of oedema (Schneider, 2011).

Arora *et al*., (2000) designed a study to evaluate the clinical safety of Traumeel® S by instructing healthy subjects to ingest two Traumeel® S tablets, sublingually, three times per day. This four week study was performed with 20 subjects, with baseline measures being measured from baseline to post treatment. Factors measured included complete blood cell count, liver profile, serum chemistry, bleeding time, coagulation time and the presence of occult blood in the gastrointestinal system. Selected lab tests were performed once a week and each subject was required to keep a daily log of study drug intake and report any adverse symptoms following drug ingestion. Results revealed that there was no statistical difference in laboratory data from baseline to post-treatment. Adverse events experienced were mild to moderate and resolved without intervention despite continued use of Traumeel® S. These events included stomach discomfort, headache, diarrhea, dizziness, nausea, insomnia and arm/leg pain. It was

concluded by the researchers that Traumeel® S is safe and well tolerated in healthy subjects as there was no significant gastrointestinal toxicity.

Acute injury to musculoskeletal structures, often results in sprains, strains, tendinopathy and stress fractures. These disorders usually occur as a consequence of sudden impact, physical muscular overloads or repetitive use of a joint resulting in significant short-term disability (Schneider, 2011). In the South African rugby union, the nature and frequency of injuries occurring in competitive matches has doubled from 1993/1994 – 1997/1998 since the introduction of professionalism (Garraway, Lee, Hutton, Russell, Macleod, 2000). Similarly, Bohmer and Ambrus (2002), reported a progressive increase in the number of sports injuries in amateur and professional areas of athletics in Germany. Although these injuries are minor in nature with a healing time of approximately two to six weeks, they have the initial effect of terminating athletic activity. The therapeutic objective is therefore the elimination of primary symptoms such as swelling, inflammation and pain to allow for complete and speedy return to sports activities (Bohmer *et al*., 2002).

2.7 Trapezius muscle overview

According to Travell*et al.,* (1999) the trapezius muscle is a tripartite muscle consisting of upper, middle and lower fibres, in different directions and having different functions. For the purpose of this research the upper fibres will be discussed.

The diamond-shaped muscle extends from the occiput (in the midline) to T12 below. 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), whist the sensory fibres receive innervations from the second to the fourth cervical nerves (Simons and Travell, 1993).

According to Travell*et al.,* (1999), trigger points in clinical settings appear to be most frequently citedin the trapezius muscleeven though they can arise in any musclegroup.Information about thesefibresis dealt with under innervation, trigger point location, pain referral patterns and function.

Innervation- this muscle is innervated by the spinal part of the accessorynerve (cranial nerve XI), supplying mainly the motor fibres. The sensory fibresof the muscle are supplied by the second to fourth cervical nerves (Travell*et al*., 1999).

Trigger point location- Trigger point (Tp) 1 is found in the mid-portion of the anterior border ofthe upper trapezius and involves the most vertical fibres that attach anteriorlyto the clavicle. Tp2 is caudal and slightly lateral to Tp1. It is located in themiddle of the more nearly- horizontal fibres of the upper trapezius muscle (Travell*et al*., 1999).

Pain referral patterns- Tp1: Pain is referred unilaterally along thepostero-lateral aspect of the neck to the mastoid process. This point can be amajor source of tension headaches and temporal headaches. When the pain isintense it can be referred up the head centering in the temple and orbitalregion. This may include the angle of the jaw. It can also produce symptoms ofvertigo and dizziness. Tp2: Pain is experienced posterior to the cervical referred pattern of Tp1 (Travell*et al*., 1999).

Function- the upper trapezius draws the clavicle (and indirectly the scapula)backwards and raises them by rotating the clavicle at the sternoclaviculajoint.This portion of the muscle also complements the serratus anterior in rotation ofthe scapula so that the glenoid fossa faces upwards (Travell*et al.,* 1999).

2.8 Summary

Myofascial pain is the most common single source of musculoskeletal pain, constituting the largest group of unrecognized and undertreated medical presentations (acute and chronic) in clinical practice today (Simons *et al*., 1993). Although a multifaceted approach is used when treating myofascial pain, ultrasound is a common modality of choice. The use of a physical agent with ultrasound is referred to as phonophoresis. Research involving phonophoresis with allopathic anti-inflammatories in the treatment of musculoskeletal injuries, has revealed a positive response. Traumeel ® S, a homeopathic anti-inflammatory, has been used

successfully in the treatment of musculoskeletal injuries. To date, research involving phonophoresis with Traumeel ® S is limited, therefore the aim of this study is to determine the efficacy of Traumeel ® S phonophoresis in the treatment of trapezius myofascitis.

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 Study Design

The study was designed as a randomized, double-blinded, placebo-controlled clinical trial, conducted at Durban University of Technology Chiropractic Day Clinic.

3.2 Sampling

Patients were selected by means of convenience sampling. As a result of the advertising process, in which adverts (Appendix A) were placed around the DUT campus, in local gyms and various sporting clubs, interested persons then contacted the Chiropractic Day Clinic or the researcher and an appointment was scheduled.

The study involved a sample size of 60 patients, divided into three groups. There were 20 patients in Group A (active phonophoresis with Traumeel® S), 20 patients in group B (sham phonophoresis with Traumeel® S) and 20 patients in group C (application of Traumeel® S only). Once accepted into the study each of the 60 patients was randomly allocated by an independent party to either group A, B or C by a draw out of a hat. The researcher was unaware as to which group patients in group A and B belonged to. Only patients in group C were known to the researcher, as this group involved the topical application of the Traumeel® S gel.

3.3 Inclusion and Exclusion Criteria

3.3.1 Inclusion Criteria

1. Patients were only accepted once they had given their informed consent(Appendix B) in writing.

2. Patients (male and female) were between the ages of 18 – 45.Restricting it to a relatively young population minimizes the likelihood of pain that may becaused by degenerative disc or joint disease (Esenyal, Caglar and Aldemir, 2000)

3. Patients had to have been suffering from myofascial trigger point pain. Trigger points were diagnosed as follows: The patient identified the painfularea. The examiner then manually palpated the area for local tenderness. Upon manual palpation of the tender area, the patient should have experienced referred pain, and a twitch response should have been felt either by the patient or the examiner (Schneider, 1996)

4. Patients on analgesics were only considered after a washout period of three days so as to prevent the analgesic effect from interfering with results obtained in the study.

5. Patients who had received treatment pertaining to the cervical area or related musculature were only considered as participants after two weeks of receiving such treatment. This was to prevent effects of previous treatment from interfering with results obtained in this study.

3.3.2 Exclusion Criteria

1. Individuals with contraindications to ultrasound according to McDiarmid and Burns (1987): areas of sensory loss, tissue already treated by radiotherapy, acute infection, hemophiliacs without factor replacement and other bleeding disorders, areas with metallic implants and cardiac pacemakers, were not considered for this study.

2. Patients pre-diagnosed with fibromyalgia were not considered for this study. Fibromyalgia is difficult to diagnose and evaluate as its clinical presentation often overlaps with myofascial pain syndrome and other chronically painful conditions (Wepner and Wepner, 2009)

3. Myofascial pain associated with trauma (motor-vehicle accident or direct blunt trauma) was not considered either. Following trauma, the development of myofascial pain syndrome has been shown to occur (Hong and Simons, 1993). Myofascial pain, together with the complications associated with the trauma itself, progressively worsens the prognosis if prompt treatment is not administered following the traumatic event (Hong and Simons, 1993).

4. Patients who may have been part of other research trials, conducted at the Chiropractic Day clinic, within the last three months, were not considered; so as to ensure naivety to the research process.

3.4 Procedure

Patients were required initially to contact the chiropractic clinic telephonically where the following questions were asked:

- Are you between the ages of 18 – 45?
- Do you have pain over your shoulder?
- Do you have other associated pain e.g. headaches, pain radiating down the hands or pain radiating to the eyes?
- Do you feel a knot over the shoulder muscle or does it feel hard?

On answering "YES" to all of these questions, an appointment was set up at the Durban University of Technology Chiropractic Clinic for an initial examination where the patient was given a verbal explanation as well as a letter of information and a consent form (Appendix B) which he were required to read and sign. The patient was given the opportunity to ask questions and made aware that he may withdraw from the study at any time.

Once a case history (Appendix E), physical (Appendix F) and cervical examination (Appendix G) was completed, by the researcher, and the patient was accepted into the study based on the fulfillment of all inclusion criteria, he was then required to complete the NRS pain rating scale (Appendix C). Measurements were also taken using the algometer (Appendix D).

Depending into which group the patient fell, the independent party set the intensity and duration of treatment on the ultrasound device. After these settings were in place, the intensity screen was covered by dark paper, so as to ensure blinding on the part of the researcher. The researcher then resumed movement of the ultrasound head over the designated area.

After treatment, the area of treatment was cleaned with water and henna was applied to mark out the area over the trapezius that had been subjected to ultrasound or topical application of Traumeel® S gel. This area was denoted by four points, within which lies the area to be exposed to ultrasound or topical application. Another point, denoted by a cross, was made central to this area, which was the point at which algometer readings were taken at initial and subsequent visits.

Patients in group A had Traumeel® S gel (15 ml) instead of the usual ultrasound gel applied as a transmission medium to the area to be treated. These patients received a pulsed wave 1:1 ratio (4 milliseconds on, 4 milliseconds off) of ultrasound as a frequency of 1 MHz at an intensity of 1.5w/cm^2 for 10 minutes (Kuntz, Griffiths, Rankin, Armstrong and Mcloughlin, 2006)

Patients in group B received sham ultrasound over Traumeel® S gel (15 ml) i.e. oW/cm^2 for 10 minutes (Kuntz *et al*., 2006).

