

**A COMPARATIVE STUDY TO DETERMINE THE EFFICACY OF TWO  
DIFFERENT MASSAGE THERAPY OILS IN THE TREATMENT OF CHRONIC  
ACTIVE TRAPEZIUS MYOFASCIAL TRIGGER POINTS**

A dissertation completed in partial compliance with the requirements for a  
Master's Degree in Technology: Chiropractic, in the Department of Chiropractic  
at the Durban University of Technology

**BY**

**CLAUDIA PEDLAR**

I solemnly declare that this is my own work in compliance and execution.

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## **DEDICATION**

**This is dedicated to my family: Broughton Crookes, Tammy Mkhize, Paulene Pedlar, Brian Pedlar and my sister Carol Pedlar, you have supported me even though times were tough. Thank you for your patience. I love you.**

**We can do all things through Christ Jesus who strengthens us (Philippians 4:13).**

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Very special thanks to my dad, Mr Broughton Crookes, for your patience, love and support in every way possible. You have taught me a lot about life and have given me an unshakable foundation of morals and principles to build onto the rest of my life. I understand now how very important they are.

Mum we have both had our fair share of hardships. I think we now both understand each others pain and my main aim in life is to make you proud of me so that your suffering would not have been in vain.

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# ABSTRACT

**Background:** Myofascial pain is the most common cause of persistent regional pain such as back pain, shoulder pain, tension-type headaches and facial pain. A variety of therapeutic modalities are proposed in the treatment of myofascial pain including massage. A variety of massage oils are available on the market, each claiming therapeutic efficacy. Most of these claims, however, have not been verified through clinical trials.

**Methods:** A double-blinded placebo controlled study in which 80 subjects were randomly divided into 4 groups of twenty. Subjects in Group 1 received unscented mineral oil; those in Group 2 received scented mineral oil. Subjects in Group 3 received Arnica Massage oil while those in Group 4 received Blue Steel Arnica Massage oil.

**Results and Conclusions:** The use of Arnica Massage oil or Blue Steel Arnica Massage oil resulted in almost 50% pain reduction in the subjects after five days of self-administered treatment. Both these products can be recommended for the treatment of myofascial pain syndromes but one cannot be placed in preference to the other, as the results were similar with regards to their effectiveness.

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# CHAPTER ONE

## INTRODUCTION

### 1. THE PROBLEM AND ITS SETTING

Regional musculoskeletal pain conditions have been documented in the European literature since the 18th century (Reynolds, 1983). Although the musculoskeletal system comprises 40% of the human body, Gatterman (1990) reports that the least amount of research is performed in this field. This is supported by Bruce (1995), who believes that despite the remarkable advances in modern health care, a void still exists in the understanding, evaluation and management of day-to-day musculoskeletal aches and pains.

Myofascial Pain Dysfunction Syndrome (MPS) (Travell *et al.*, 1999) has gone by a variety of names throughout the years. The condition has been known as muscular rheumatism, myalgia, interstitial myofibrositis, fibromyositis, myofasciitis and many others and yet often goes unrecognized, misdiagnosed, mistreated, leading to unnecessary pain, suffering and disability (Auleciems, 1995). Travell *et al.*, 1999, state that MPS is characterised by the sensory, motor and autonomic symptoms caused by myofascial trigger points.

“Myofascial trigger points (TrPs) are hyperirritable spots in skeletal muscles that are associated with hypersensitive palpable nodules in taut bands” (Travell *et al.*, 1999). According to Friction (1994), myofascial pain is the most common cause of persistent regional pain such as back pain, shoulder pain, tension-type headaches and facial pain.

Confusion regarding this syndrome seems to stem from lack of obvious organic findings, the lack of a unified theory to explain it, and inconsistencies in the literature defining the syndrome (Fricton, 1990).

Auleciems (1995) furthermore stated that the incidence of MPS is reported to be as high as 85% at certain American pain clinics. Gatterman (1990) and Travell and Simons (1999) both state that active trigger points are most likely to occur in the postural muscles of the neck with the trapezius muscle being the most likely muscle to be involved.

The proposed principle of treatment of MPS is to inactivate the active TrPs through the use of various therapeutic modalities (Hong *et al.*, 1993). A variety of hands-on skills, such as stretching, massage, manipulation, mobilization and strengthening: and a wide variety of modalities namely, heat, ice, ultrasound, electrical stimulation, mechanical pressure and light energy, are available to physicians and therapists for the treatment of trigger points (Rosen, 1994; Fricton, 1994; Auleciems, 1995 and Bruce, 1995).

Massage is a healing art involving the manipulation of the soft tissues of the body. It can be used to enhance relaxation, to relieve aches and pains, to encourage lymph flow (Battaglia, 2005). Massage is possibly the only situation in which one can be touched in a caring way by someone who is not close to us and not feel uncomfortable. Touch is a basic behavioral need, in much the same way as breathing is a basic physical need. Massage has both physical and psychological benefits (Batalgia, 2005).

Essential oils are complex mixtures of individual chemical constituents, the precise nature and proportions of which determine their therapeutic and fragrant properties (Battaglia, 2005). They generally contain alcohols, esters, ketones, aldehydes, and terpenes (Tisserand, 1997). These oils are found in aromatic plants and are highly volatile, meaning that they readily evaporate, transforming

from liquid to vapor. Essential oils can be found in flowers, leaves, roots, stems, fruits and in other parts of green plants. The more oil glands or ducts present in the plant the higher the yield of essential oil, thus the less expensive the cost of the oil (Battaglia, 2005).

Aromatic oils are used in three classes of consumer goods: foods, toiletries and medicines. In foods they are used as natural flavorings, such as oils of lemon, orange, and lime in marmalades. In cosmetics they are incorporated both in perfumes and less often as natural active ingredients; they are also used in toothpaste flavorings. In medicine they are used as therapeutic ingredients such as clove oil for toothache, peppermint oil for indigestion, eucalyptus for inhalation (Tisserand, 1997).

Arnica oil has gained popularity as the massage oil of choice for the treatment of muscle aches and pains (Stamatis, 2006 and Mahomed, 2006). The number of massage products claiming to have remarkable pain relieving effects on muscle aches and pains are on the rise as indicated by recent television advertisements e.g. Remedy Blue. The validity of the majority of these claims is not verified by clinical trials.

Amongst these massage products is Blue Steel Arnica Massage Oil (which is made up of arnica and other essential oils), which is well advertised ([www.bluesteelsports.com:au/shop](http://www.bluesteelsports.com:au/shop)) and claims to relieve muscle pain and stiffness. Many therapists/ patients could be utilizing Blue Steel Arnica Massage oil (or an oil with a similar essential oil blend) thinking that it has clinical benefits for the patients when this may not be the fact.

Due to the daily demands of modern society, many people are looking for efficient, effective and cheap means of treatment. As a result many people will try home treatments before seeking medical advice. Blue Steel Arnica Massage oil

and pure Arnica oil are products that can be used (and are used) as home therapy for muscle aches and pains.

It is therefore important to establish whether a blend of essential oils (as is the case with Blue Steel Arnica Massage Oil) thought to have synergistic anti-inflammatory effects is as effective or more effective than just pure Arnica oil in the treatment of aches and pains of muscular origin.

## **1.2 AIMS AND OBJECTIVES OF THE STUDY**

### **1.2.1 Aim**

The aim of the study is to determine the efficacy of two different massage therapy oils in the treatment of chronic active trapezius myofascial trigger points.

### **1.2.2 Objectives**

1. To evaluate the efficacy of Arnica Massage oil compared to placebo (scented mineral oil and non-scented mineral oil) using objective and subjective measures in order to determine its effectiveness in the treatment of chronic active trapezius myofascial trigger points.
2. To evaluate the efficacy of Blue Steel Arnica Massage Oil compared to placebo (scented mineral oil and non-scented mineral oil) using objective and subjective measures in order to determine its effectiveness in the treatment of chronic active trapezius myofascial trigger points.
3. To evaluate the efficacy of Blue Steel Arnica Massage Oil compared to Arnica Massage oil using objective and subjective measures in order to determine its effectiveness in the treatment of chronic active trapezius myofascial trigger points.

### 1.3 HYPOTHESES

1. The Null hypothesis ( $H_0$ ) states that there will be no significant difference between subjective and objective findings when comparing Arnica Massage oil to the two placebo massage oils. The Alternate hypothesis ( $H_a$ ) states that there will be a significant difference between subjective and objective findings when comparing Arnica Massage oil to the two placebo massage oils.
2. The Null hypothesis ( $H_0$ ) states that there will be no significant difference between subjective and objective findings when comparing Blue Steel Arnica Massage Oil to the two placebo massage oils. The Alternate hypothesis ( $H_a$ ) states that there will be a significant difference between subjective and objective findings when comparing Blue Steel Arnica Massage Oil to the two placebo massage oils.
3. The Null hypothesis ( $H_0$ ) states that there will be no significant difference between subjective and objective findings when comparing Blue Steel Arnica Massage Oil to Arnica Massage oil. The Alternate hypothesis ( $H_a$ ) states that there will be a significant difference between subjective and objective findings when comparing Blue Steel Arnica Massage Oil to Arnica Massage oil.



# CHAPTER TWO

## REVIEW OF THE RELATED LITERATURE

### 2.1 INTRODUCTION TO MYOFASCIAL PAIN DYSFUNCTION SYNDROME (MPS)

Myofascial Pain Dysfunction Syndrome (MFPDS/MPS) refers to a regional muscle pain syndrome of any soft tissue origin that is associated with muscle tenderness and trigger points (Travell *et al.*, 1999).

A myofascial trigger point is a hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. Active trigger points (TrPs) produce a clinical complaint (usually pain) that is spontaneous. The characteristics of active trigger points include: A palpable band, spot tenderness, jump sign, pain recognition, twitch response, elicited referred pain and tenderness, restricted range of motion and muscle weakness (Hong *et al.*, 1996; Travell *et al.*, 1999).

#### 2.1.1 Incidence of MPS

Musculoskeletal disorders were recognized by Bruce (1995) as the key occupational injury or illness challenge of the 1990's and as a major cause of concern to employers due to disability and the mounting costs of workers compensation. Even though the incidence of trigger points is higher in women it affects both sexes (Han and Harrison, 1997).

According to Friction (1994), myofascial pain is the most common cause of persistent regional pain such as back pain, shoulder pain, tension-type headaches and facial pain. Hong *et al.* (1993) further state that myofascial pain syndrome is one of the most common painful muscular dysfunctions found in patients.

Han and Harrison (1997) examined extensive periodical literature, textbooks and critically analyzed selected manuscripts in their review of the epidemiology, pathogenesis and a variety of treatment methods in the treatment of myofascial pain syndrome and reported that the incidence of trigger points ranged from 30-80% of patients presenting with pain. Chaiamnuay *et al.* (1998) in an epidemiological study of rheumatic disease in Thailand also reported similar incidences of myofascial pain syndrome (30-80%).

### **2.1.2 Etiology of MPS**

Travell *et al.*, (1999) reported the following as important factors that lead to the formation of trigger points: sustained postural overload, prolonged immobilization and poor ergonomics. Gatterman (1990) states that many factors interact to create trigger points. Usually, one stress activates the trigger point, and then other factors perpetuate it.

The aetiology of trigger points is not clear, but the two most widely accepted theories (energy crisis theory and motor endplate hypothesis), when combined, provide a plausible explanation. There is a third (radiculopathic model), which suggests the primary site of pathology to be the spinal nerve, with secondary muscle changes occurring (Gunn, 1997). This theory is yet to be experimentally verified. The more widely accepted theory is centred on the muscle cell and motor endplate being the sites of primary pathology (Travell *et al.*, 1999).

## **2.2 PATHOPHYSIOLOGY OF MPS**

### **2.2.1 Energy crisis theory**

Travell *et al.*, 1999; Hong, 1996 and Bengtsson *et al.*, 1986 state that the energy crisis theory is the earliest explanation of trigger point formation. It is postulated that increased demands on a muscle (increased neural input), macrotrauma, or recurrent microtrauma lead to an increased release of calcium from the sarcolemma and prolonged shortening of the sarcomeres. Examples of macro and micro traumatic events that cause muscle injury are according to Travell *et al.* (1999), Han and Harrison (1997), Friction (1994), Gatterman (1990), and Sandman (1981) whiplash, or sustained muscular contraction as in the case of poor postural habits. Prolonged shortening compromises the circulation, with the subsequently reduced oxygen supply leaving the cells unable to produce enough ATP to initiate the active process of relaxation. Depleted ATP reserves and decreased functioning ability of the calcium pump set up an accumulation of noxious metabolites. These include lactic acid, serotonin, kinins, histamines and prostaglandins that have the effect of increasing local muscle acidity with the resulting activation and firing of muscle nociceptors resulting in pain.

### **2.2.2 Motor end plate hypothesis**

It is possible that the energy crisis theory could well co-exist with the motor end plate hypothesis. The motor nerve synapses with a muscle cell at the motor endplate. Needle electromyography studies (EMG) done by Hubbard and Berkhoff (1993) have found that each trigger point contains minute loci that produce characteristic electrical activity. It was found that these loci are predominantly located at the motor endplate zone (Simons *et al.*, 2002; Simons, 2001). The endplate “noise” seen on EMG is thought to represent an increased rate of release of acetylcholine (ACh) from the nerve terminal. A small amount of

activity at the motor endplate is insufficient to cause muscle contraction, but can result in action potentials being propagated a small distance along the muscle cell membrane. This small amount of propagation may be enough to cause activation of a few contractile elements and be responsible for some degree of muscle shortening (Simons, 1996).