Patients in group C had Traumeel ® S gel (15 ml) topically applied to the area to be treated for 10 minutes (Kuntz *et al*., 2006).

The study took place over a period of two weeks, involving four visits. Patients were assessed subjectively and objectively prior to the first and third sessions and after the fourth treatment sessions.

The ultrasound unit used was a Dynatron 850 plus (manufactured by Dynatronics, Salt Lake City-Utah), with a 5cm^3 sound head.

3.5 Measurement Tools

a. Subjective measurements

- Numerical Pain Rating Scale was used. This is a questionnaire consisting of a numerical scale from 0-100, with 0 representing one extreme (no pain) and 100 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 simple to score (Jensen, Karoly and Braver, 1986).

b. Objective measurements include:

- Pressure Algometer – Wagner FDEK20 Force Dial(manufactured by Wagner instruments: P.O Box 1217, Greenwich T 06836), measures pain threshold in an area of tenderness (Fischer, 1987). Trigger point two of the trapezius muscle was assessed with the algometer.

The procedure according to Fischer (1987):

- The dial on the gauge was set to zero.
- The disc was placed on the point of maximum sensitivity.
- Pressure was increased at 1kg/cm^2/sec.
- The patient was asked to indicate by saying “yes” at the point where pain was first perceived.
- The exertion of pressure was stopped at this point and the reading was taken.

3.6 Statistical Analysis

SPSS version 18 was used to analyse the data. A p value <0.05 was considered statistically significant. One-way ANOVA testing and Pearson’s chi square test were used to compare age and gender respectively between the three treatment groups to ensure that the randomization process had been complete.

Repeated measures ANOVA testing was used to examine the intra-group effect of time and the inter-group effect of treatment on the outcomes of NRS and the algometer. Profile plots were used to assess the direction and trends of the effects.

3.7. Definitions of tests used

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).

Pearson’s chi square tests: Pearson's correlation reflects the degree of linear relationship between two variables. Pearson's correlation coefficient for continuous data ranges from -1 to +1. Positive correlation indicates that bothvariables, increase or decrease together, whereas negative correlationindicates that as one variable increases, so the other decreases, and vice versa (www.isixsigma.com, 2005).

KEY:

- GROUP A: active phonophoresis with Traumeel ® S
- GROUP B: sham phonophoresis with Traumeel ® S
- GROUP C: application of Traumeel ® S only

ABBREVIATIONS

- SD: Standard Deviation
- %: Percentage
- N Number
- NRS: Numerical pain rating scale (Appendix C)
- Alg: Algometer readings
- Sig: Significance

CHAPTER 4

RESULTS

This chapter discusses the results of the demographic data as well as the results and discussion of the statistical analysis of the subjective and objective data. These were further evaluated in terms of intra- and inter-group comparisons.

4.1 Demographics by group

Table 4.1 a: Mean and standard deviation for age of subjects

GROUP	Mean	N	Std. Deviation
A	23.60	20	7.126
B	23.75	20	5.447
C	26.80	20	8.231
Total	24.72	60	7.066

Table 4.1a depicts the 60 participants who were randomly placed into three equal groups (n=20). The mean age of the sample was 24.72 years (SD 7.066 years). The table also reflects the mean age of each group. The mean age was highest in the application of Traumeel® S only group and lowest in the active phonophoresis with Traumeel ® S group. This was a random event as subjects were allocated to their groups according to the randomization process.

Table 4.1 b: ANOVA test for age between treatment groups

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	130.433	2	65.217	1.320	.275
Within Groups	2815.750	57	49.399		
Total	2946.183	59			

Table 4.1b reflects the analysis of variation (ANOVA) of age between treatment groups. A significance of 0.275 suggests a statistically insignificant difference with respect to age within the three groups.

4.2 Demographics by Gender:

Table 4.2 : Treatment by gender group

			GENDER		Total
			F	M	
GROUP	A	Count	13	7	20
		% within GROUP	65.0%	35.0%	100.0%
	B	Count	15	5	20
		% within GROUP	75.0%	25.0%	100.0%
	C	Count	13	7	20
		% within GROUP	65.0%	35.0%	100.0%
Total		Count	41	19	60
		% within GROUP	68.3%	31.7%	100.0%

Table 4.2 reflects that the female population comprised 68.3% of the total population whilst the male population was 31.7%. The number of females dominated in all three groups with 65%,

75% and 65% in Groups A (active phonophoresis with Traumeel®S), B (sham phonophoresis with Traumeel ® S and C (application of Traumeel ® S only) respectively.

4.3 Objective 1

To determine the relative effectiveness of Traumeel® S with active phonophoresis (Group A) in the treatment of upper trapezius myofascitis using subjective and objective measures

NRS (Subjective outcome)

Table 4.3: Within-subjects effects for NRS in Group A

Effect	Statistic	P value
Time	Wilk's lambda= 0.157	<0.001

Table 4.3 indicates that in group A, there was a highly significant effect on time on NRS meaning that the NRS values changed significantly over the three time points (p< 0.001), with a steady decrease in NRS values with each successive appointment, indicating a reduction of pain.

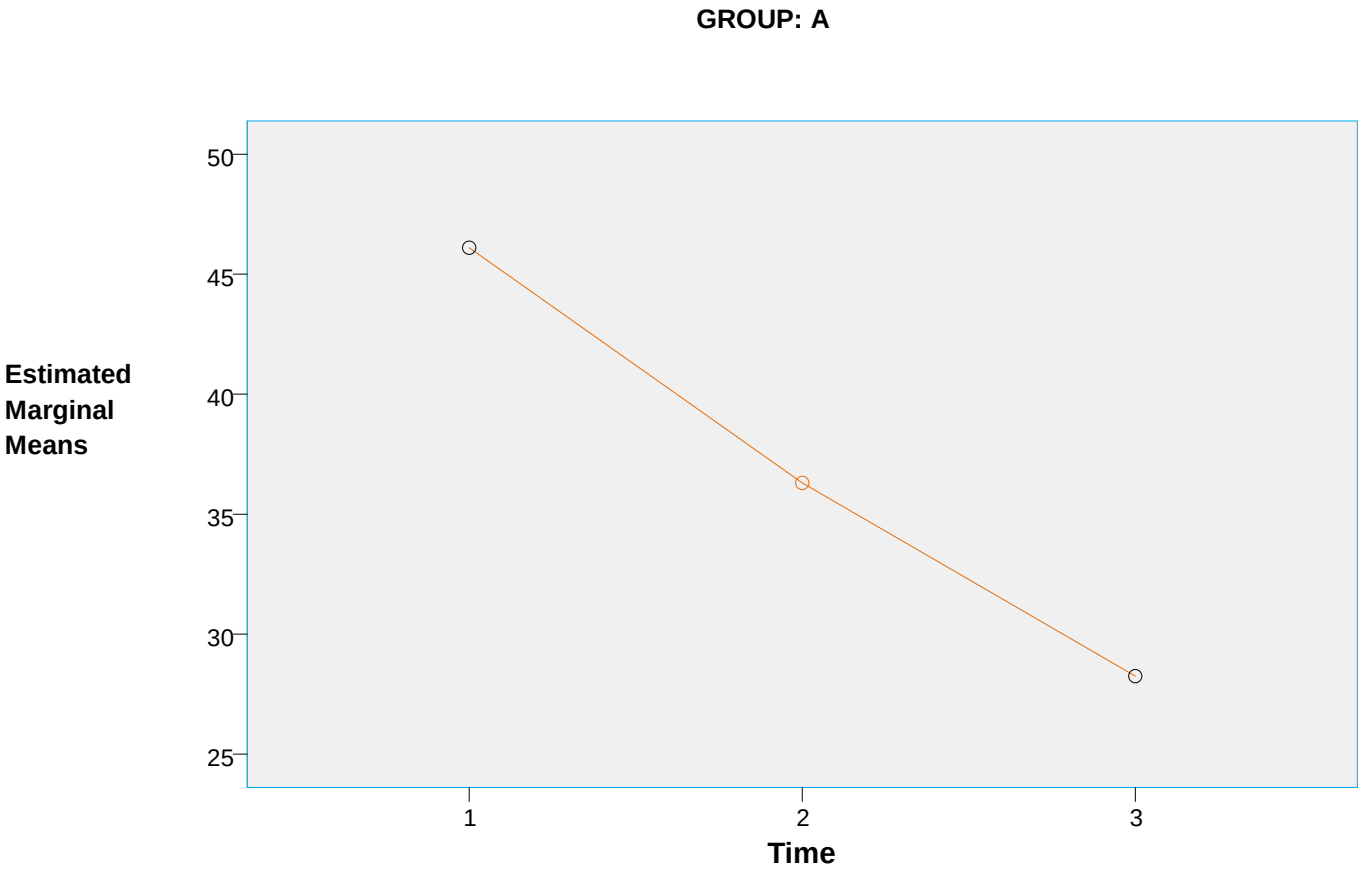


Figure 4.1: Mean NRS over time in Group A

Figure 4.1 suggests that in Group A there was a significant decrease in pain over the three time points ($p < 0.001$).

Algometer (objective outcome)

Table 4.4: Within-subjects effects for Algometer in Group A

Effect	Statistic	P value
Time	Wilk's lambda=0.537	0.004

Table 4.4 implies that there was a statistically significant effect of time on algometer measurements in Group A (p=0.004). This means that the algometer readings increased on successive appointments, indicating an increase in pain threshold resulting from decreased TrP sensitivity.

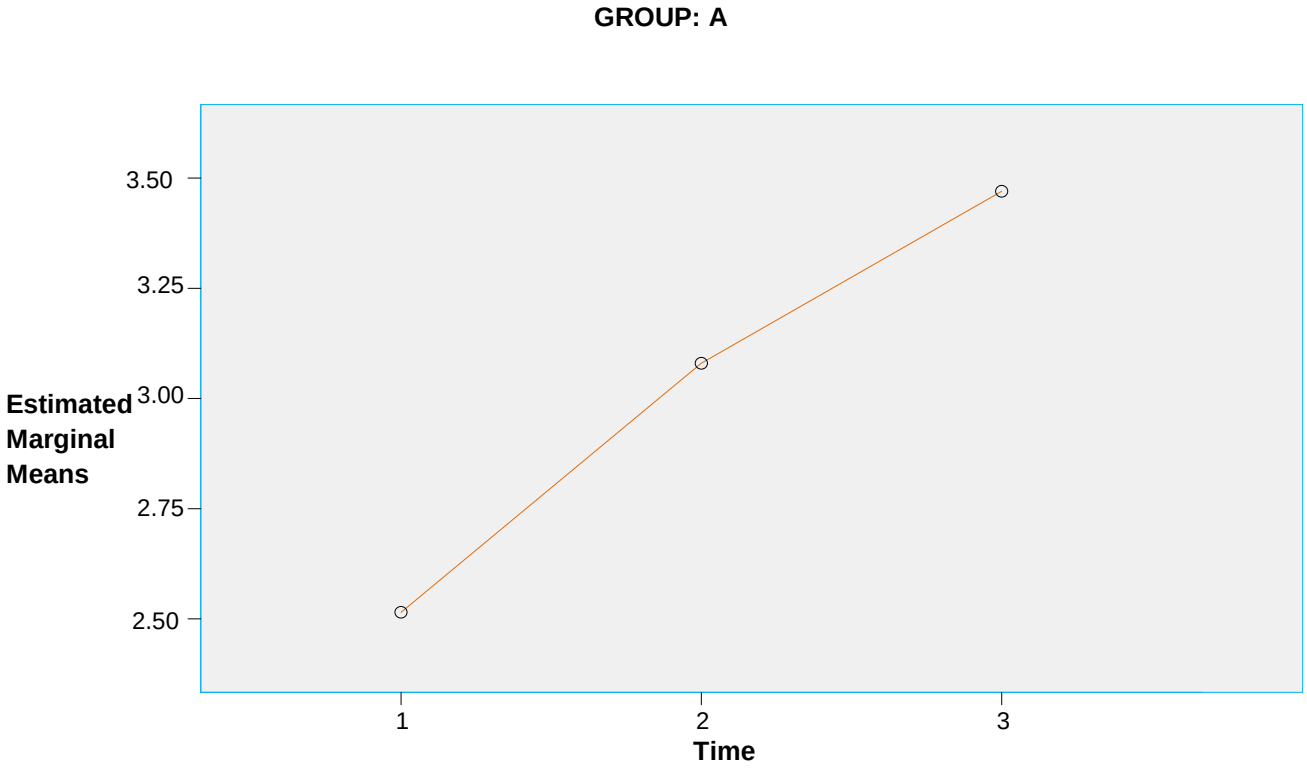


Figure 4.2: Algometer Readings over time in Group A

Fig 4.2 suggests that there was a steady increase in Algometer readings over the three time points indicating a decrease in pain sensitivity.

4.4 Objective 2

Todetermine the relative effectiveness of Traumeel® S with placebo phonophoresis in the treatment of upper trapezius myofascitis using subjective and objective measures.

NRS (Subjective Outcome)

There was a highly significant effect of time on NRS in group B, (p=0.001).

Table 4.5: Within-subjects effects for NRS in Group B

Effect	Statistic	P value
Time	Wilk's lambda=0.444	0.001

Table 4.5 suggests that there was a highly significant effect of time on NRS in group B, this indicating a reduction of pain as treatment progressed.

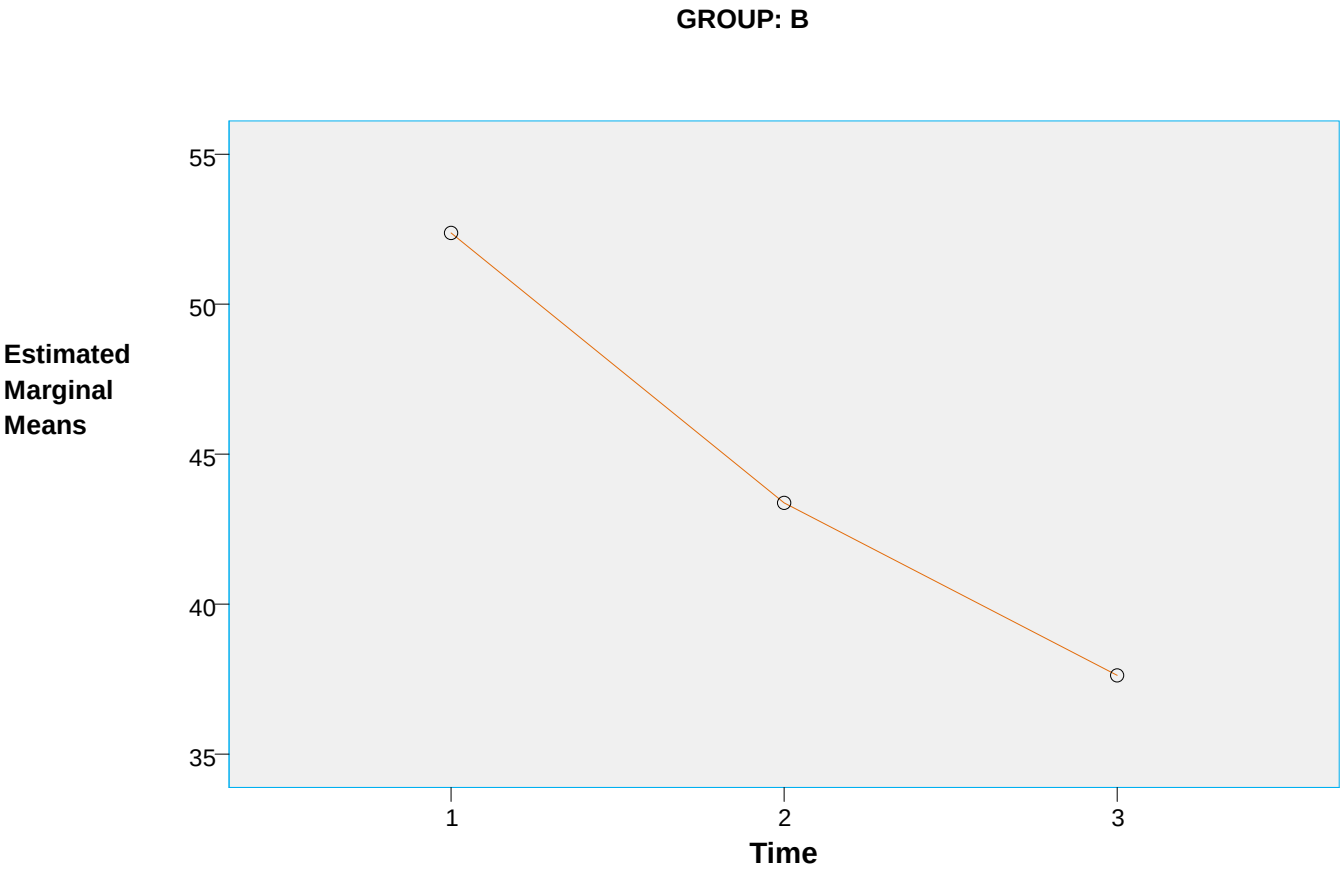


Figure 4.3: Mean NRS over time in Group B

Figure 4.3 suggests that in Group B there was a significant decrease in pain, as the NRS values decreased, over the three time points. This indicates that NRS values decreased steadily over the three time points.

Algometer (Objective Outcome)

Table 4.6: Within-subjects effects for Algometer in Group B

Effect	Statistic	P value
Time	Wilk's lambda=0.689	0.035

Table 4.6 reflects that there was a significant effect of time on algometer in group B, (p=0.035),indicating that algometer readings increased with treatment.