### **2.2.3 Radiculopathic model for muscular pain**

Most opposing theorists postulate a neurological cause as the primary stimulus and trigger points as a secondary phenomenon (Gunn, 1997 and Quintner and Cohen, 1994). Gunn (1997) suggested a radiculopathic model for muscular pain and states that 'myofascial pain describes neuropathic pain that presents predominantly in the musculoskeletal system'. This model is based on all denervated structures exhibiting super sensitivity. From clinical observations, Gunn (1997) states that neuropathic nerves are most commonly found at the rami of segmental nerves, and therefore represent a radiculopathy. He believes that because of the lack of pathology seen in muscle and the sensory, motor, and autonomic changes seen in myofascial pain syndromes, the site of origin of this pathology could be as a result of neural injury or compression and partial denervation.

Quintner and Cohen (1994) suggest that the characteristics of the pain from trigger points are not distinguishable from neural pain, and that a primary neurological cause is a much more likely explanation for the local and referred sensations of myofascial pain. Hong and Simons (1998) reported that recent studies on referred pain and the local twitch response (LTR) have supported the concept that the myofascial trigger point mechanism is closely related to spinal cord integration. They further state that when the input from nociceptors in an original receptor field persists (pain from a trigger point), central sensitization in the spinal cord may develop and the receptive field corresponding to the original dorsal horn may be expanded (referred pain). Through this mechanism new

myofascial or satellite myofascial trigger points may develop in the referral zone of the original myofascial trigger point (Hong and Simons, 1998).

### **2.3 Perpetuating Factors**

The following factors are believed to perpetuate myofascial trigger points:

- Stress (Sola *et al.*, 1981; Kathleen *et al.*, 1984; Friction, 1994; McNulty *et al.*, 1994 and Chen *et al.*, 1998).
- Poor posture and lack of exercise (Friction, 1994; Rosen, 1994 and Bruce, 1995).
- Mechanical stress e.g. skeletal asymmetry (short leg or small hemipelvis), disproportion (long second metatarsal and short upper arms), misfitting furniture, poor posture and prolonged immobilization. (Travell *et al.*, 1999)
- Nutritional abnormalities e.g. vitamin and mineral deficiency and excessive consumption of stimulants (including caffeine) (Travell *et al.*, 1999).
- Metabolic and endocrine disorders e.g. hypothyroidism, hyperuricaemia and anemia (Travell *et al.*, 1999).
- Bacterial and parasitic infestations e.g. bacterial infections resulting in abscesses, sinusitis and chronic urinary tract infections; viral infections (particularly herpes simplex) and parasitic infestations (Travell *et al.*, 1999).

The role of nutritional abnormalities in the perpetuation and possible cause of myofascial trigger points needs further research as disputed by studies done by Morgan (1997) and Van Aardenne (2002). Morgan (1997) did a controlled, double blinded study to assess the effectiveness of supplementing the dry needling method of treatment for myofascial pain syndrome with a course of

vitamin C and B complex tablets. Both the experimental and control groups received dry needling and stretches for the involved muscles the exception being that the control group received blank sugar tablets instead of the vitamin supplements given to the experimental group. It was concluded that subjects in the experimental group responded no better than subjects in the control group. A similar study was done by Van Aardenne (2002) where both treatment and placebo groups received dry needling, the exception being that the treatment group received Magnesium phosphate tissue salt instead of vitamin C and B complex supplements. It was concluded that the treatment group had statistically significant improvement with regards to objective measures that was not noted in the control group.

Activation and perpetuation of trigger points in the upper trapezius depend, in part, on such skeletal variations as a lower limb-length inequality, a small hemipelvis, or short upper arms. Activation very commonly results from the stress of sustained elevation of the shoulders, as when using a telephone receiver without elbow support, or working at a high keyboard with inadequate armrests. Acute trauma, as in a “whiplash” from the side, and chronic trauma, as in compression of the muscle by tight bra straps or a misfitting heavy coat, can activate trapezius TrPs (Travell *et al.*, 1999)

## **2.4 TREATMENT**

Rachlin (1994) states that much of the recommended treatment strategies of myofascial pain syndrome remain empirical and many modalities that are often used are essentially unproven.

It is the opinion of Hong *et al.* (1993) that although there are many treatment protocols aimed at treating myofascial pain, few research studies have assessed

the effectiveness of therapeutic modalities in the management of myofascial pain syndrome.

Trigger point therapy is essentially divided into invasive and non-invasive techniques. Non-invasive techniques are those that have been traditionally employed by physical and manual therapists. In recent years, there has been marked increase in the use of invasive therapies, in particular, dry needling to manage trigger points. Because massage is the non-invasive treatment choice of this study it will be discussed later. The non-invasive techniques include the following:

#### **2.4.1 The non-invasive techniques of MPS treatment**

##### **2.4.1.1 Temperature dependent modalities**

###### **Cryotherapy**

For centuries superficial heat and cold (cryotherapy) has been used for the treatment of soft tissue and joint injuries with the specific goal of relieving pain. The primary physiological effect of cryotherapy includes vasoconstriction, reduced blood flow, reduced cellular metabolism and permeability, decreased sensory and motor nerve conduction, decreased muscle spasm and temporary reduction of spasticity before exercise (Oslo and Stravino, 1972; McMaster, 1977). Decreased metabolic rate limits further injury and aids the tissue in surviving the cellular hypoxia that occurs after injury (Knight, 1995).

Cryotherapy is indicated in the treatment of the acute inflammatory phase of tissue healing (bursitis, tenosynovitis, tendinopathy), after exercise to minimize inflammation and for acute post operative pain relief (Cameron, 1999). The modalities used for cryotherapy include cold packs, ice massage, vapor coolant sprays, cold compression units and cold baths. Cold water emersion (cold baths)

results in the greatest temperature decline compared to the other modalities of cold delivery because a greater surface area is in contact with the cooling modality (Bocobo *et al*, 1991). Ice massage is applied parallel to the muscle fibers with the muscle to be treated being in a stretched position (Knight, 1995). This is also an effective method as the pressure applied in ice massage stimulates the mechanoreceptors more than in other forms of cryotherapy (Knight, 1995). Vapor coolant sprays are the most widely used form of cryotherapy in the treatment of myofascial trigger points (Travell *et al*, 1999).

## **Heat**

According to Cameron (1999), heat is used in rehabilitation for its homodynamic, neuromuscular, metabolic and connective tissue effects. The application of heat is indicated for treatment after the acute inflammatory phase of tissue healing has resolved. Superficial heating agents (hot packs, hot baths) have the greatest effects on cutaneous blood vessels. Firstly, the increased superficial tissue temperature results in the release of chemical mediators such as histamine and prostaglandins which result in vasodilatation. Secondly, there is stimulation of cutaneous thermoreceptors that synapse on the cutaneous blood vessels resulting in the release of bradykinin which relaxes the smooth muscle walls causing vasodilatation. Thirdly, there is reduction of sympathetic activation via spinal dorsal root ganglia to reduce smooth muscle contraction resulting in vasodilatation (Cameron, 1999). Heat also lowers the stimulus threshold for muscle spindle activity resulting in muscle relaxation (Mense, 1978).

### **2.4.1.2 Spray and stretch**

Travell *et al*. (1999) describe the spray and stretch technique as being the “workhorse” of myofascial therapy. It is their opinion that this technique is “the single most effective non-invasive method” to inactivate acute trigger points. Hans Kraus (1941) discovered that spraying ethyle chloride on the skin relieves



musculoskeletal pain. Kraus was looking for a substitute for alcohol-soaked towels exposed to live steam that were then used in Germany by the wrestlers as a treatment for painful sprains (Kraus 1941).

The vapocoolant sprays used in the spray and stretch technique and currently commercially available are Fluori-Methane and ethyl chloride. Both are sterile as dispensed and can be sprayed on a sterile field without contaminating it (Abeles and Garjian, 1986) Fluori-Methane is non-flammable, chemically stable, non-toxic, non-explosive and does not irritate the skin. Ethyl chloride is a rapidly acting general anesthetic that has a dangerously low margin of safety, is flammable and is explosive when 4-15% of the vapour is mixed with air (Kraus, 1941). It is likely that patients could suffer injuries while using this product. If a patient utilizes this product without medical supervision, the possibility of frostbite also exists.

The essential therapeutic component is the stretch. “Stretch is the action, spray is distraction” (Travell *et al.*, 1999). However, the expression “spray and stretch” is preferred to “stretch and spray” because it is important that the spray be applied before or concurrently with, but not after, the muscle is stretched (Travell *et al.*, 1999). Stretch without some additional technique to release muscle tension and suppress pain is likely to aggravate TrPs. Travell *et al.* (1999) refer to this technique as the “distraction”, as it applies to any technique that causes muscle relaxation and pain relief and therefore setting the stage for an effective stretch to take place. A rapid forceful stretch by itself causes pain, protective contraction, and reflex spasm of the muscles, all of which hurt the patient and obstruct further elongation of the muscle (Travell *et al.*, 1999).

The results of a home program of ischaemic pressure and stretching were compared to a program of stretching alone in subjects with trigger points in the trapezius region (Hanten *et al.*, 2000). Ischaemic pressure combined with stretching resulted in a greater improvement in pain scores and pain pressure

threshold. The pressure was applied prior to the stretching and, therefore, could have been the “distraction” as stated by Travell *et al.* (1999), that resulted in pain relief and muscle relaxation in the group treated with ischaemic pressure and stretching.

In a study done by Backlund (1999) on the relative effectiveness of spray and stretch compared to ice and stretch in the treatment of myofascial trigger points of the trapezius muscle on 30 subjects (15 in each group), it was concluded that neither the ice and stretch group nor the spray and stretch group were statistically significantly better than the other.

#### **2.4.1.3 Ischaemic Compression**

Ischaemic compression is described by Schneider (1996) as a firm, non-painful, direct pressure to the centre of the trigger point which causes a specific localised stretch of the contracted fibres and may mechanically separate actin-myosin cross fibre links. This prolonged deep pressure may induce a so-called “nerve block by inhibiting the reflex pathways that perpetuate the trigger point (Schneider, 1996).

Patients can now perform a home programme of ischaemic pressure using a device called the Thera-Cane. This device was successfully used to perform a home programme of ischaemic pressure in a study done by Hanten (2000). The Thera-Cane is a J-shaped cane with six knobs placed at various points on the cane. It is a non-invasive passive device designed to allow minimal exertion by the user to create sustained pressure in hard-to-reach areas.

Quinton Webb (2003) did a prospective, randomised clinical trial involving 40 patients with active myofascial trigger points of the levator scapulae muscle. One group performed a home programme of self applied ischaemic compression using the Thera-Cane device, while the other group also applied self ischaemic

pressure with the Thera-Cane device but under clinical observation. It was concluded that a home programme of ischaemic compression using the Thera-Cane device is an effective treatment for patients suffering with active myofascial trigger points.

#### **2.4.1.4 Transcutaneous electrical nerve stimulation (TENS)**

Melzack and Wall (1965), postulated that with low intensity stimulation of TENS, the low-threshold large diameter fibres could be stimulated selectively, which can suppress the pain impulses from small nociceptive fibres through the gate control mechanism resulting in pain relief.

A study done by Hsueh *et al.* (1997) comparing electrical nerve stimulation (ENS) to electrical muscle stimulation (EMS) in the treatment of myofascial trigger points revealed that ENS is more effective for immediate relief of myofascial trigger point pain than EMS, however, EMS has a better effect on immediate release of muscle tightness than ENS. This was a controlled study having one placebo group (Group A, n=18), Group B (n=20) treated with ENS and Group C (n=22) treated with EMS.

According to Travell *et al.* (1999), TENS is not a first line treatment modality for myofascial TrPs, but rather an accessory technique as non specific pain relief afforded by this modality can in addition to improving the quality of life, help the patient achieve increased mobility and a degree of muscle stretching that otherwise might not occur. This statement was confirmed by a randomised controlled trial (done on 119 subjects with palpably active myofascial trigger points) done by Hou *et al.* (2002) where the immediate effects of various physical therapeutic modalities on cervical myofascial pain and trigger point sensitivity were examined. It was established that pain relief was greater when TENS was used in combination to the other treatment modalities which included hot pack,

active range of motion, ischemic compression, stretch and spray, myofascial release and interferential.

#### **2.4.1.5 Ultrasound**

According to Esenyel *et al.* (2000) ultrasound treatment involves the use of high-frequency acoustic energy that is generated using the reverse piezoelectric effect. Ultrasound transmits vibrational energy at the molecular level, approximately 50% of which reaches a depth of 5cm. These vibrations not only generate heat within the tissue, but also have additional, less clearly understood, chemical effects due to intense molecular excitation that may play a role in TrP applications.

Therapeutic ultrasound was used in a three-armed trial with subjects randomized to receive ultrasound with home exercise and massage (Group 1), sham ultrasound with home exercise and massage (Group 2) and the last group being a non-intervention control group (Group 3). Both intervention groups showed significant improvements in the number and sensitivity of trigger points, but the ultrasound was found to have no additional advantage (Gam *et al.*, 1998)

Van der Windt *et al.* (1999) evaluated the effectiveness of ultrasound therapy in the treatment of musculoskeletal disorders. Thirty-eight studies were included in the review, which evaluated the effects of ultrasound in the treatment of lateral epicondylitis, shoulder pain, degenerative rheumatic disorders, ankle distortions, temporomandibular pain and myofascial pain and a variety of other conditions. Van der Windt *et al.* (1999) reported in conclusion that at the time of their study there seemed to be little evidence to support the use of ultrasound therapy in the treatment of musculoskeletal disorders.