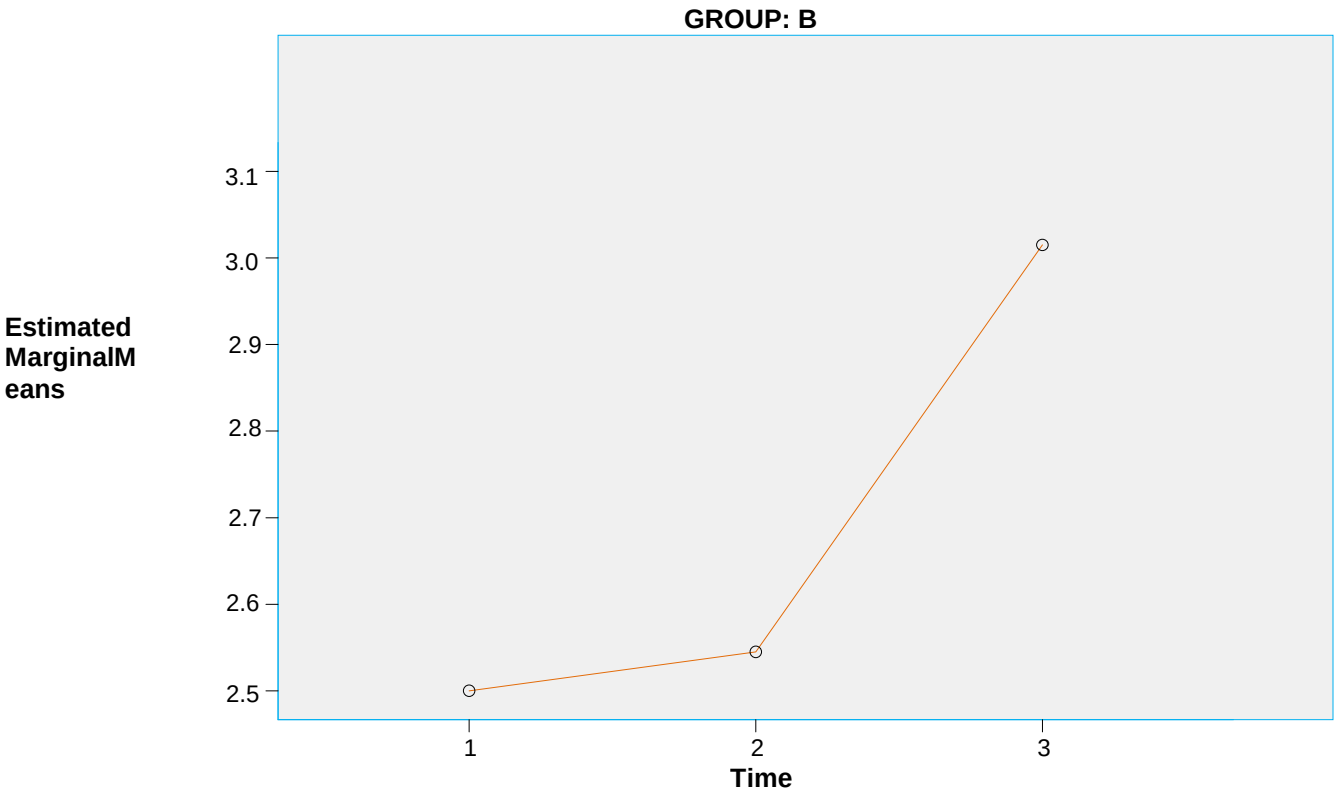


Figure 4.4: Algometer Readings over time in Group B

In Figure 4.4, it is evident that the algometer reading between the first and third treatments had marginally increased. However, at the fourth treatment there was a significant increase in the algometer readings, suggesting a decrease in TrP sensitivity.

4.5 Objective 3

To determine the relative effectiveness of the topical application of Traumeel® S gel in the treatment of upper trapezius myofascitis using subjective and objective measures.

NRS (Subjective Outcome)

Table 4.7: Within-subjects effects for NRS in Group C

Effect	Statistic	P value
Time	Wilk's lambda=0.420	<0.001

Table 4.7 implies that there was a highly significant effect of time on NRS in group C, ($p<0.001$). A decrease in NRS values signifies a steady decrease in pain perception over the duration of the treatment.

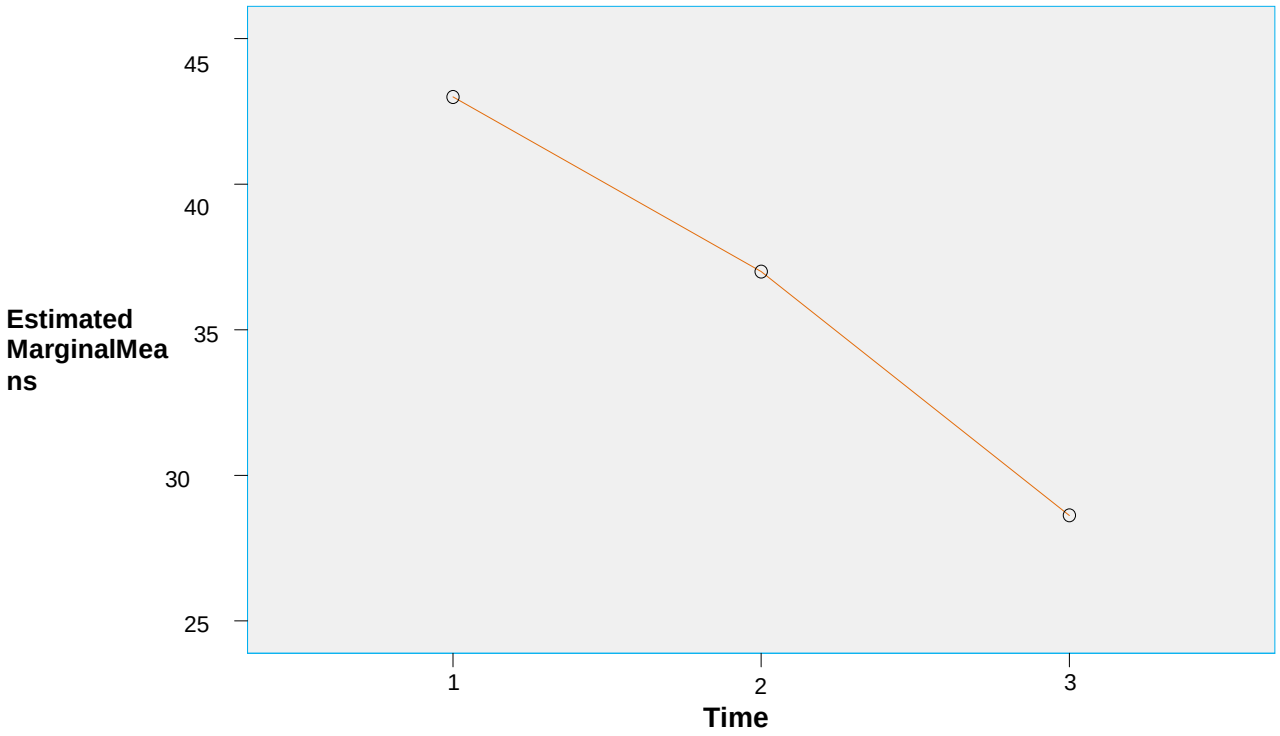


Figure 4.5: Mean NRS over time in Group C

In Figure 4.5, it is evident that NRS scores significantly decreased over the 3 time points, implying a reduction in pain.

Algometer

Table 4.8: Within-subjects effects for Algometer in Group C

Effect	Statistic	P value
Time	Wilk's lambda=0.667	0.026

Table 4.8 indicates that there was a significant effect of time on algometer readings in group C, (p=0.026), translating to a decrease in TrP sensitivity over the duration of treatment.

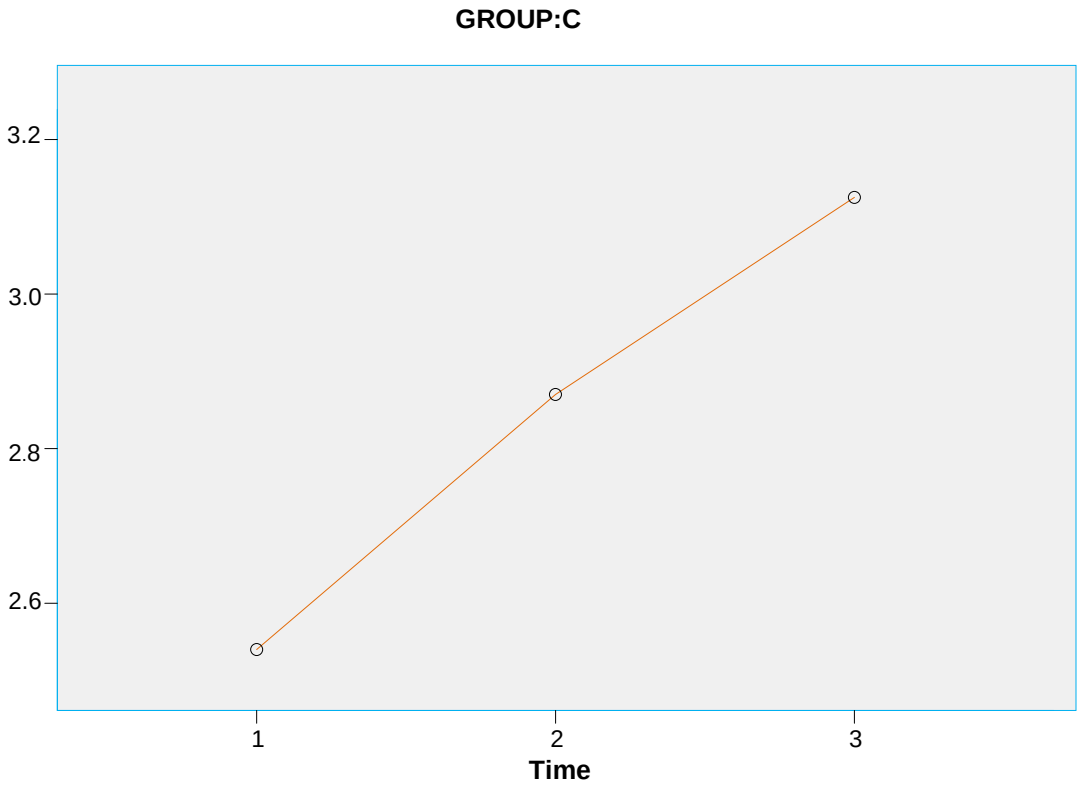


Figure 4.6: Algometer Readings over time in Group C

In figure 4.6 it is evident that there was a steady and gradual increase in algometer readings over the three time points

4.6 Objective 4

To determine by means of statistical analysis of the data obtained from Objectives 1,2 and 3, which combination is more effective in the treatment of active myofascial trigger points in the upper trapezius muscle.