In contrast to Van der Windt *et al.* (1999) and Gam *et al.* (1998) a double-blinded placebo controlled study (unpublished) was done by Pillay (2003) on sixty subjects between the ages of 18-35 years comparing the effects of pulsed and continuous waveforms of ultrasound to sham ultrasound. Subjects were randomly placed into three groups A, B or C (Group A received ultrasound with a continuous wave form, Group B received ultrasound with a pulsed wave form and Group C was the placebo group that received the sham ultrasound). All subjects had to have been diagnosed with active trapezius myofascial trigger points (the same criteria as this study). He concluded that both waveforms of ultrasound are more effective than placebo ultrasound in the treatment of myofascial pain syndrome. No statistically significant difference was observed when considering the relative effectiveness of the two waveforms. Pillay (2003), therefore, recommended the use of ultrasound in the treatment of myofascial trigger points. This is in contrast with the views of Van der Windt *et al.* (1999) and Gam *et al.* (1998); therefore, more studies are required in this field of investigation.

## **2.4.2 Invasive techniques of MPS treatment**

### **2.4.2.1 Dry needling of trigger points**

The therapeutic factor in dry needling is the mechanical disruption by the needle of nerve endings or contractile elements of the muscle. Disruption of the trigger point contraction terminates the basis for a local energy crisis and its sensitization of nearby nerves (Hong, 1994).

In a study done by Hong (1994), comparing dry needling to injection of lidocaine into trigger points both groups experienced the same degree of improvement immediately and two weeks later. More significantly Hong (1994) pointed out that achieving a local twitch response with the needle was the most important factor in achieving an effective response (more important than what treatment was utilized i.e. dry needling vs. injection of lidocaine). The long-term therapeutic

effect of these two techniques appears to be attributed to the needle rather than to any substance injected into the myofascial trigger point (Lewit, 1979 and Hong, 1994).

A randomized clinical trial with the objective of comparing the relative effectiveness of a single dry needle insertion to that of multiple fanning dry needle insertion in the treatment of active myofascial trigger points was done by Rowley (2001), and it was concluded that subjective and objective improvement was noted in both groups. The Mann-Whitney U test used for inter-group comparison of the results showed that there were no statistically significant differences in the effectiveness of the two-treatment protocols in terms of objective and subjective clinical findings.

#### **2.4.2.2 Trigger point injection**

Trigger point injection has the same therapeutic factors as dry needling with the added benefit of the injected substances. Han and Harrison (1997) prefer injection to dry needling because of its analgesic effect. There appears to be little consensus on whether dry needling or trigger point injection is the more popular of the trigger point therapy modalities (Simons, 1976; Broome, 1996). Patient preferences with regards these techniques may be affected by multiple factors such as their like or dislike of needles, sensitivity to injected substances, skill of their practitioner etc.

Historically, therapeutic soft-tissue injections have been used empirically in myofascial pain disorders often resulting in variable or temporary benefit despite risk and potential complications (Wheeler, 2004). Common trigger point injections include local anaesthetics, corticosteroids, normal saline and less commonly, neurolytic agents.

Unfortunately trigger point injections may have associated adverse effects:

- Local anaesthetics: anaphalaxis, myotoxicity and myocardial conduction alteration. (Dreyer, 2000; Criscuolo, 2001)
- Corticosteroid injections: commonly experienced adverse reactions are dizziness, nervousness, facial flushing, insomnia transient increased appetite, injection site hypopigmentation, subcutaneous fat atrophy, peripheral oedema, dyspepsia and malaise (Dreyer, 2000).
- Neurolytic agents: intravascular or CNS placement can result in serious complications which include cardiac dysrhythmia, hypertension, venous thrombosis, soft tissue and neural infarction, and chemical meningitis (Dreyer, 2000)

### **2.4.3. Massage**

When an individual experiences pain or discomfort, the natural reaction is to rub or hold the affected area to reduce the sensation. The English word “massage” is derived from the Arabic word “mass’h”, which means to press gently (Furlan *et al.*, 2002). Massage, as defined by Tappan and Benjamin (1998) is the intentional and systematic manipulation of the soft tissues of the body to enhance health and healing.

The goal of massage therapy according to Rachlin (1994) is to restore the muscle to normal length thus allowing for posture correction and full range of motion. Pain relief (of the effected area/limb) as a result of massage has a number of physiologic explanations. One is the removal of metabolic waste products, which can be responsible for cramping and soreness in muscles. Another reason pain is reduced is due to the stimulation of non- nociceptive nerve endings by pressure and movement. It is also thought that massage can

contribute to the release of endorphins, a neurotransmitter that acts as a “central pain suppressant” (Rachlin, 1994).

The gate-control theory predicts that massaging a particular area stimulates large diameter nerve fibres. These fibres have an inhibitory input onto T-cells (which within the spinal cord are the first cells that project into the central nervous system). T-cell activity is depressed (whereas, conversely, small diameter nociceptive fibres have an excitatory input), and pain relief follows (Melzack and Wall, 1996).

Massage is used both for prevention and treatment of injury. It is often used before physical activity it can improve the flexibility of muscles, preventing adhesions and reducing the risk of sprain or strain (Rachlin, 1994). According to Hong et al. (1997) the main aim of treating MFPS, is to inactivate the active TrPs by releasing the taut bands through the use of various techniques and massage is one of them.

Deep or kneading massage strokes, like muscle contraction, have been found to mechanically aid blood and lymph movement thereby increasing blood supply and nutrients in an area and speeding up the removal of metabolic waste products (Rachlin, 1994). The stretching force that massage has on or across muscle fibers can mechanically break down adhesions in the muscle and in its surrounding tissues (Rachlin, 1994).

One systematic review on massage (using the hands or a mechanical device) for nonspecific low back pain (LBP) done by Furlan *et al.* (2002) where massage was compared with an inert treatment (sham laser) indicated that massage was superior. Another trial into the effectiveness of soft tissue massage in the treatment of nonspecific shoulder pain concluded that soft tissue massage around the shoulder is effective in improving range of motion, pain and function in patients with shoulder pain (Van den Dolder and Roberts, 2003).



#### **2.4.4 Massage treatment with the use of essential oils**

According to Battaglia (2005), essential oils occur widely in the plant kingdom in the flowers, leaves, fruit, roots and stems of aromatic plants. They are complex mixtures of individual chemical constituents (which are mainly hydrocarbons and oxygenated compounds derived from hydrocarbons such as alcohols, aldehydes, esters, ethers, ketones, phenols and oxides), the precise nature and proportions of which determine the oil's therapeutic and fragrant properties.

Because essential oils are highly volatile (readily evaporate), they are mixed into a carrier oil which is vegetable based and is composed of fat soluble molecules allowing it to be absorbed easily into the skin (Battaglia, 2005). Mineral oils should not be used as carrier oil as they impede the absorption of essential oils into the skin (Battaglia, 2005).

Many authors recognise massage with therapeutic or essential oils as an effective and non-invasive means of treating MPS (Fricton, 1994; Rosen, 1994; Auleciems, 1995 and Bruce, 1995).

Blue Steel Arnica Massage Oil manufactured by Leechem laboratories is one such modality with the following claims being advertised:

- “Warms and stimulates muscles when used prior to activity.”
- “It effectively relieves muscular aches and strains; soothes bruised and tired muscles as the active components in arnica are recognised for healing muscles and reducing inflammation.”

Blue Steel Arnica Massage oil product is advertised on-line at [www.bluesteelsports.com.au/shop](http://www.bluesteelsports.com.au/shop) (2004), and was actively promoted by being handed out as samples to the general public in different malls in Durban.

Arnica oil has been used for the treatment of muscle aches and pains. *Arnica Montana* is the herb used to extract Arnica oil, which is therapeutic oil thought to have anti-inflammatory effects and as a result is used in the treatment of muscle aches and pains (Battaglia 2005). Discussions with local pharmacists and health shop assistants revealed that the preferred choice of massage oil utilised by the public for relieving muscle aches and pains was Arnica Massage Oil (personal communication Mahomady, 2006 and Stamatīs, 2006).

According to Battaglia (2005), the main application of Arnica oil is for external treatment of all types of injuries in which the skin is not broken, such as bruises, strained muscles and tendons.

A study by Gertsch et al. (2003) investigated the influence of helanolide-type sesquiterpene lactones, found in Arnica on gene transcription profiles in Jurkit T cells and human peripheral blood cells (anti inflammatory and cytotoxic effects) and it was concluded that it is likely that the sesquiterpene lactones exert their anti inflammatory action via different mechanisms mediated by distinct structural elements.

An experiment was conducted on rats whereby rat paw oedema was induced in two inflammation models. In the acute inflammatory model carrageenin (an experimental model used to induce inflammation via mediators such as prostaglandins and kinins) was used to induce rat paw oedema. Nystatin was used to induce chronic inflammation in the second model. Histamine causes increased vascular permeability, which was significantly reduced by Arnica pre-treatment regimens. It was found that Arnica (*Arnica Montana* tincture) and placebo (*Arnica Montana* 6cH) caused significant reduction of inflammation in the chronic model when compared to the control, which was 30% alcoholic solution in distilled water (Macedo et al. 2004).

A multicenter clinical trial investigated the beneficial effects of a gel made from a fresh arnica tincture on osteoarthritis of the knee. The trial lasted six weeks and almost 90% of the patients improved. There was a recorded marked improvement in pain and stiffness as well as increased function in the research subjects (Kneusel *et al.*, 2002).

Alcoholic preparations of *Arnica Montana* are widely used for the topical treatment of various anti-inflammatory diseases (Wagner *et al.*, 2004). Wagner *et al.* (2004) states that Sesquiterpene lactones (SLs) are mainly responsible for the anti-inflammatory activity. They did a study on the penetration kinetics of arnica tinctures prepared from dried Arnica flowers as well as of their respective dominating SLs, helenalin isobutyrate and 11 alpha, 13-dihydrohelenalin acetate. Some alcoholic preparations of fresh Arnica flowers and a fresh Arnica plant gel were also included in the study. Pigskin was used as a model and all these preparations were secured onto it by adhesive tape. It was then determined, using the stripping method, how much of the SLs penetrated and eventually permeated the stratum corneum of the pigskin. This study concluded that a sufficient amount of SLs might permeate the skin to exert anti-inflammatory effects (it is important to note that permeation was greater for the fresh Arnica preparations).

Most massage oils sold to the public today for muscular aches and pains are composed of a mixture of essential oils specially blended to create certain desired effects (Heart, 2006). Unlike pure Arnica oil, Blue Steel Arnica Massage Oil has Arnica and an added mixture of essential oils, which are thought to have anti-inflammatory and analgesic effects:

*Calendula Officinalis* (Calendula) - Triterperoids (triterpene alcohols) from calendula have been shown to promote anti-inflammatory activity. In one clinical trial done by Akihisa *et al.* (1996), 11 triterpene alcohols from composite flowers were evaluated with respect to their anti-inflammatory activity against 12-O-

tetradecanoylphorbol-13-acetate (TPA) induced inflammation (1 microgram per ear) in mice. The inhibitory effects were compared to those of the commercially available anti-inflammatory drugs, indomethacin and hydrocortisone. All of the triterpene alcohols markedly inhibited the TPA induced inflammation with 0.1-0.8mg per ear of the 50% inhibitory dose. While the inhibitory effects of the triterpene alcohols were weaker than hydrocortisone some triterpene alcohols had inhibitory effects at the same level comparable to that of indomethacin (Akihisa *et al.*, 1996).

*Rosmarinus Officinalis* (Rosemary) - Reduced iso-alpha acids (RIAA) component of rosemary has anti-inflammatory effects reducing inflammation by decreasing cyclo-oxygenase-2 (Cox-2) activity (Liska *et al.*, 2004). An in-vitro clinical trial investigating the effects of reduced iso-alpha acids (RIAA) on parameters of cardiovascular health and kidney function indicated that reduced iso-alpha acids RIAA inhibit the formation of Cox enzymes after an inflammatory like stimulus, but does not inhibit the enzymes themselves once they are already formed (Liska *et al.* 2004).

*Lavendula Angustifolia* (Lavender) - The anti-inflammatory and analgesic effects are due to a component of the Lavender essential oil called 1,8-cineole/eucalyptol. Kim and Cho (1999) demonstrated that topically or intradermally applied lavender oil inhibited mast cell-mediated ear swelling response in mice in a dose dependent manner. The study also showed inhibition of histamine and tumour necrosis factor release from mast cells. In yet another experiment by Sosa *et al.* (2005), the anti-inflammatory activity of the ethanol and aqueous extracts from the aerial parts of *Lavendula multifida* L. (Lamiaceae), was investigated by inhibition of the croton oil-induced ear oedema in mice. The biological assay revealed a dose dependent anti-inflammatory activity for the ethanol extract, while the aqueous one was less active. Bioassay guided fractionation of the ethanol extract led to the identity of four triterpenic acids of the oleanane series. Some of these compounds revealed an anti-inflammatory

activity comparable to that of indomethacin (Sosa *et al.* 2005). If these results are extrapolated to humans, they could explain some of the hypothesised anti-allergic and anti-inflammatory properties of lavender essential oil. This may explain why individuals who utilise lavender oil experience relief of muscular aches.

*Thymus Vulgaris* (Thyme) - Thymol is the principal active constituent of thyme oil. It is thought to possess anti-rheumatic, antiseptic and antispasmodic actions. Thyme oil is used to ease gout, rheumatic pain and arthritis and sporting injuries. It is recommended for fixed pain of a contracted or cramping nature (Battaglia 2005).

A study done by Christoffel (1998) on the pharmacological profile of thyme preparation BN01018 with respect to inflammatory diseases of the airways tested the anti-inflammatory, antibacterial, antispasmodic and radical scavenging effects. With respect to the antiinflammatory effects, paw edema assays were done by injecting 0.5% carrageenin in the hind paw of rats to induce inflammation. Dose dependant suppression of the edema was noted with both oral and paw injection administration of the BN01018 thyme preparation. After 3 hours 162m/kg of BN01018 were equally effective as 123mg/kg of phenylbutazone.

The above mentioned oils are therapeutic oils which are composed of fat soluble molecules allowing them to be easily absorbed into the skin (Battaglia 1995). Once the oils have penetrated the skin they are absorbed into the dermal and muscle capillaries. Blood flow in the skin is low compared to that in muscle. Massage can be expected to increase the rate of systemic absorption because it enhances blood flow (Battaglia 2005).

Oils with similar actions have a synergistic activity and therefore enhance the treatment outcome (Battaglia 2005). Blue Steel Arnica Massage Oil is an essential oil blend.

## **2.5 SUMMARY**

Pain of muscular origin is one of the most common medical conditions affecting people. There are still many controversies and debates with respect to the proper definition and diagnosis of muscle related pain. According to Travell et al. (1999), a myofascial trigger point refers to a hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. In the modern society, sitting for hours on end at the desk, answering calls or working on the computer has become the norm for most people. Long hours at work, with little or no rest, as well as the day- to- day stresses of life have led to a rise in the number of patients suffering from myofascial pain syndrome (MPS). The most commonly affected muscles are the postural muscles of the neck and shoulder, namely the trapezius and levator scapula muscles.

Treatment given for MPS ranges from dry needling, vapocoolant stretch and spray, injection of saline or anaesthetic, acupuncture, ultrasound, ischaemic compression to massage. Of these massage is non- invasive, popular, effective in giving pain relief and has been used for muscle pain relief for centuries. For this reason, the market is flooded by various topical medications, which include non-steroidal anti-inflammatory drug (NSAID) creams, oils and lubricants all claiming to aid in the relief of muscle pain. The nature of the claims made by the manufacturers about their products' efficacy in relieving muscle pain needs to be investigated, as some of these claims are not backed up by clinical trials. Blue Steel Arnica Massage Oil is one such product ([www.bluesteelsports.com:au/shop](http://www.bluesteelsports.com:au/shop)) that is advertised on the Internet and various

health brochures claiming to relieve muscle pain by reducing inflammation and healing muscle tissue.

Furthermore Blue Steel Arnica Massage oil is an essential oil blend containing arnica, calendula, lavender, rosemary and thyme. An essential oil blend is obtained by mixing two or more essential oils into carrier oil. Theoretically, essential oils in a blend work synergistically to bring about physiological effects provided that the blend contains essential oils with known same/similar physiological effects. Blue steel Arnica Massage oil contains a blend of essential oils which claim to have anti-inflammatory and analgesic physiological effects. Blue Steel Arnica Massage oil is a blend of essential oils with similar physiological effects it should, therefore, be more efficacious than Arnica Massage oil containing one essential oil (*Arnica Montana*) in the treatment of muscle aches and pains.

# **CHAPTER THREE**

## **MATERIALS AND METHODS**

### **3.1 INTRODUCTION**

In this chapter we discuss the study methodology, which includes patient recruitment, sampling methods, group allocation, inclusion and exclusion criteria, preparation of placebo treatments, the measuring process, management of the research subjects, measurements as well as data analysis.

### **3.2. SAMPLING PROCEDURE**

#### **3.2.1 Patient Recruitment**

The selection of patients was by means of convenience sampling. The Durban University of Technology (DUT) research committee granted permission to the researcher to do the research at a clinic in the town of Umzinto (south of Durban), under the supervision of a medical doctor. Patients were selected from those who responded to advertisements (Appendix H) placed in local newspapers, sport clubs, shopping centres, gyms, pharmacies, pamphlet distribution and notice boards around Umzinto. No restrictions were placed on the patient's race, sex, occupation, or residential area. All patients were between the ages of 30-60 and were screened to make sure that they satisfied the inclusion criteria in order to participate in this study.



### **3.2.2 Sampling method**

The subjects were randomly divided into two treatment groups and two placebo groups (There was an envelope containing papers with 1, 2, 3 or 4 written on them. This randomly placed the subjects into either the placebo or treatment groups according to the piece of paper they drew out of the envelope viz. Groups 1 and 2 were the placebo groups, Groups 3 and 4 were the treatment groups.

### **3.2.3 Sample size**

For the purpose of this study 80 subjects were recruited (40 treatment and 40 placebo). Although a larger sample size would have been appropriate for this study, budget constraints were the main factor for selecting a smaller sample size.

### **3.2.4 Sample characteristics**

Subjects that responded to the advertisements were briefly interviewed telephonically. A few basic questions referring to the site of the pain, the age of the subject and the chronicity of the condition were asked; those having met the basic requirements, were given an appointment date for a consultation at the clinic in Umzinto.

## **3.3 RESEARCH METHOD**

### **3.3.1 First consultation**

At the first consultation, a case history (Appendix A), physical examination (Appendix B) and cervical orthopaedic examination (Appendix C) were performed after which subjects were selected only after they satisfied the inclusion criteria.

### 3.3.1.1 Inclusion Criteria:

- Subjects must have been between the ages of 30 and 60. Based on the literature review (Travell *et al.*, 1999), the peak incidence of MPDS is within this age range (30-55).
- The duration of the condition must have been for at least four weeks (Travell *et al.*, 1999)
- Subjects must have had active trigger points 1 and 2 of the trapezius muscle (as these are easily accessible for self massage, Figure 1). These trigger points will be diagnosed according to the essential diagnostic criteria for identifying active myofascial trigger points which according to Travell *et al.* (1999) are:
  - Referred pain in the specific region of the body at a distance from the trigger point, where phenomena (sensory, motor, and/or autonomic) caused by the trigger point are observed (zone of reference).
  - Local twitch response
  - Palpable taut band.
  - Focal tenderness.
- The subjects were required to have a Numerical Pain Rating Scale 101 (NRS 101) of between 5 and 8 (to maintain sample homogeneity)
- Subjects were accepted once they had undergone a full case history, physical examination and signed the informed consent form.

### 3.3.1.2 Exclusion Criteria:

- Subjects on allopathic or homeopathic pain medication. Subjects on any medication (Non Steroidal Anti Inflammatory Drugs, Analgesics, and Muscle Relaxants etc.) for the condition that was researched who indicated a willingness to participate in the research had to undergo a 48-hour wash out period.
- Subjects receiving any manual therapy for the above mentioned condition.
- Pregnant women or breastfeeding mothers (see below).
- Subjects with acute trauma/fracture/muscle tears or with an acute condition e.g. cervical facet syndrome or adhesive capsulitis, which have concomitant MFPDS.
- Patients refusing to sign the informed consent form.
- Patients with known sensitivity/ allergy to any of the ingredients found in Blue Steel Arnica Massage oil and/or Elizabeth Anne's baby oil. Arnica used in topical administration is relatively benign, but can cause contact dermatitis, irritation and burning (Newwall *et al.*, 1996). Calendula may cause allergic reactions and is contraindicated in pregnancy (Barnes and Anderson, 2002; Akihisa *et al.*, 1996). Rosemary should also be avoided in pregnant or breast-feeding patients (Ernst, 2002). Lavender may cause contact dermatitis (Kim and Cho, 1999).
- According to Battaglia (2005), subjects developing the following side effects to essential oil application during the course of the research should also be excluded:
  1. Irritation (local inflammation over the area of application).
  2. Dermal sensitisation (rash, blotches, irritation or even slight blistering over the area of application which will get worse with subsequent applications).

- Subjects with contraindications to massage (Vickers and Zollman, 1999):
  1. Acute inflammation of the area concerned.
  2. Skin infections.
  3. Non-consolidated fracture.
  4. Burn areas
  5. Deep vein thrombosis.
  6. The presence of metastatic cancer.

Subjects satisfying the inclusion criteria were then given an explanation about the research and encouraged to ask questions. They were handed a patient information sheet (Appendix D) and an informed consent form (Appendix E), which they were required to read and sign. Subjects wishing to participate had to have signed the informed consent form. Refusal to sign the form meant immediate exclusion for that subject. They were also instructed on the use of the five-day diary (Appendix F) which served as a means of ensuring compliance as not all subjects could be contacted telephonically and therefore reminded of their treatments. Each subject was to tick his or her diary before each application at breakfast, lunch and supper (i.e. 3 times a day).

### **3.3.1.3 Location of trigger points**

Active trigger points 1 and 2 of the trapezius muscle were identified unilaterally on the subjects according to the anatomy of the upper trapezius muscle as follows:

The paired trapezii form a diamond shape that extends in the midline from the occiput above to T12 below. It reaches anteriorly to include the lateral one-third

of the clavicle, laterally to include the acromion, and posteriorly throughout the length of the spine of the scapula (Travell *et al.*, 1999).

The trapezii are tripartite having upper, middle and lower fibres, which have different fibre directions and different functions. Trigger points 1 and 2 were found in the upper trapezius fibres. Trigger point 1 was located in the midportion of the anterior border of the upper trapezius and involved the most vertical fibres that attach anteriorly to the clavicle. Trigger point 2 was located caudal and slightly lateral to trigger point 1. The trigger point 2 region was located in the middle of the more nearly-horizontal fibres of the upper trapezius (Travell *et al.*, 1999). These points were marked with a skin-marking pencil.

#### **3.3.1.4 Subjective measures**

Thereafter subjective measures were taken using the NRS 101 (Jensen *et al.*, 1986). The Numerical Pain Rating Scale (NRS-101) assesses the perceived level of pain intensity of the patient (Appendix G). The questionnaire consists of a numerical scale from 0-100, where 0=no pain and 100=pain at its worst. In a group of 75 chronic pain patients Jensen *et al.* (1986) examined the usefulness of six different pain intensity measures and the NRS 101 proved to be most practical. The subjects were shown how the NRS 101 was to be completed and then asked to complete a new NRS 101 form.

#### **3.3.1.5 Objective measures**

Objective pre-treatment measures were taken using a digital algometer (Livingston *et al.*, 1998). The Algometer Commander (a digital force gauge) was used. Trigger points 1 and 2 of the trapezius muscle were palpated at the site indicated by the skin mark. The subject was asked to inform the researcher when

the pain produced by the pressure from the digital algometer became unbearable. The digital algometer was zeroed and held onto the skin pencil marking perpendicularly to the contour of the area each time a reading was taken. A continuous pressure was applied ending only at the subjects command. Care was taken not to reveal the measurements to the research subjects.

### **3.3.1.6 Group allocation**

Subjects were then directed to the receptionist of the clinic where they drew from an envelope a piece of paper with either numbers 1, 2, 3 or 4 on it. This randomly placed subjects into either the treatment or placebo groups. Those selecting 1 were placed in Group 1. Those selecting 2 were placed in Group 2 (Groups 1 and 2 being the placebo groups). Those selecting 3 were placed in Group 3 and those selecting 4, into Group 4 (Groups 3 and 4 being the treatment groups). The receptionist kept a record of which group a subject belonged to and did not inform the researcher which group each subject belonged to until all the subject data was collected. Subjects then returned to the consulting room where they were reminded not to divulge to the researcher which number they had drawn from the envelope.

### **3.3.1.7 Intervention**

#### **a) Skin Patch Test**

A skin patch test was then done on the inner surface of the upper arm of every research subject. This patch test was done by rubbing a small amount of the oil selected by the research subjects at reception on the skin of the inner surface of the upper arm. Subjects were told to report the development of any skin side effects over the area of application (skin patch test) and to immediately

discontinue the application and inform the researcher as soon as possible. According to Battaglia (2005), side effects included the following:

- Irritation (local inflammation over the area of application).
- Dermal sensitisation (rash, blotches, irritation or even slight blistering over the area of application which will get worse with subsequent applications).
- Photosensitization (in this case a skin reaction will only occur when there has been sun exposure to the area of application).

These individuals were then to be excluded from the study. Any subject developing a side effect over the area of application qualified for one free consultation with a general practitioner or homeopath of their choice. The cost of this consultation did not include any medication/treatment prescribed by the said practitioner.

#### **b) Directions on use of massage oil**

All research subjects were instructed to use four quick squirts of their oil onto their hand for the area to be treated to maintain homogeneity (about 15ml of oil, enough to cover the marked areas sufficiently). Subjects were encouraged to use a mirror whilst applying the oil so as to see the target area clearly. A brief demonstration and explanation of how to massage the area to be treated was given to each subject as described by Rachlin (1994):

The area to be treated was warmed up with gentle stroking, progressing to kneading. Kneading was a moderately deep massage technique performed by contouring or “sinking” the hands into the underlying tissues and firmly gliding into or across the length of the muscle creating a squeezing or “milking” of the tissues. Subjects were warned not to begin the treatment by working too deeply because if pain was caused muscle spasm would occur. Kneading strokes, which gently “milk the muscle” were used periodically to soothe the area, facilitate

circulatory exchange to speed up evacuation of metabolic waste products, and to rest the practitioner/ massager's hands. Overall, Rachlin (1994) recommended a combination of deep concentrated attention to the trigger point and milking of the muscles in general and therefore subjects were told to concentrate their massage over the area marked as it represented the location of trigger points.

### **c) Subject demonstration on the use of massage oil**

Thereafter, subjects were required to give a quick demonstration of this technique by attempting to massage the researcher. This was an important part of the research procedure as the subjects were going to apply the oil at home and not under professional supervision.

### **d) Frequency of oil application**

The frequency of application of the oil was strictly confined to 'breakfast', 'lunch' and 'supper' times as these were easy times to remember. Massage over the treatment area was done for a period of five to ten minutes. The subjects were told not to apply the oil over any other painful areas of the body. Each subject was to make a tick in his or her five-day diary after each oil application, which meant three ticks per day.

### **e) Henna markings**

The trapezius muscle trigger points 1 and 2 were marked unilaterally with a henna stain so that the subject would know exactly where to apply the oil. This procedure also allowed the researcher to determine the exact site for the placement of the algometer at the second consultation (as it formed a lasting stain). The henna stain was covered with clear adhesive tape to insure that a stain lasting for the duration of the study was formed. The tape was to be removed the following day (Day 2, refer to Table 1) when the first application of



oil had to be made at breakfast. Subjects were also instructed on the date of their second consultation when the five-day diary was to be handed in and when the last measurements were to be taken.