NRS (Subjective outcome)

Table 4. 9: Within-subjects and between-subjects effects for NRS

Effect	Statistic	P value
Time	Wilk's lambda=0.346	<0.001
Time*group	Wilk's lambda=0.931	0.403
Group	F=3.71	0.031

Table 4.9 shows that all groups changed significantly over time. However, this change was not significantly related to which treatment group the participant was in. There was also a persistent difference between the groups independent of time (p=0.031)

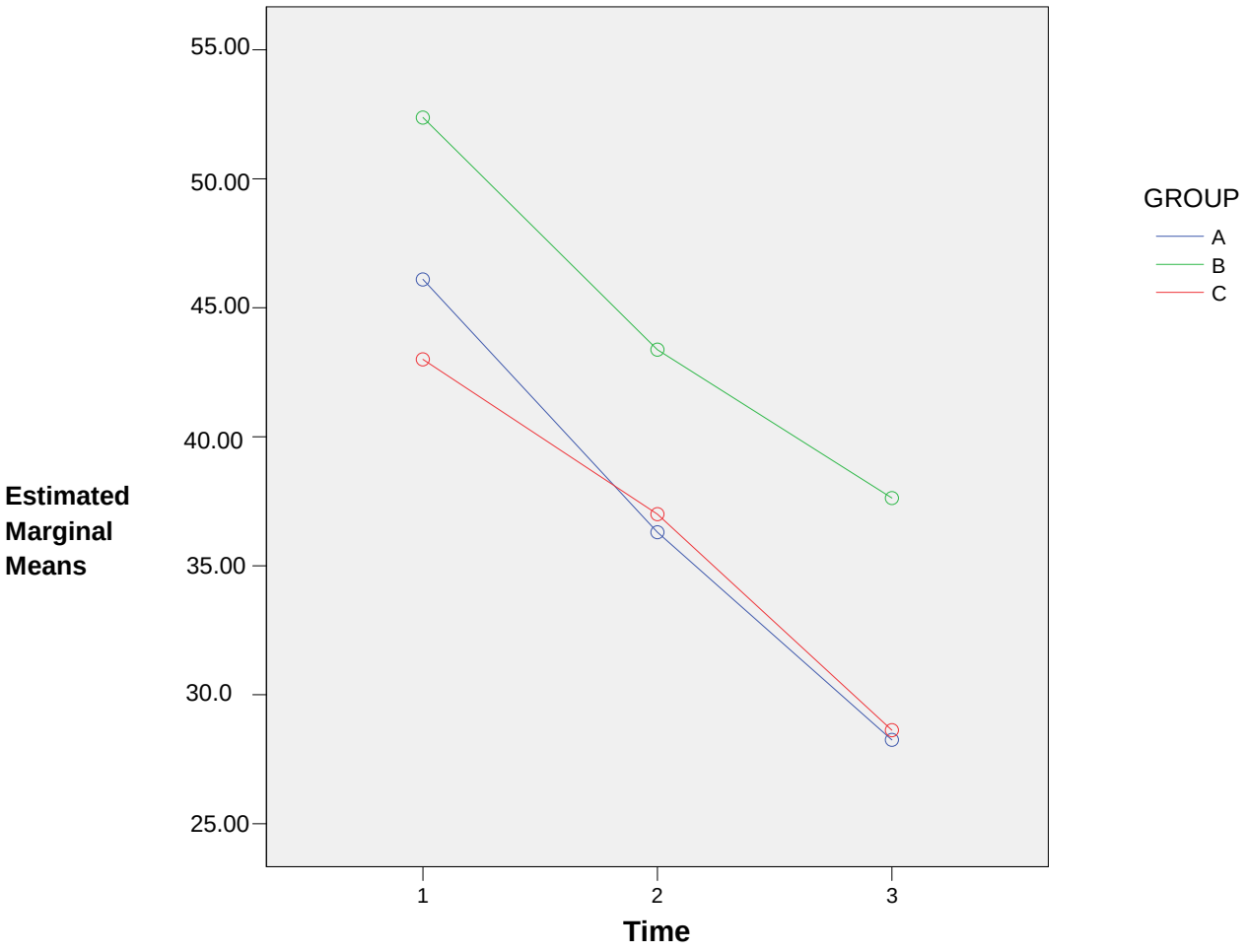


Figure 4.7 : Within-subjects and between-subjects effects for NRS

Figure 4.7 shows parallel profiles of the three groups and that group B had higher pain scores at baseline which persisted throughout the study time periods.Therefore the intervention had no effect on NRS scores. All subjects' pain decreased at the same rate.

Algometer (objective outcomes)

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

Effect	Statistic	P value
Time	Wilk's lambda=0.645	<0.001
Time*group	Wilk's lambda=0.895	0.178
Group	F=0.668	0.517

Table 4.10 shows that although the effect of time was statistically significant, there is no significant time-group interaction (p=0.178) which means that all treatment groups changed significantly over time in algometer measurements; the change was not significantly different between the groups.

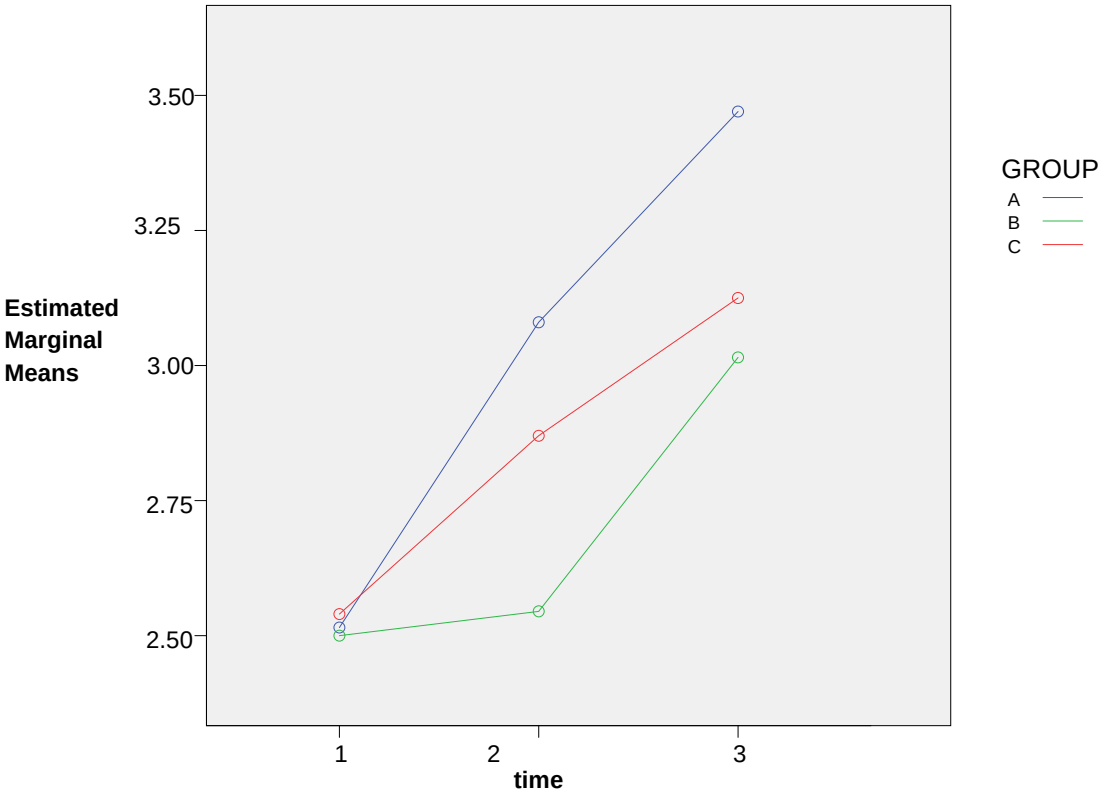


Figure 4.8 : Within-subjects and between-subjects effects for Algometer

Figure 4.8 shows almost parallel profiles of the three groups, and possibly a slight trend towards a steeper rate of increase in measurements in group A over time, but this difference was not statistically significant. All groups' measurements increased at the same rate.

CHAPTER 5

DISCUSSION OF RESULTS

5.1 Demographic Data

5.1.1 Age distribution

The age range for the study was 18-45 years of age. Similar mean ages were reported for groups A and B while group C had a higher mean age (26.8). Restricting the group to a relatively young population means that pain caused by degenerative disc or joint disease is kept to a minimum (Esenyal*et al.*, 2000). Seventy-five percent of participants were students, thus the majority of patients was between 18 – 23 years of age. Location of the adverts, which was mainly around the DUT campuses, may have resulted in the high number of students who participated in the study.However 95% of the student sample population, indicated pain along the middle trapezius and attributed it to poor posture during prolonged periods of studying. It was noted by these students that the intensity and incidence of trapezius pain was heightened during periods of exams/tests.