### 3.3.2 Second Consultation:

Subjects returned after five days to the Umzinto Clinic with their diaries, which were handed to the researcher and another set of objective (digital algometer readings) and subjective (NRS 101) readings were taken on day 7 (post-treatment measurements). The subjects that received the placebo treatments qualified for 2 free physical therapy treatments for the initial complaint within 1 month after their last research consultation with the researcher.

**Table1: Procedure for all participating research subjects from day 1-7**

<b>DAY 1</b>	<b>DAY 2</b>	<b>DAY 3</b>	<b>DAY 4</b>	<b>DAY 5</b>	<b>DAY 6</b>	<b>DAY 7</b>
First Consultation Clinic	Oil Application Home	Oil Application Home	Oil Application Home	Oil Application Home	Oil Application Home	Second Consultation Clinic

### 3.4 MANAGEMENT OF RESEARCH SUBJECTS BETWEEN CONSULTATIONS

To ensure compliance, the researcher telephonically contacted the subjects once or twice during the five days of self- treatment. Some subjects could not be contacted telephonically and the five-day diary (designed by the researcher and research supervisor) given to all subjects was to ensure patient compliance especially in these subjects.

### **3.5 PREPARATION OF THE PLACEBO AND TREATMENT OILS**

Pure Mineral oil (a by-product of crude oil) has no smell, is not a natural product and cannot be absorbed into the skin but instead forms a plastic layer over the skin (Holy and Cook, 2003; Bradford and Lousada, 2000). Each subject in the first placebo group (Group 1) received pure non-scented mineral oil packaged into the 125 ml Blue Steel Arnica Massage Oil bottles. These 20 bottles were also placed into a box, marked as Group 1 and given to the receptionist.

Group 2 received Unisex CK-1 type oil mixed into mineral oil. Unisex CK-1 type neutral oil is manufactured by Sensetek C.C. (P. O. Box 2598, Bedfordview, Johannesburg, contact number + 2711 6084944) and is used for cosmetic purposes and has no known physiological effects (Revie, 2006). The Unisex CK-1 type oil is perfume oil with a herbal scent (the researcher requested an oil sample before purchasing the oil for research purposes). The pungency of the oil meant that only 25ml of it was mixed into 2.5 litres of pure mineral oil. This oil mixture (scented mineral oil) was packaged by the researcher into 20 Blue Steel Arnica Massage oil bottles (125 ml). The box containing the oils was marked by the researcher as Group 2 and given to the receptionist. This placebo preparation was used to help rule out the aromatic effects of pure Arnica oil and that of Blue Steel Arnica Massage Oil.

Group 3 received Arnica massage oil (this was a mixture of macerated arnica diluted 5% into a carrier oil). Vegetable oils are used as carrier oils as they are fat-soluble and do not evaporate like essential oils which are volatile; they also contain vitamins, minerals and lipids which are biologically active substances that nourish and protect the skin. Vegetable oils aid in the penetration of essential oils during massage (Pitman, 2004). Essential oils are diluted between 1% and 5% into the carrier oil to enhance physiological effects and to minimise toxic effects (Heart, 2006). A dilution of 5% arnica into 2.5l of grape-seed (carrier) oil was prepared by a registered aroma therapist and poured into 20 Blue Steel Arnica

Massage Oil bottles (125ml) by the researcher. The box containing these oils was marked Group 3 and handed to the receptionist.

Finally, Group 4 received Blue Steel Arnica Massage Oil (125ml bottles), which was the essential oil blend of arnica, lavender, rosemary, calendula and thyme. Blue Steel Arnica Massage Oil together with 80 Blue Steel Arnica Massage Oil bottles was sponsored by Leechem Laboratories (P. O. Box 3009, 12 Walter Place, Mayville 4059 in Durban, contact number 031 2083099). The twenty 125ml bottles of Blue Steel Arnica Massage Oil were placed into a box, marked as Group 4 and given to the receptionist.

### **3.6 STATISTICAL ANALYSIS**

Data was entered into a MS Excel spreadsheet and imported into SPSS version 11.5 (SPSS Inc., Chicago, Illinois, USA), which was used for data analysis.

Demographics and baseline outcome measurements were compared between the four treatment groups using Pearson's chi square tests for categorical variables and ANOVA tests with Bonferroni post hoc tests for quantitative variables.

Participants were randomised into four groups:

1. Mineral oil (Group 1)
2. Scented mineral oil (Group 2)
3. Arnica Massage oil (Group 3)
4. Blue Steel Arnica Massage oil (Group 4)

Since there were no missing data points at all follow up times, and since the outcome variables were quantitative and reasonably normally distributed, repeated measures ANOVA was used to assess the treatment effect. A time by exposure group interaction effect of  $p < 0.05$  was considered as a significant

treatment effect. Profile plots were generated to examine the direction in which the treatment effect was founds and to examine trends in the data.

# CHAPTER 4

## RESULTS

### 4.1 INTRODUCTION

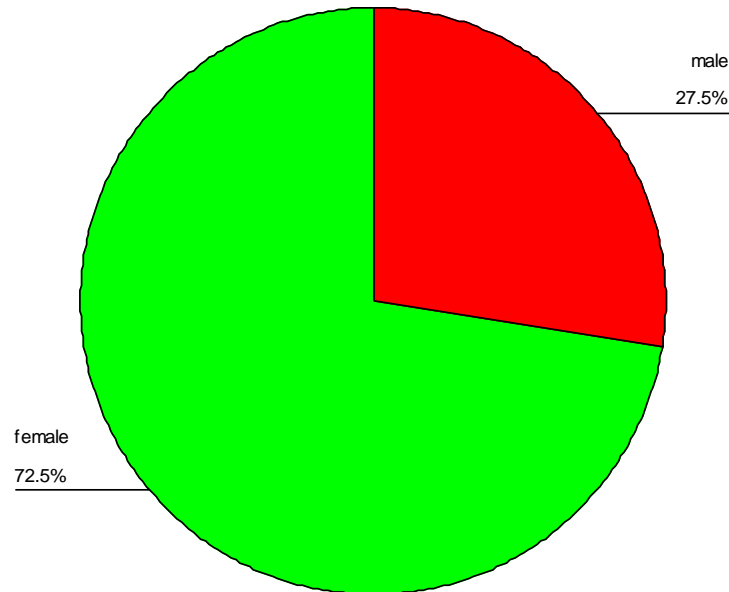
In this chapter we analyzed the data obtained from each subject in the form of subjective and objective measures, as described in chapter 3. The demographics were obtained from the patient information sheet (Appendix J).

Pearson's chi square tests for categorical variables were used to analyse demographics between the four treatment groups and outcome measurements were analysed according to the three hypotheses stated in Chapter 1 using Bonferroni post hoc tests for quantitative variables within the four treatment groups.

Since there were no missing data points at all follow up times, and since the outcome variables were quantitative and reasonably normally distributed, repeated measures ANOVA was used to assess the treatment effect. A time by exposure group interaction effect of  $p < 0.05$  was considered as a significant treatment effect. Profile plots were generated to examine the direction in which the treatment effect was found and to examine trends in the data.

## 4.2 DEMOGRAPHICS

The sample consisted of 80 subjects, 22 were male (27.5%) and 58 were female (72.5%). The gender distribution is shown in Figure 1. Their mean age was 47.8 years with a standard deviation of 8.35 years and a range of 30 to 60 years.



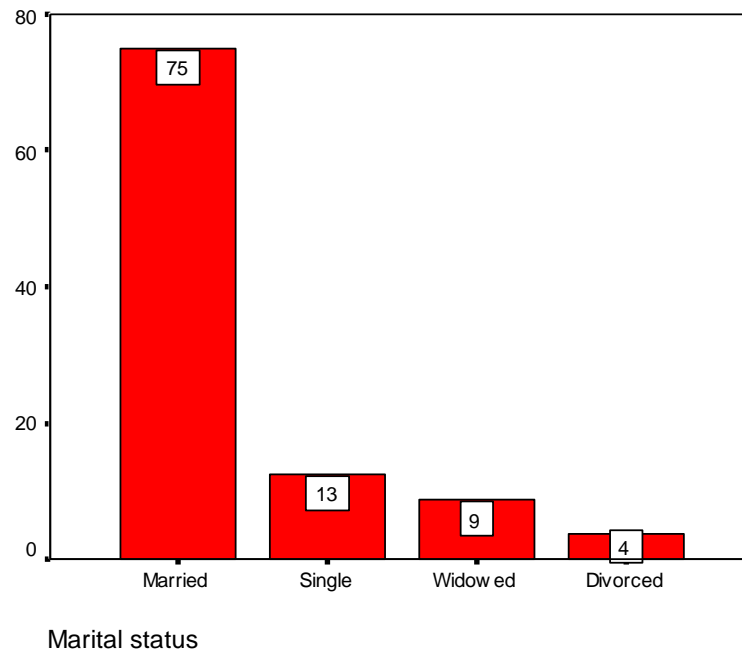
**Figure 1: Gender distribution of study subjects (n=80)**

Racial distribution of the sample is shown in Table 1. The majority were Indian (80%), while only 17.5% were African and 2.5% were White.

**Table 1: Racial distribution of the sample**

Race	Frequency	Percent
Indian	64	80.0
African	14	17.5
White	2	2.5
Total	80	100.0

Figure 2 shows the marital status of the 80 subjects. The majority were married (n=60, 80%), while 10 were single (12.5%), 7 were widowed (8.8%) and 3 were divorced (3.8%).



**Figure 2: Marital status of subjects (n=80)**

The subjects were randomised into 4 treatment groups of n=20 each. The demographics were compared between the treatment groups to ensure that there were no significant differences, which could result in differential outcomes after treatment.

Table 2 shows that the demographic factors were equivalently distributed between the four treatment groups so there were no significant differences between the groups with respect to these factors.

**Table 2: Comparison of demographics by treatment group**

		GROUP											p value	
		Mineral Oil			Mineral Oil Scented			Arnica			Blue Steel Arnica			
		Count	Row %	Mean (Sd)	Count	Row%	Mean (Sd)	Count	Row %	Mean (Sd)	Count	Row %		Mean (Sd)
gender	male	4	18.2%		9	40.9%		3	13.6%		6	27.3%		0.153
	female	16	27.6%		11	19.0%		17	29.3%		14	24.1%		
Race	Indian	14	21.9%		13	20.3%		20	31.3%		17	26.6%		0.130
	African	5	35.7%		6	42.9%		0	.0%		3	21.4%		
	White	1	50.0%		1	50.0%		0	.0%		0	.0%		
Marital status	Married	13	21.7%		15	25.0%		16	26.7%		16	26.7%		0.770
	Single	4	40.0%		2	20.0%		2	20.0%		2	20.0%		
	Widowed	2	28.6%		1	14.3%		2	28.6%		2	28.6%		
	Divorced	1	33.3%		2	66.7%		0	.0%		0	.0%		
	Other	0	.0%		0	.0%		0	.0%		0	.0%		
AGE				44.8 (7.99)			50.3 (8.29)			47.6 (8.64)			48.6 (8.11)	0.206



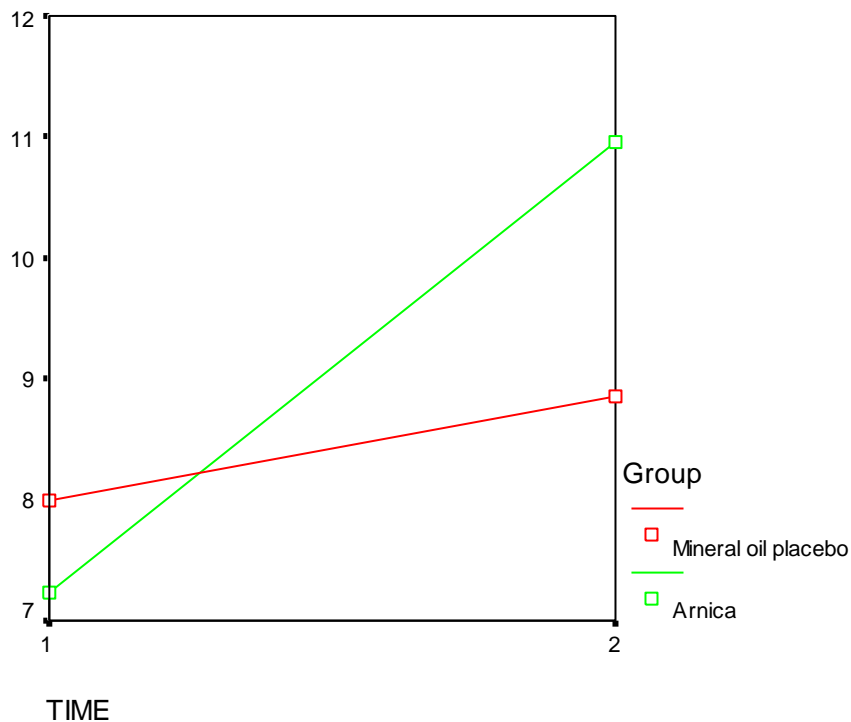
### 4.3 ASSESSMENT OF THE TREATMENT EFFECT

#### 4.3.1 Analysing the first Null hypothesis.

The first Null hypothesis stated that: There is no difference in the efficacy of Arnica massage oil compared to the placebo (scented and non scented mineral oil) using objective and subjective measures in the treatment of chronic active trapezius myofascial trigger points.

**Table 3: Within-subjects and between- subjects effects for Algometer testing  
Group 3 vs. Groups 1 and 2 combined (n=60)**

Effect	Statistic	p value
Time	Wilk's lambda =0.570	<0.001
Time group	Wilk's lambda = 0.770	<0.001
Group	F=0.726	0.398



**Figure 3: Profile plot of algometer measurements over time by treatment groups  
(Group 3 vs. Groups 1 and 2 combined)**

## **a) Objective outcome measurements**

### **The Digital Algometer readings**

Digital algometer readings were taken at two time points (pre and post treatment referring to Day 1 which was the first subject consultation and Day 7 which was the second subject consultation). These readings reflected the measurements (digital algometer readings) taken for the trigger points 1 and 2 of the trapezius muscle respectively. The measurements for trigger points 1 and 2 of the trapezius muscle were averaged at each time point.

A highly significant time effect was observed in both groups ( $p < 0.001$ , Table 3). Figure 3 shows that both treatments showed a general increase in algometer measurements over time, however the rates of increase (slopes of the lines) varied between the treatment groups.

Table 3 shows that the interaction effect of time group was statistically significant ( $p < 0.001$ ). This means that the change in digital algometer readings over time was influenced by whether the group used arnica or not i.e. there was a treatment effect for arnica versus placebo. Figure 3 shows this interaction graphically. The groups not containing arnica (Group 1 and Group 2) did not improve to the same extent as the arnica-containing group (Group 3). Therefore there is statistical evidence for this outcome of a beneficial treatment effect of arnica. Therefore we fail to accept the Null hypothesis by the objective outcome of the digital algometer measurements.

## **b) How to interpret repeated ANOVA measures**

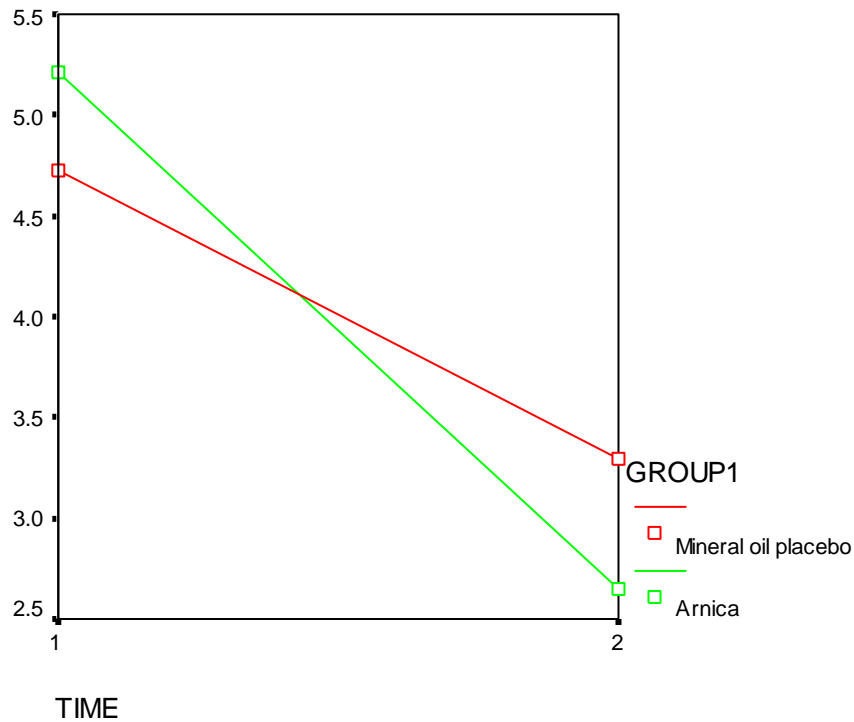
With repeated measures ANOVA you test 3 hypotheses: the time effect, the group effect and the time by group interaction. The first 2 are called main effects and the latter is the treatment effect. If the treatment effect (interaction between time and group) is significant ( $p < 0.05$ ) then you ignore the main effects. A significant time by group interaction effect tells you that the effect over time was dependant on which

treatment group the individual was in, i.e. there is a differential effect over time in the treatment group compared with the control group. Usually this reflects as non parallel (or crossing over) lines in the profile plot. If the slope of the line for the treatment group is in a more favourable direction than the control group and your p value for the time group interaction is significant then you can conclude that the treatment is significantly beneficial compared to the control.

If there is no significant treatment effect ( $p > 0.05$ ) then you can look at the significance of the main effects as possible explanations. If there is a significant time effect it means that both groups are changing over time at the same rate, i.e. the treatment has no differential effect over the control. If there is a significant group effect it means that regardless of time the one group was always higher than the other. This is not a treatment effect but rather reflective of baseline differences between the groups which persisted over time.

**Table 4: Within-subjects and between- subjects effects for NRS in Group 3 vs. Groups 1 and 2 combined (n=60)**

Effect	Statistic	p value
Time	Wilk's lambda =0.219	<0.001
Time group	Wilk's lambda = 0777	<0.001
Group	F=0.052	0.820



**Figure 4: Profile plot of NRS over time by treatment group (Group 3 vs. Groups 1 and 2 combined)**

**c) Subjective outcome measurements**

**The Numerical Pain Rating Scale 101 (NRS 101) readings**

The NRS 101 was measured pre (baseline) and post treatment at two time points (at the first consultation which was Day 1 and at the second consultation which was Day 7)

Table 4 shows that there was a highly significant time effect in all groups ( $p < 0.001$ ), which is shown graphically in Figure 4. All groups showed a mean decrease in pain over the study period, but the rate of decrease was different in the treatment groups.

There was a highly significant time group interaction ( $p < 0.001$ ), thus the presence of arnica was a significant factor in the rate of decrease in pain. Figure 4 shows that the group with arnica (Group 3) showed a faster rate of descent than the groups without

arnica (Group 1 and Group 2). Therefore we fail to accept the Null hypothesis by the subjective outcome of the NRS101 measurements.

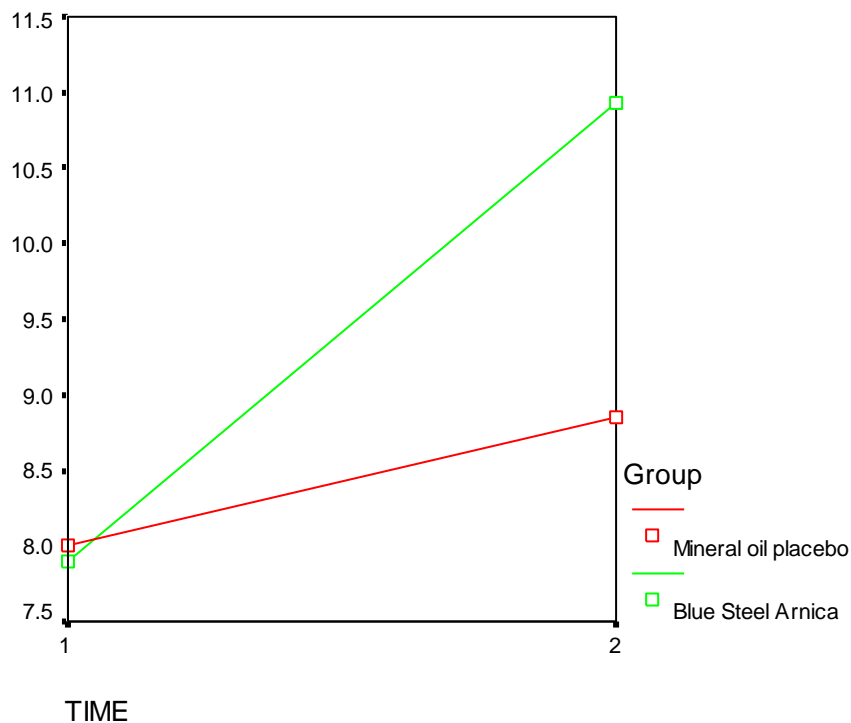
### 4.3.2 Analysing the second Null hypothesis

The second Null hypothesis stated that: There is no difference in the efficacy of Blue Steel Arnica massage oil compared to the placebo (scented and non scented mineral oil) using objective and subjective measures in the treatment of chronic active trapezius myofascial trigger points.

**Table 5: Within-subjects and between- subjects effects for Algometer testing**

**Group 4 vs. Groups 1 and 2 combined (n=60)**

Effect	Statistic	p value
Time	Wilk's lambda =0.191	<0.001
Time group	Wilk's lambda = 0.706	<0.001
Group	F=0.503	0.481



**Figure 5: Profile plot of algometer measurements over time by treatment group (Group 4 vs. Groups 1 and 2 combined)**

## a) Objective outcome measurements

### The Digital Algometer readings

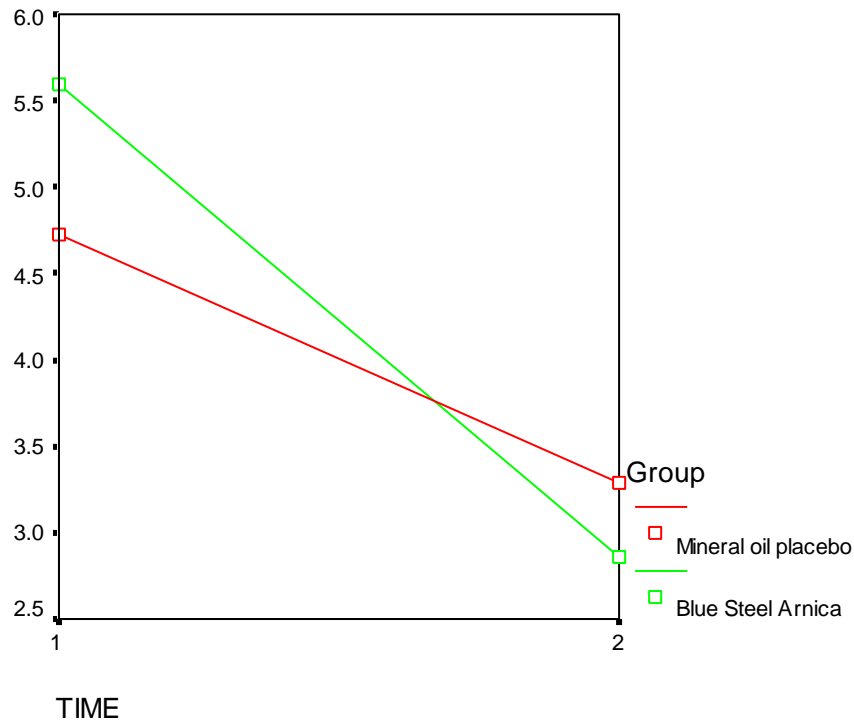
Digital algometer readings were taken at two time points (pre and post treatment referring to Day 1 which was the first subject consultation and Day 7 which was the second subject consultation). These readings reflected the measurements taken for the trigger point 1 and 2 of the trapezius muscle respectively. The measurements for trigger points 1 and 2 of the trapezius muscle were averaged at each time point

A highly significant time effect was observed in both groups ( $p < 0.001$ , Table 5). Figure 5 shows that both treatment groups showed a general increase in algometer measurements over time, however the rates of increase (slopes of the lines) varied with the treatment groups.

Table 5 shows that the interaction effect of time group was statistically significant ( $p < 0.001$ ). This means that the change in digital algometer readings over time was influenced by whether the group used Blue steel arnica (Group 4) or placebo (Group 1 and Group 2) i.e. there was a treatment effect for Blue steel arnica versus placebo. Figure 5 shows this interaction graphically. The groups that did not contain arnica (Group 1 and Group 2) did not improve to the same extent as the group containing Blue steel arnica (Group 4). Therefore there is statistical evidence for this outcome of a beneficial treatment effect of Blue Steel arnica. Therefore we fail to accept the Null hypothesis by the objective outcome of the digital algometer measurements.

**Table 6: Within-subjects and between- subjects effects for NRS in Group 4 vs. Groups 1 and 2 combined (n=60)**

Effect	Statistic	p value
Time	Wilk's lambda =0.363	<0.001
Time group	Wilk's lambda = 0.848	0.002
Group	F=1.634	0.206



**Figure 6: Profile plot of NRS over time by treatment group (Group 4 vs. Groups 1 and 2 combined)**

**b) Subjective outcome measurements**

The Numerical Pain Rating Scale 101 (NRS 101) readings

The NRS 101 was measured pre (baseline) and post treatment at two time points (at the first consultation which was Day 1 and at the second consultation which was Day 7)

Table 6 shows that there was a highly significant time effect in all groups ( $p < 0.001$ ), which is shown graphically in Figure 6. All groups showed a mean decrease in pain over the study period, but the rate of decrease was different in the treatment groups.

There was a significant time group interaction ( $p = 0.002$ ), thus the presence of Blue Steel arnica was a significant factor in the rate of decrease in pain. Figure 6 shows that the group with Blue Steel arnica (Group 4) showed a faster rate of descent than the

groups without arnica (Group1 and Group 2). Therefore we fail to accept the Null hypothesis by the subjective outcome of the NRS 101 measurements.

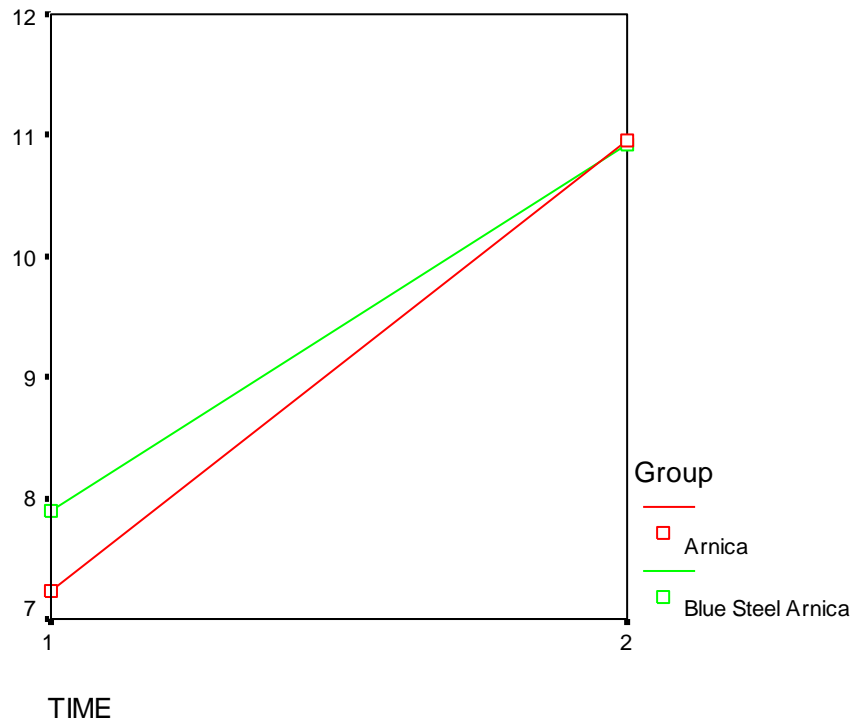
### 4.3.3 Analysing the third Null hypothesis

The third Null hypothesis stated that: There is no difference in the efficacy of Blue Steel Arnica massage oil compared Arnica massage oil using objective and subjective measures in the treatment of chronic active trapezius myofascial trigger points.