5.1.2 Gender distribution

The distribution of men and women among the three groups was varied. However women predominated in numbers within each group. It was noted that women comprised 68 % of the participants in the study. 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 women with regards to advertisements and participation in the study. It has been reported that women experienced more pain during the second week of their menstrual cycles thus this hormonal link may be a contributing factor to the severity of myofascial pain syndrome (Broome, 1996 and Miller, 2000). Rollman and Lautenbacher, 2001 has reported that tension-type headache and muscle tenderness is more common in females than males, which is a matter of importance considering the role of myofascial trigger point pain in the genesis of tension type headaches. The gender predominance in fibromyalgia, defined as chronic widespread pain (Macfarlane, 1999) has also been reported, where it was found that women are affected more than men (Macfarlane, 1999). The aforementioned studies thus account for the greater response to the adverts by females rather than males.

5.2 Subjective data

5.2.1 Numerical Pain Rating Scale 101 (NRS)

This scale is used to monitor levels of pain perception experienced by patients. A reduction in the mean score indicates a reduction in the pain experience.

Although the effect of time and group were statistically significant, there is no significant time-group interaction (p=0.403), which means that all treatment groups changed significantly over time (improvement) in NRS scores and the change was not different between the groups. Also, there was a persistent difference between the groups which is independent of time (*p*=0.031).

Studies conducted by Vlak (1999) and Shin and Choi (1997) indicated positive results in using diclofenac gel phonophoresis with painful shoulder syndrome and indomethacin phonophoresis in treating temperomandibular joint pain respectively. In this study it was found that patients in Group A had a steeper rate of improvement compared with patients in group B and group C. Drug penetration is enhanced by the thermal, mechanical and chemical alterations of biological tissues by ultrasonic waves (Tyle and Agrawala ,1989). This may have resulted in the rate of improvement seen in patients within this group.

The control group in this study (Group B) received placebo ultrasound therapy, with the application of Traumeel ®S gel. Patients in this group had higher pain scores at baseline which persisted throughout the study time periods. Although all groups experienced a reduction in pain at the same rate, improvements seen in Group B maybe accounted for by the application of placebo ultrasound which involves the rhythmic movement of the transducer head over the trigger point, with the muscle thus generating a therapeutic massage effect (Binder, Hodge, Greenwood, Hazelman and Page*,* 1985).

The efficacy of the application of Traumeel® S (Group C) may be compared with the study conducted by Bohmer and Ambrus (1992), in which Traumeel ® S ointment was compared with a placebo in the treatment of various musculoskeletal injuries. Traumeel® S was found to be superior in all investigated parameterssuch asswelling, pain and joint circumference. Similarly, in this study, patients in Group C experienced a reduction in triggerpoint sensitivity with the mere application of the gel.

Other reasons that may be attributed to the efficacy of the application is that body heat may have assisted in the transmission of the Traumeel® S gel. It cannot be said that group B was more superior to group C, as the efficacy of treatment in both groups were maintained similarly, throughout the study.

5.3. Objective Data

5.3.1 Algometer

The algometer was used to measure the amount of force that the patient could tolerate on the TrP. An increase in readings indicates an increase in pain threshold resulting from decreased TrP sensitivity

Although the effect of time was statistically significant, there is no significant time-group interaction (p=0.178) which means that all treatment groups changed significantly over time in algometer measurements and the change was not different between the groups. A slight trend towards a steeper rate of increase in measurements in group A over time was noted, but this difference was not statistically significant.

In the evaluation of both subjective and objective findings, it was found that all three treatment groups (A, B and C) showed a significant decrease in the levels of pain perception (NRS) and an overall increase in pain thresholds (Algometer).

It was anticipated that group A wouldhave more favourable results than groups B and C. Although there was a trend of a steeper rate of increase in pain threshold, this was statistically insignificant. However, it was seen that results were favourable, with an improvement in both objective and subjective findings. This could be attributed to the efficacy of the pulsed ultrasound on myofascial trigger points and the efficacy of the Traumeel ® S gel. Pillay (2003) reported that the pulsed waveform of ultrasound was observed to have immediate and better sustained therapeutic benefits when compared with continuous or placebo waveforms in the treatment of trapezius myofascitis.Also, mechanical stimulation of the superficial nerve endings by means of the head of the ultrasound, causes an increase in mechano-receptive activity as per the “Gate control theory” (Melzack and Wall, 1965).

Binder *et al.,* 1985, attributed the improvement experienced in group B to the massage effect of the transducer head over the affected area during mock insonation in which proprioceptive stimulation contributes to pain reduction via the Gate Control theory as described by Melzack and Wall (1965).

In group C, the mere application of Traumeel ® S gel for 10 minutes was sufficient to decrease pain perception and increase pain threshold similarly to Groups A and B. The efficacy of the application of Traumeel® S gel versus a placebo gel, was demonstrated by Zell *et al*., (1989) in the treatment of acute ankle sprains. It was concludedthat there was 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 summary, the results of this study indicate that the three treatments were equally effective at reducing pain and can be incorporated successfully in the treatment of myofascial pain syndrome. Although, statistically insignificant, participants in group A did experience a faster rate of improvement, with a steady decrease in pain over the three time points. Traumeel® S is effective at reducing pain in the treatment of trapezius myofasciitis, with or without the use of phonophoresis, as it was the constant variable in each of the three groups.

CHAPTER SIX

Conclusions and Recommendations

6.1 Conclusion

The aim of this study was to determine the efficacy of Traumeel® S gel with active phonophoresis in the treatment of upper trapezius myofascitis.

This study consisted of 60 patients, divided into 3 groups of 20 each. Every patient underwent a full case-history, physical, and cervical regional examination in order to determine that they fitted the inclusion and exclusion criteria with respect to active Trapezius trigger points.

Thereafter, each patient was randomly placed into either the active phonophoresis with Traumeel® S (Group A), sham phonophoresis with Traumeel® S (Group B) or application of Traumeel® S (Group C). All patients received a total of four treatments within a two week period, with data being recorded at the 1st; 3rd and 4th visit.

Results revealed that for pain measured by NRS 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 and there was no evidence of a differential time effect with treatment.

All of the treatments received was effective.Statistically there was no difference between them.However, this may have been due to small sample size as one of the outcomes shows a trend which suggests a greater rate of improvement in one group compared with the others.

This study concludes that any of the three treatments is equally effective at reducing pain and can be incorporated successfully in the treatment of myofascial pain syndrome. If the minor trend found is considered clinically important then a larger study sample is required to confirm the findings.

Trigger points found in patients with Myofascial Pain Syndrome often require specific treatment, directed to the muscle tissue. Schneider (1996), states that Chiropractors who use only osseous manipulative techniques will have great difficulty when attempting to treat patients with Myofascial Pain Syndrome. This study provides the Chiropractor with a simple, effective, non-

invasive modality to add to the choice of myofascial treatments currently available for use in the clinical environment.

6.2 Recommendations

It is recommended that larger sample sizes be used for future studies which may result in more statistically significant results.

There should be equal representation of males and females so as to avoid gender pain perception.

With regard to the treatment of myofascial pain syndrome, 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 the treatment within an exact time period.

The effects of perpetuating factors and psychological aspects (depression and anxiety) should be considered in further studies in the treatment of myofascial pain syndrome, as these factors are not clinically quantifiable, yet they do contribute to the severity of myofascial pain syndrome.

The age range should be narrower eg. 18 - 30 or 30 – 45, to allow for homogeneity within the study population.

Finally,all treatments appeared to be effective for the treatment of trapezius myofascitis. However, clinically, the treatment of myofascial pain syndrome often requires a multi-disciplinary approach, hence further study suggestions include:

- Comparison of this modality with other forms of treatment for myofascial pain (for example dry needling, laser, infra-red, stretching)

- Using Traumeel ® S phonophoresis as part of a treatment protocol, including chiropractic adjustive techniques and education with regard to stretching and exercise routines at home. This protocol should be compared with others.

References

Abrams, S.E.2006. Myofascial Pain Syndrome. In Fernandez, C.B. Pain Medicine: The requisites in Anaesthesiology. Philadelphia : Elsevier. Pp. 163-169.

Allison, M.C., Howatson, A.G., Torrance, C.J., Lee, F.D., Russell, R.I.1992. Gastrointestinal damage associated with the use of non-steroidalantiinflammatory drugs. *New England Journal of Medicine.* 327:749–754.

Alvarez, D.J., Rockwell, P.G. 2002. Trigger Points: Diagnosis and Management. *American Family Physician*. 65(4):1-7.

Argoff, C.E. 2004. Topical Treatments for Pain.*Current Pain and Headache Reports.* 8: 261-267

Argoff, C., Smith, H. 2010. Myofascial Pain syndrome.Medlink[online]. Available at: http://www.medlink.com/medlinkcontent.asp [Accessed 2 February 2011]

Arora,S., Harris, T. and Scherer, C. 2002.Clinical Safety of a Homoeopathic Preparation.*Biomedical Therapy*, 17(2): 222-225.

Basford, J.R.1998. Physical Agents. In DeLisa, J.A, Gans, B.M. (ed.) Rehabilitation Medicine. Philadelphia: Lippincott-Raven. pp. 483 – 503.

Binder, A., Hodge,G., Greenwood,A.M., Hazelman, B.L and Page, T.D.P (1985). Is therapeutic ultrasound effective in treating soft tissue lesions? *British Medical Journal,* 290:512-514.

Birnesser, H., Oberbaum, M., Klein, P.,Weiser, H. 2004. The Homeopathic preparation Traumeel® S compared with NSAIDS for symptomatic treatment of.*Journal of Musculoskeletal Research*, 8: 119- 128.