**Table 7: Within-subjects and between- subjects effects for Algometer testing Group 4 vs. Groups 3 (n=40)**

Effect	Statistic	p value
Time	Wilk's lambda =0.470	<0.001
Time group	Wilk's lambda = 0.899	0.498
Group	F=0.114	0.738





**Figure 7: Profile plot of algometer measurements over time by treatment group (Group 4 vs. Group 3)**

**a) Objective outcome measurements**

The Digital Algometer readings

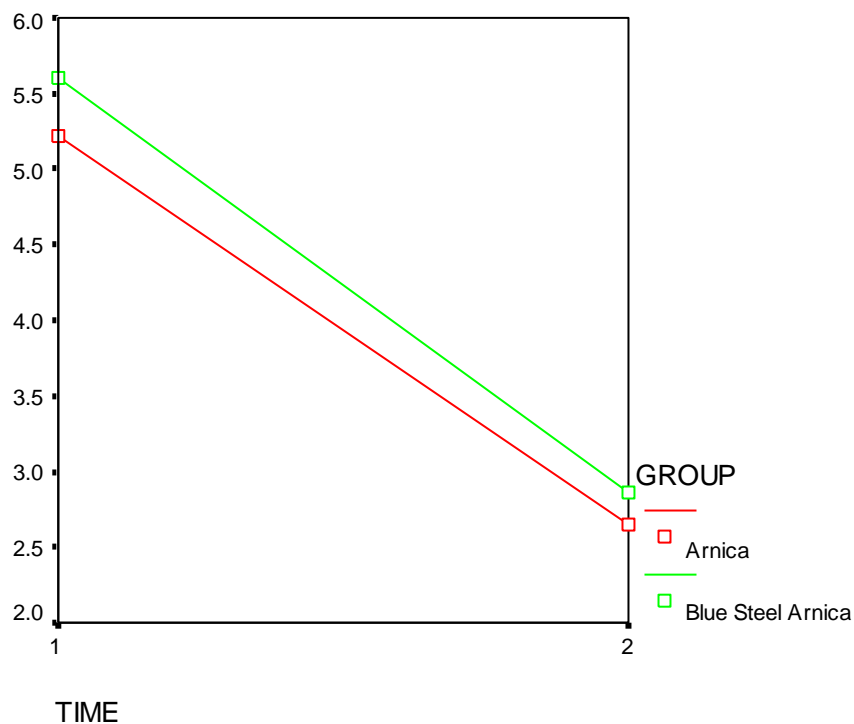
Digital algometer readings were taken at two time points (pre and post treatment referring to Day 1 which was the first subject consultation and Day 7 which was the second subject consultation). These readings reflected the measurements taken for the trigger point 1 and 2 of the trapezius muscle respectively. The measurements for trigger points 1 and 2 of the trapezius muscle were averaged at each time point

A highly significant time effect was observed in both groups ( $p < 0.001$ , Table 7). Figure 7 shows that both treatments showed a general increase in digital algometer measurements over time.

Table 7 shows that the interaction effect of time group was not statistically significant ( $p=0.498$ ). This means that the change in algometer readings over time was not influenced by whether the group used Blue steel arnica or Arnica i.e. there was no beneficial treatment effect for Blue steel arnica (Group 4) versus Arnica (Group 3). Figure 7 shows this graphically. The groups improved at the same rate (the profiles were almost parallel). Therefore there is no statistical evidence for this outcome of a beneficial treatment effect of Blue Steel arnica over Arnica. Therefore we fail to reject the Null hypothesis by the objective outcome of the digital algometer measurements.

**Table 8: Within-subjects and between- subjects effects for NRS in Group 4 vs. Group 3 (n=40)**

Effect	Statistic	p value
Time	Wilk's lambda =0.102	<0.001
Time group	Wilk's lambda = 0.991	0.550
Group	F=0.722	0.401



**Figure 8: Profile plot of NRS over time by treatment group (Group 4 vs. Group 3)**

## b) Subjective outcome measurements

### The Numerical Pain Rating Scale 101 (NRS 101) Readings

The NRS 101 was measured pre (baseline) and post treatment at two time points (at the first consultation which was Day 1 and at the second consultation which was Day 7)

Table 8 shows that there was a highly significant time effect in all groups ( $p < 0.001$ ), which is shown graphically in Figure 8. Both groups showed a mean decrease in pain over the study period.

There was no significant time group interaction ( $p = 0.550$ ), thus Blue Steel arnica was not more beneficial than Arnica for pain. Figure 8 shows that the group with Blue Steel arnica (Group 4) did not show a faster rate of descent than the Arnica group (Group 3), the profiles were parallel. Thus the null hypothesis is not rejected for the subjective outcome of pain.

## 4.4 CLINICAL RELEVANCE OF THE FINDINGS

**Table 9: Mean percentage change in NRS by treatment group**

GROUP	Mean	N	Std. Deviation
Mineral Oil	-31.463	20	24.8083
Mineral Oil Scented	-30.898	20	20.6013
Arnica	-51.589	20	18.9393
Blue Steel Arnica	-50.091	20	16.7172
Total	-41.010	80	22.3998

Table 9 shows that there was on average a 41% decrease in NRS in the study overall. By treatment group the decrease was highest in the Arnica and Blue Steel Arnica groups (51.6% and 50.1% respectively). Thus both treatment groups achieved on

average over 50% decrease in pain over the study period, which is the benchmark of clinical significance.

#### **4.5 SUMMARY AND CONCLUSION**

In this study a general improvement or reduction of pain measured subjectively and objectively was shown by all treatment groups. However certain treatment groups showed a faster rate of pain reduction than others.

The results have also shown that the presence of arnica is a significant factor that is associated with the fastest rate of improvement for both objective and subjective outcomes. Both Arnica and Blue steel arnica showed significantly faster rates of improvement than the placebo.

Blue steel arnica was not found to show a significantly faster rate of pain reduction than arnica using objective and subjective tests. Both treatments were equally effective in the treatment of chronic active trapezius myofascial trigger points. Both treatment groups achieved an average of 50% reduction in pain over the study period. Thus, both Arnica and Blue Steel Arnica showed clinically and statistically significant pain reduction in this study.

# CHAPTER 5

## DISCUSSION OF THE RESULTS

### 5.1 DEMOGRAPHIC DATA

#### 5.1.1 Gender

Figure 1 represents the gender distribution of the 80 subjects that participated in the research. There were more female (72.5%) than male (27.5%) subjects who participated in this study. Previous studies done by Pillay (2003), Chettiar (2001) and Backlund (1999) on myofascial pain syndromes also had a greater number of female than male participants. This is in congruence to Han and Harrison (1997) and Yunus *et al.* (1981) who stated that females are more commonly affected than males by myofascial trigger points.

We can assume from this information that females are more prone to developing myofascial pain syndromes than males. There seems to be no literature to explain why females are more commonly affected by this condition. A possible explanation could be that females have less muscle mass than males (Doherty, 2001) and therefore their muscles are more vulnerable to physical strain. This could most likely lead to the development of trigger points in the muscles.

#### 5.1.2 Age

In a study done by Chettier (2001) on 60 subjects between the ages of 18 and 60 with myofascial trigger points, it was found that 52% of these were aged between 32-55yrs with a mean of 43.5. This mean age closely relates to the mean age of 47.8yrs established in this study.

According to Bland (1994), working individuals between the ages of 25 and 29 years have 25%-30% incidence of one or more attacks of neck pain this figure rising to 50%

for those over 45yrs of age. A common cause of neck pain is myofasciitis of the paraspinal muscles (Travell and Simons, 1999; Gatterman 1990). The age range for inclusion into this study was 30-60 years of age based on the views of Travell and Simons (1999). Therefore, those younger than 30 years of age and older than 60 years of age were excluded from this study. The age mean with reference to the general population could not be established.

### **5.1.3 Marital status**

The marital status of all the subjects is represented in Figure 2. A large percentage (%) of the subjects were married (75 %). This is not an entirely unexpected finding since we expected that most persons over the age of 40 years would most likely be married.

### **5.1.4 Race**

Table 1 shows the racial distribution (80 % = Indian, 17.5 % = African, 2.5 % = White). Due to population dynamics, the area in which the research took place was previously classified as an Indian township; therefore, the majority of the subjects who participated in this study were of the Indian race. We cannot claim that those of the Indian race are more affected by myofascial trigger points as this was not a true reflection of racial distribution.

These findings coincide with the findings in a study done by Webb (2003) on myofascial pain syndrome of the levator scapulae muscle. Evaluation of the race groups represented by his study showed the majority of patients to be Caucasian (85%) and the remainder of the patients being Indian (15%) while no Black or Coloured had taken part. This was not a true representation of the South African race distribution. The most likely explanation for his findings was that advertisements for the study were in English and these were posted in the area surrounding the Durban University of Technology, which consisted of mainly White and Indian communities.

## **5.2 ANALYSING THE FIRST NULL HYPOTHESIS.**

The first Null hypothesis states that: There is no difference in the efficacy of Arnica massage oil compared to the placebo (scented and non scented mineral oil) using objective and subjective measures in the treatment of chronic active trapezius myofascial trigger points. In this study we failed to reject the Null hypothesis.

### **5.2.1 Discussing the Objective and Subjective outcomes**

#### **5.2.1.1 Massage**

The claims made by many authors (Auleciems, 1995; Bruce, 1995; Friction, 1994 and Rosen, 1994) about the therapeutic effects of massage on muscle aches and pains are confirmed by the increase in digital algometer readings and the decrease in NRS 101 readings in Groups 1 and 2 (as reflected by the profiles in Figures 3 and 4 respectively).

#### **5.2.1.2 Scent Effect**

Since most essential oils are scented, this study utilised a placebo scented oil to determine any therapeutic benefit of scent. The mineral oil was scented by perfume oil which contained no active ingredients. Both digital algometer and NRS 101 readings were almost the same as those in the plain mineral oil group (Group 1). Scent did not add to the therapeutic effect of massage when compared to the unscented placebo group. As a result both Group 1 and Group 2 measurements were combined and compared against the Arnica Massage oil group (Group 3). Essential oils can enter the body via inhalation, skin penetration or the oral route (Battaglia, 2005). Arnica is an essential oil with a unique scent and we therefore cannot exclude the aromatic effect it could have had on subjects in Group 3. The area that was massaged was in close proximity to the subject's nose; therefore, it is possible that some of the essential oil entered the circulation via inhalation (through the nasal capillaries) resulting in a reinforcement (together with absorption through the skin) of the anti-inflammatory

effects (Battaglia, 2005). This implies that a minute amount of the active ingredients in Arnica Massage oil entered the circulation. However, the scented placebo oil could have also been inhaled by the subjects and since it contained no active ingredients, the therapeutic benefits were minimal when compared to Arnica Massage oil.

### **5.2.1.3 Factors affecting absorption of essential oils**

From the literature review we determine that essential oils are absorbed through the skin (epidermis) and transported by the capillary blood circulating in the dermis below. Blood flow in the skin is low compared to the muscle below and massage is expected to increase the rate of absorption as it greatly enhances blood flow. But there are many factors, according to Battaglia (2005), which can affect absorption of essential oils into the skin such as:

- a) The integrity of the stratum corneum- any conditions (e.g. eczema, psoriasis, diabetes) that are known to either thicken or thin the skin may cause decreased absorption (for thickened skin as seen in eczema), or increased absorption (for thin skin as seen in psoriasis and diabetes). None of the subjects used in this study were reported to having eczema or psoriasis. But 17 subjects had Type II diabetes mellitus in the following distribution: Group1=5, Group 2=4, Group 3=4, and Group 4=4. Therefore any changes caused by this condition would have affected each group equally.
  
- b) Skin hydration- skin hydration occurs through bathing, sweating, being in an area of high humidity, occlusion (application of an occlusive dressing increases skin hydration, this can be in the form of wearing clothes, bandages, plasters, masks and materials such as petroleum jelly) or application of a film forming product such as a moisturiser. Water increases the absorption ability of the stratum corneum and taking a hot bath or shower stimulates blood flow in the dermis which can increase the absorption of essential oils. Subjects in this study were instructed on having three oil applications at breakfast, lunch and supper times. The breakfast and supper applications could have coincided with the



bathing times of subjects therefore increasing the absorbability of the essential oil applications at these times.