Böhmer, D, Ambrus, P. 1992. Treatment of sports injuries with Traumeel® ointment: a controlled double blind study. *Biological Therapy*.10:290–300.

Broome, R. 1996. *The Therapeutic efficiency of invasive needling techniques in the management of Myofascial Pain and Dysfunction Syndrome*. M. Tech: Chiropractic dissertation, Technikon Natal, Durban, South Africa.

Cagnie, B., Vinck, E., Rimbaut, S. 2003. Phonophoresis versus topical application of ketoprofen: comparison between tissue and plasma levels. *Physical Therapy.* 83:707–12.

Cunha, A., Parizotto, N.A., and Vidal, B.C. 2001. The effect of therapeutic ultrasound on repair of the Achilles Tendon (Tendo calcaneus) of the rat. Ultrasound Medical Biology. 27:1691-1696.

Darrow, H., Schulthies, S.,Draper, D., Ricard, M and Meason, G.J. 1999. Serum dexamethasone levels after decadron phonophoresis. *Journal of Athletic Training*. 34:338-341.

Denegar, C.R., Saliba, E., Saliba, F.S. 2006.Therapeutic modalities for muscular skeletal injuries. 2nd ed. Leeds: Human Kinetics.

Esenyel, M., Caglar, N. and Aldemir, T. 2000.Treatment of myofascial pain. *American Journal of Physical Rehabilitation,* Jan-Feb; 79(11): 48-52.

Finley, J.E. 2010.*Myofascial Pain*[online]. Available at: http://emedicine.medscape.com/article/313007-treatment [Accessed 2 February 2011]

Fischer, A.A. 1987. Algometry in Daily Practise of Pain Management.*Journal of Back and Musculoskeletal Rehabilitation*, 8:157 – 163.

Fricton, J.R. 1985.Myofascial Pain Syndrome of the head and neck: A review of clinical characteristics of 164 patients. *Oral Surgeons Oral Pathology*. 69:615-623

Gerwin, R.D. 2001. Classification, epidemiology and natural history of Myofascial pain syndrome. *Current Pain and Headache Reports*.5(5): 412 – 420.

Grosshandler, S.L., Stratas, N.E., Toomey, T.C., Gray, W.F., 1985.Chronic neck and shoulder pain: focusing on myofascialorigins. *Postgraduate Medicine*. 77: 149–158.

Han, S.C., Harrison, P., 1997.Myofascial pain syndrome and trigger point management. *Regional Anesthesia*. 22: 89–101.

Hepburn, S. 2000. *The Relative Effectiveness of Nonsteroidal Anti-Inflammatory Medication as compared to a homoeopathic complex in the treatment of Cervical Facet Syndrome.*Masters Dissertation – Chiropractic.Durban Institute of Technology, Durban, South Africa.

Hong, C.Z., 1994. Lidocaine injection versus dry needling to myofascial trigger point.The importance of the local twitch response.*American Journal of Physical Medicine and Rehabilitation.*73: 256–263.

Hong, C.Z., Simons, D.G., 1998. Pathophysiologic and electrophysiologic-mechanism of myofascial trigger points. *Archives of Physical Medicine and Rehabilitation*. 79:863–872.

Jacobs LR.1998. Prescription to over-the-counter drug reclassification.*American Family Physician.* 57:2209–2214.

Jensen, M.P., Karoly, P and Braver, S. 1986. The Management of Clinical Pain Intensity: a comparison of six methods. *Pain.*27:117 – 126.

Kassan, D.G., Lynch, A.M., Stiller, M.J. 1996. Physical enhancement of dermatologic drug delivery: iontophoresis and phonophoresis. *Journal of the American Academy of Dermatology*. 34 (4):657 – 66.

Klaiman, M.D., Shrader, J.A., Danoff, J.V., Hicks, J.E., Pesce, W.J and Ferland, J. 1998. Phonophoresis versus Ultrasound in the treatment of common musculoskeletal conditions.*Official Journal of the American College of Sports Medicine*.May : 1349 – 1355

Kozanoglu, E., Basaran, S., Guzel, R and Uysal, F.G. 2003.Short term efficacy of Ibuprofen phonophoresis versus continuous ultrasound therapy in knee osteoarthritis. *Swiss Medical Weekly.*133: 333- 338.

Kuntz, A.R., Griffiths, C.M., Rankin, J.M., Armstrong, C.W and McLoughlin, T.J. 2006.Cortisol Concentrations in Human Skeletal Muscle Tissue After Phonophoresis With 10% Hydrocortisone Gel. *Journal of Athletic Training* .41(3): 321–324.

Lussignoli.S., Bertani, S., Metelmann, H., Bellavite, P., Conforti, A. 1999. Effect of Traumeel S®, a homeopathic formulation, on blood-induced inflammation in rats. *Complementary Therapies in Medicine.*7:225–230.

Macfarlane, G.J. 1999. Fibromyalgia and chronic widespread pain. *Epidemiology of Pain*. 113 – 123.

McCaffrey, A.M., Pugh, G.F., O'Connor, B.B. 2007. Understanding patient preference for integrative medical care: results from patient focus groups. *International journal of General Medicine*.22:1500–1505.

McDiarmid, T. and Burns, P. N. 1987. Clincial Application of TherapeuticUltrasound. *Physiotherapy;* 73(4) 155-160.

Melzack,R and Wall,P.D. 1965. Pain mechanisms: A new Theory. *Science* 150:971-979

Miller, K.J.2000. *The relative effectiveness of Lazer versus Dry Needling in the treatment of Myofascitis.* M. Tech: Chiropractic dissertation, Technikon Natal, Durban, South Africa.

Mitragotri, S. 2000. Synergistic effect of enhancers for transdermal drug delivery.*Pharmaceutical Research.*17: 1354-1359.

Mitragoti, S. and Kost, J. 2004. Low frequency sonophoresis : a review. *Advanced Drug Delivery Reviews.*56 : 589 – 601.

Muller, M., Mascher, H., Kikuta, C., Chafer, S., Brunner, M. and Dorner, G. 1997. Diclofenac concentrations in defined tissue layers after topical administration.*Clinical Pharmacological Therapy.*62: 293-299.

Oberbaum, M. 1998. Experimental Treatment of Chemotherapy-Induced Stomatitis using a homoeopathic complex preparation: A Preliminary Study. *Biomedical Therapy*. 16(4): 261-265.

Oberbaum, M., Yaniv, I., Ben-Gal, Y., Stein, J., Ben-Zvi, N., Freedman, L.S., Branski D.2001.A randomized, controlled clinical trial of the homeopathic medication TRAUMEEL S® in the treatment of chemotherapy-induced stomatitis in children undergoing stem cell transplantation. *Cancer.*92**:**684-90.

Penas, C.F., Campo, M.S., Carnero, J.F. and Page, J.C.M. 2003. Manual therapies in myofascial trigger point treatment: A systematic review. *Journal of Bodywork and Movement Therapies.*9:27-34.

Pillay, M. G. 2003. *The treatment of myofascial pain syndrome using therapeuticultrasound, on upper trapezius myofascial trigger points. A double- blindedplacebo controlled study comparing the continous and pulsed wave modes ofultrasound.* M. tech. Dissertation, Durban Institute of Technology.

Porozov.S., Cahalon, L., Weiser, M., Branski, D., Lider, O., Oberbaum, M. 2004.Inhibition of IL-1-beta and TNF-alpha secretion from resting and activated human immunocytes by the homeopathic medication Traumeel S. *Clinical and Developmental Immunology*. 2:143–149.

Richards, L.D. 2006. The effectiveness of non-invasive treatments for active myofascial trigger point pain : A systematic review of the literature. *International Journal of Osteopathic Medicine.* 9: 120 – 136.

Robertson, V., Ward, A., Low, J. and Reed, A. 2006.*Electrotherapy Explained: Principles and Practice*. 4th ed. London: Butterworth Heinemann.

Rollman, G.B., Lautenbacher, S. 2001. Sex differences in musculoskeletal pain. *Clinical Journal of Pain.* (17): 20 – 24.

Schneider, M.J. 1996. Chiropractic Management of Myofascial and Muscular Disorders. Advances in Chiropractic: volume three. St. Louis, Missosuri: Mosby-Year Book Inc, 459. ISBN 0-8151-5308-2.

Schneider, C., Klein, P., Stolot, P. and Oberbaum, M. 2005. A homoeopathic ointment preparation compared with 1% Diclofenac gel for acute symptomatic treatment of tendinopathy. *Explore!* 1(6):261- 265.

Schneider, C. 2011. Traumeel – an emerging option to nonsteroidal anti-inflammatory drugs in the management of acute musculoskeletal injuries.*International Journal of General Medicine.*

Sciotti, V.M., Mittak, V.L., DiMarco, L., Ford, L.M., Plezbert, J., Santipadri, E., Wigglesworth, J., Ball, K. 2001. Clinical Precision of Myofascial Trigger Point Location in the trapezius. *Pain.*93:259-266.

Shin, S.M. and Choi, J.K. 1997.Effect of indomethacin phonophoresis on the relief of temperomandibular joint pain.*Cranio*. 15:345-348.

Simons, D.G and Travell, J.G. 1993. Myofascial Pain and Dysfunction: the trigger point manual. Philadelphia : Lippincott Williams and Wilkins.

Simons, D.G. 2004. New Aspects of Myofascial Trigger points: aetiological and clinical.In Pongratz, D.E, Mense, S., Spaeth, M. Soft Tissue Pain Syndromes : Clinical Diagnosis and Pathogenesis. New York : The Haworths Medical Press. Pp 15 – 23.

Skootsky, S.A., Jaeger, B. and Oye, R.K, 1989. Prevalence of myofascial pain in general internal medicine practice. *The Western journal of Medicine.* 151:157-160.

TerHaar, G., Dyson, M. and Oakley, E.M. 1985.The use of ultrasound by physiotherapists in Britain.*Ultrasound Medical Biology*. 13(1987): 659- 663.

Travell, J.G ,Simons, D.G., Simons, L.S.1999. Myofascial Pain and Dysfunction: the trigger point manual. Philadelphia : Lippincott Williams and Wilkins.

Tyle, P., Agrawala, P. 1989. Drug Delivery by Phonophoresis.*Pharmaceutical Research.* 6 (5): 355 – 361.

Unlu, Z., Orguc, S., Eskiizzmir, G., Aslan, A., Tasci, S. 2008**.** The role of phonophoresis in dyshpagia due to cervical osteophytes.*International journal of General Medicine*.1: 11–13.

Van der Windt, D.A.W.M., van der Heijden, G.J.M.G, van den Berg, S.G.M., Ter Riet, G., de Winter, A.F., Bouter, L.M. 1998. Ultrasound therapy for musculoskeletal disorders: a systematic review*. International Association for the Study of Pain*. 81: 257-271.

Vlak, T. 1999. Comparative study of the efficacy of ultrasound and sonophoresis in the treatment of painful shoulder syndrome.*Rheumatism*. 46: 5-11.

Warden, S.J. 2005. Cyclo-oxygenase-2 inhibitors: beneficial or detrimental for athletes with acute musculoskeletal injuries? *Sports Medicine*.35:271–283.

Watson, T. 2002*. Electrotherapy: Evidence-Based Practice*. 12th ed. London: Churchill Livingstone.

Wreje, U and Brorsson, B. 1995.A multicentre randomized controlled trial of injections of sterile water and saline for chronic myofascial pain syndromes.*Pain.* 61 (3): 441- 444.

Yap, E.C. 2007.Myofascial Pain- An Overview.*Annals Academy of Medicine.*36(1):43-48.

Zell, J., Connert, W.D., Mau, J. and Feuerstake, G. 1989. Treatment of Acute sprains of the ankle: A controlled double-blinded trial to test the effectiveness of a homoeopathic ointment. *Biological Therapy*. 7(1): 1 – 6.

Zenner, S., Metelmann H. 1992. Therapy experience with a homoeopathic experience: Results of a drug surveillance conducted on 3422 patients. *Biological Therapy.* 21 (5): 341-349.

Zieglgansberger, W. 2004.Mechanism of the transition from Acute to Chronic Pain.In Pongratz, D.E, Mense, S., Spaeth, M. Soft Tissue Pain Syndromes : Clinical Diagnosis and Pathogenesis. New York : The Haworths Medical Press. Pp 13-15.

www.isixsigma.com. 2003 [online]. Available from: *http://isixsigma.com*. [Accessed 24 May 2011].

APPENDIX A:

Are you between the ages of 18 – 45 and suffering from:

Neck or Shoulder pain?

Do you have that **painful knot in your shoulder muscles**, after studying or working at a computer all day?

If you've answered **YES**, then you may qualify to become a participant in research that is currently being carried out at the **Durban University of Technology Chiropractic Day Clinic**

FREE TREATMENT !!!

IS AVAILABLE TO THOSE WHO QUALIFY TO TAKE PART IN THIS STUDY

CONTACT **VIROSHA DEONARAIN** ON 073 949 2273 or 031 373 2205/2512 FOR MORE INFORMATION

APPENDIX B:

Letter of information and informed consent

Title of the Research Study: The efficacy of phonophoresis with Traumeel ® S in the treatment of upper trapezius myofascitis.

Principle Investigator/s: ViroshaDeonarain

Co-Investigator/s: Dr. A. Docrat

Brief Introduction and Purpose of the Study:I am investigating the effect of the Phonophoresis with Traumeel® S gel for the treatment of neck pain. Phonophoresis involves using ultrasound over an active substance (Traumeel® S), to drive the substance into the skin and into the area to be treated. Traumeel® S gel is a homeopathic anti-inflammatory gel which contains no steroids and thus has no side effects. The specific area that will be treated is a trigger point over the trapezius muscle. Trigger points are tender areas in the muscles that, when active they refer pain that mimics other painful conditions. Trigger points are very common and are often overlooked as a source of pain. Thus treatment will help in developing more clinically sound treatment protocols within the scope of Chiropractic care.

Outline of the Procedures: At the initial consultation you will undergo a History, Physical, and a Regional examination, after which you will be accepted, providing you fit the necessary criteria for the research.

Once accepted into the study you will receive two treatments within the first week and two within the second week . You will remain in the study for as long as you commit to the appointment schedule.

Risks or Discomforts to the Subject:

There are no risks or discomforts associated with the treatment.

Benefits: All treatment will be free of charge and will be conducted at the Durban University of Technology Chiropractic Day Clinic. Please be assured that all information will be regarded as strictly confidential.

Reason/s why the Subject May Be Withdrawn from the Study:

The participant may not take any form of medication that will influence the results of the study or undergo any other treatment during the duration of the study (i.e. Analgesics, muscle relaxants, NSAIDS, steroids or manual therapy).

The participant must not change his lifestyle and enter into any new activity. A consent form will be required to be filled out prior to the treatment.

Remuneration: none

Costs of the Study: none

Confidentiality: All the information will be coded so identification will not be disclosed.

Research-related Injury:

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

Researcher :Virosha Deonarain Tel num: 073 949 2273

Supervisor : Dr. D Docrat Tel num: 031 -373 2589

Statement of Agreement to Participate in the Research Study:

(I, (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 by ……...to 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) signature: ……...

Witness signature:……..Date:…….….

APPENDIX C:

Numerical Pain Rating Scale- 101

Date:_____ **File number:**_____ **Visit number:**_____

Patient name:_____

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

Please write only one number.

0_____100

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

Please write only one number.

0_____100

APPENDIX D:

ALGOMETER DATA

Date:_____ File number:_____

Patient name:_____

DATE	VISIT NO.	ALGOMETER (R)	ALGOMETER (L)
	1		
	3		
	4		

APPENDIX E

DURBAN UNIVERSITY OF TECHNOLOGY

DURBAN UNIVERSITY OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

DURBAN 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
- Psychiatric

APPENDIX F

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 G

DURBAN UNIVERSITY OF TECHNOLOGY
REGIONAL EXAMINATION - CERVICAL SPINE

Patient: _____ File No: _____

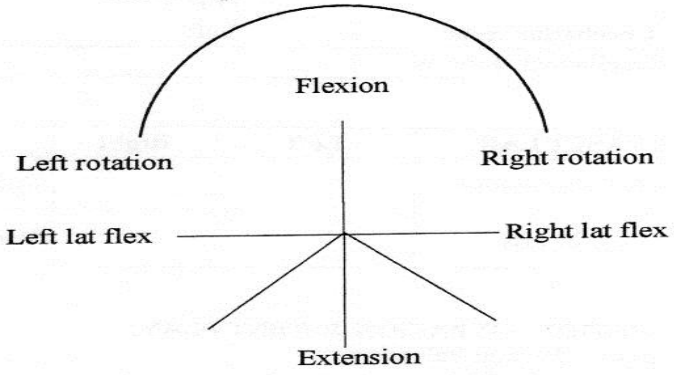
Date: _____ Student: _____

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:

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

Cerebellar tests:	Left	Right
Disdiadochokinesis		

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

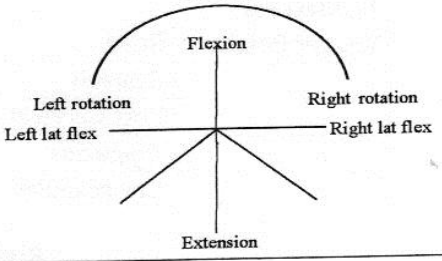
MOTION PALPATION & JOINT PLAY:
Left: Motion Palpation:
Joint Play:
Right: Motion Palpation:
Joint Play:

BASIC EXAM: SHOULDER:
Case History:

ROM: Active:
Passive:
RIM:
Orthopaedic:
Neuro:
Vascular:

BASIC EXAM: THORACIC SPINE:
Case History:

ROM:



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

UNIVERSITY of TECHNOLOGY

Faculty of Health Sciences

ETHICS CLEARANCE CERTIFICATE

Student Name	Virosha Deonarain	**Student No**	20417867
Ethics Reference Number	099/10	**Date of FRC Approval**	31/08/2010
Qualification	**M.Tech. Chiropractic**		
Research Title:	**The efficacy of phonophoresis with Traumeel ® S in the treatment of upper trapezius myofascitis**		

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

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

	YES	NO	N/A
❖ Provision has been made to obtain informed consent of the participants	√		
❖ Potential psychological and physical risks have been considered and minimised	√		
❖ Provision has been made to avoid undue intrusion with regard to participants and community			√
❖ Rights of participants will be safe-guarded in relation to: - Measures for the protection of anonymity and the maintenance of Confidentiality.	√		
- Access to research information and findings.	√		
- Termination of involvement without compromise	√		
- Misleading promises regarding benefits of the research	√		

[redacted]

07/10/2010
DATE

07/10/2010
DATE

7/10/10
DATE

19/10/10
D

25