- c) Viscosity of base oils- viscosity refers to the thickness of the carrier oil being used. The more viscous the carrier-oil the slower the absorption of the essential oil into the skin. Essential oils are highly soluble in vegetable oils but the saturation of these also effects absorption (polyunsaturated oils are absorbed easier than monounsaturated oils).
- d) Temperature- Either a rise in ambient room temperature or the use of warm oil will lead to an enhanced absorption. Such conditions would also increase vaporisation, thus increasing the amount of essential oil inhaled. As mentioned before, the breakfast and supper oil applications could have coincided with the subjects bathing times therefore the oil used after a hot bath or shower would be warmed up by the increased body temperature.
- e) The use of surfactants- Surfactants (surface active agents) are widely used in skin products to serve a variety of functions. It has been found that many surface active agents such as soaps and detergents can increase the permeability of the skin. Again we can assume that the use of surfactants may have coincided with the breakfast and supper applications as most people bathe at these times.

#### **5.2.1.4 *Arnica Montana* Essential oil**

Group 3 performed significantly better than the placebo groups with regards to both subjective and objective outcomes, massage alone cannot account for this added benefit as it (massage) was done by subjects in all treatment groups. Therefore we can conclude that *Arnica Montana* is responsible for the added increase (over and above the increase caused by massage alone) in digital algometer readings and added decrease (over and above the decrease caused by massage alone) in NRS 101 readings.

The time group effects shown on Tables 3 and 4 (for objective and subjective measurements) had a p-value of 0.01 which is significant (significance is described as a p value of less than 0.05 ( $p < 0.05$ )). This significance was found in the Arnica Massage oil group, meaning that the difference between the placebo groups and the Arnica massage oil group could only be accounted for by the presence of *Arnica Montana*. Application of the oils was at three time frames (breakfast, lunch and supper times) and the breakfast and supper applications could have been made after the subjects had taken a hot bath or shower. Water increases the absorption ability of the stratum corneum and taking a hot bath or shower stimulates blood flow in the dermis which can increase the absorption of essential oils. The soaps used during a bath or shower could have acted as surfactants and therefore further increased the permeability of the skin. It is also entirely possible that *Arnica Montana* has greater skin permeability irrespective of the condition of the skin. This claim, however, needs to be further investigated.

Essential oils are generally diluted in a base of vegetable oil (carrier oil) for aromatherapy massage treatments. The recommended dilutions are between 1% and 5% (Battaglia, 2005). The dilution of *Arnica Montana* into the carrier oil (grape-seed oil) was 5% in this study. Based on the results of this study, this appears to be an appropriate dilution percentage.

### **5.3 ANALYSING THE SECOND NULL HYPOTHESIS**

The second Null hypothesis states that: There is no difference in the efficacy of Blue Steel Arnica Massage oil compared to the placebo (scented and non scented mineral oil) using objective and subjective measures in the treatment of chronic active trapezius myofascial trigger points. In this study we failed to reject the Null hypothesis.

#### **5.3.1 Discussing the Objective and Subjective outcomes**

As mentioned previously, massage was responsible for the increase in digital algometer readings and the decrease in NRS 101 readings in Groups 1 and 2 as

stated by Friction (1994), Rosen (1994), Auleciems (1995) and Bruce (1995). But because Group 4 performed significantly better than the placebo groups with regards to both subjective and objective measurement, massage alone cannot “take credit” for this added benefit as it was done by subjects in all four groups.

Blue Steel Arnica Massage oil contains a blend of essential oils with known analgesic and anti-inflammatory effects (Macedo *et al.* 2004, Gertsch *et al.* 2003 and Kneusel *et al.*, 2002). Absorption of these oils into the muscle capillaries (aided by massage) exerts its physiological effects against inflammation in painful muscles.

It is worth noting that Blue Steel Arnica Massage oil contains *Arnica Montana* as an active ingredient. Therefore the factors that facilitated the absorption of *Arnica Montana* could have the same effect for the Blue Steel Arnica Massage oil. At this point, we can speculate that Blue Steel Arnica Massage oil was superior to the placebo oils due to the effect of *Arnica Montana* and the blend of essential oils.

## **5.4 ANALYZING THE THIRD NULL HYPOTHESIS**

The third Null hypothesis states that: There is no difference in the efficacy of Blue Steel Arnica massage oil compared to Arnica Massage oil using objective and subjective measures in the treatment of chronic active trapezius myofascial trigger points. In this study we accepted the Null hypothesis.

### **5.4.1 Objective and Subjective measures**

There was no significant difference with regards to subjective and objective measures between the two groups (Arnica Massage oil and Blue Steel Arnica Massage oil) as illustrated by Figures 7 and 8. Group 4 failed to perform better than Group 3 with regards to both subjective and objective measures, we cannot claim that Blue Steel Arnica Massage oil, an essential oil blend, is better than Arnica Massage oil. The results were almost parallel for both massage oils.

#### **5.4.1.1 Essential oil blends**

When blending essential oils for massage, a dilution of 1% and 2% is recommended instead of 1%-5% (Battaglia, 2005). It is possible that a higher dilution percentage may exert toxic rather than therapeutic effects. Absorption of essential oils blends depend on the skin area covered and the permeability of the skin (Battaglia, 2005).

The exact dilution percentage of the essential oil blend in Blue Steel Arnica Massage oil is not revealed by the manufacturers, possibly due to commercial competition. It is possible that the dilution percentage is different to that recommended by Battaglia (2005) and this could explain why Blue Steel Arnica Massage oil was not significantly better than Arnica Massage oil.

#### **5.4.1.2 Factors affecting essential oil quality**

According to Tisserand (1995) and Lawrence (1980) the quality of essential oils can be influenced by contamination (contaminants may include pesticides) and adulteration (adulterants may include synthetic constituents [e.g. synthetic phenyl ethyl alcohol, occurring naturally in rose otto, Price and Price 2002]). Furthermore, according to Battaglia (2005), plant pesticides can contaminate and chemically degrade essential oils found in a plant. It is possible that the extraction process of the essential oil does not fully remove the pesticide contaminant (if pesticides are used on the essential oil plants). This could contribute to the gradual “inertness” of the essential oil blend.

Prolonged storage and exposure to heat and light are other factors that contribute to chemical degradation of essential oil blends (Orafiduja, 1993) similar to pharmaceutical products. No specific storage instructions were given to the subjects. Therefore some form of chemical degradation of the essential oils could have occurred during storage by subjects. This possibility could have been avoided by giving prior instruction to the subjects and by giving the samples in dark coloured bottles (all Blue Steel Arnica Massage Oil bottles are black).

## **5.5 REPORT OF SIDE EFFECTS**

None of the subjects reported any side effects implying that these oils are generally safe to use by the general public. But it must be noted that the sample size of this study was small. Side effects may be noted in studies with larger sample sizes and in studies where subjects are subjected to chronic exposure to the essential oils. The researcher recommends that a physician's advice be sought prior to the use of these oils.

## **5.6 CLINICAL SIGNIFICANCE**

Table 9 shows that there was on average a 41% decrease in NRS 101 readings in the study overall. The decrease of NRS 101 readings was highest in the Arnica Massage oil and Blue Steel Arnica Massage oil groups (51.6% and 50.1% respectively). The benchmark of clinical significance was set at 50% in this study. Both treatment groups achieved on average over 50% decrease in pain over the study period, which means that subjects in the Blue Steel Arnica Massage oil group and in the Arnica Massage oil group felt that their pain had been reduced by more than 50% at the second consultation after the five days of self-administered treatment.

This finding is important as both these products can be recommended by therapists for the effective relief of muscular aches and pains for subjects as part of a home treatment program, provided that they are used on a regular basis similar to that of the study. However, the long-term efficacy of these products has not yet been established.

# CHAPTER 6

## CONCLUSION AND RECOMMENDATIONS

### 6.1 CONCLUSION

This was a double blinded, randomized, placebo controlled clinical study comparing the efficacy of two different massage therapy oils in the treatment of chronic active trapezius myofascial trigger points.

Arnica massage oil was tested against two placebo groups (plain mineral oil and scented mineral oil) and even though on average there was a 40% decrease in NRS 101 readings, the group containing Arnica Massage oil had a 51.6% decrease in NRS 101 readings. A reduction of 50% is clinically significant as it indicates that subjects felt that their pain had been reduced by half after only five days of treatment. This finding has clinical relevance to therapists as they too can use Arnica Massage oil with confidence in its effectiveness in the treatment of myofascial pain syndromes.

Blue Steel Arnica massage oil was tested against two placebo groups (plain mineral oil and scented mineral oil) and even though on average there was a 40% decrease in NRS 101 readings, the group containing Blue Steel Arnica Massage oil had a 50.1% decrease in NRS 101 readings, a clinical significance similar to Arnica Massage oil.

Blue Steel Arnica Massage oil was tested against Arnica Massage oil to establish whether or not an added essential oil blend (the Blue Steel brand contains *Arnica montana*, *Lavendula angustifolia*, *Thymus vulgaris*, *Rosemarinus officinalis* and *Calendula officinalis*) containing essential oils with similar physiological effects (anti-inflammatory and analgesic effects) is more effective than just one essential oil containing anti-inflammatory and analgesic effects (*Arnica montana*). Theoretically an essential oil blend containing essential oils with the same/similar physiological effects should be more efficacious because of the synergistic activity that is unique to an

essential oil blend (Battaglia, 2005). Blue Steel Arnica Massage oil was not statistically significant in its efficacy when compared to Arnica Massage oil as their objective and subjective measurements were almost equal as shown by the parallel profiles in Figure 7. According to our findings, the use of Arnica Massage oil or Blue Steel Arnica Massage oil resulted in almost 50% pain reduction in the subjects after five days of self-administered treatment. Both these products can be recommended for the treatment of myofascial pain syndromes but one cannot be placed in preference to the other as the results were similar with regards to their effectiveness.

## **6.2 RECOMMENDATIONS**

- The sample size could be increased as each group consisted of only 20 subjects. This would reduce the possibility of Type I or Type II errors (Graziano and Raulin, 2004)
- The dilution percentage (%) of essential oil blends needs to be investigated for determining the correct dilution % for therapeutic efficacy and for toxic dilution %.
- A one-month follow-up should be included in future studies to determine the long-term efficacy of the massage oils.
- Another study can be done comparing the effectiveness of essential oil massage treatment (non-invasive treatment) to the effectiveness of dry needling (invasive treatment) in the treatment of myofascial pain syndromes.
- Patients may be advised to apply massage oils after a warm shower/bath to enhance absorption.
- Guidelines on correct storage should be emphasized on the bottle containing the essential oil as incorrect storage (e.g. exposure to direct sunlight) may result in the degradation of the massage oils.

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

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:

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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:**

	<b>Complaint 1</b>	<b>Complaint 2</b>
< 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

**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: B**

**Durban Institute 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

NEUROLOGICAL EXAMINATION: See Regionals

**Clinician:**

**Signature :**



**APPENDIX: C**

**DURBAN INSTITUTE OF TECHNOLOGY  
REGIONAL EXAMINATION - CERVICAL SPINE**

Patient: \_\_\_\_\_ File No: \_\_\_\_\_

Date: \_\_\_\_\_ Student: \_\_\_\_\_

Clinician: \_\_\_\_\_ Sign: \_\_\_\_\_

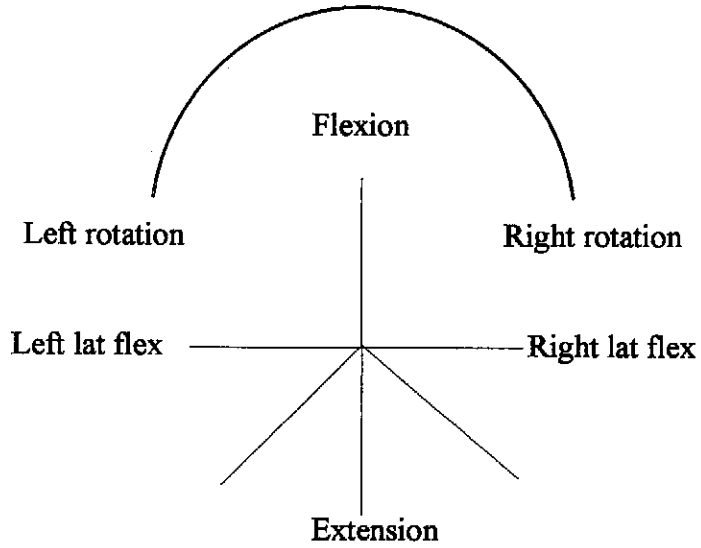
**OBSERVATION:**

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

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

**RANGE OF MOTION:**

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



**PALPATION:**

- Lymph nodes
- Thyroid Gland
- Trachea

**ORTHOPAEDIC EXAMINATION:**

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

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

**NEUROLOGICAL EXAMINATION:**

Dermatomes	Left	Right	Myotomes	Left	Right	Reflexes	Left	Right
C2			C1			C5		
C3			C2			C6		
C4			C3			C7		
C5			C4					
C6			C5					
C7			C6					
C8			C7					
T1			C8					
			T1					
<b>Cerebellar tests:</b>		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:

Upper Thoracics:  
 Motion Palpation:  
 Joint Play:

**BASIC EXAM: SHOULDER:**

Case History:

**BASIC EXAM: THORACIC SPINE:**

Case History:

ROM: Active:  
 Passive:  
 RIM:  
 Orthopaedic:  
 Neuro:  
 Vascular:  
 Observ/Palpation:

ROM: Motion Palp:  
 Active:  
 Passive:  
 Orthopaedic:  
 Neuro:  
 Vascular:  
 Observ/Palpation:

**APPENDIX: D**

**Patient Information Sheet**

Dear patient,  
I hope you thoroughly enjoy taking part in my research study!

Supervisor: Dr. J. Shaik

Research Student: Claudia Pedlar (039) 9741579 / (084) 2682424

Title of my research

- **A comparative study to determine the efficacy of two different massage therapy oils in the treatment of chronic, active trapezius myofascial trigger points.**

Procedure:

Eighty subjects will be required to participate in the research. Participation will be determined by whether or not you fit the inclusion criteria. A full case history, physical examination and cervical spine regional will be performed. You will be randomly allocated into one of 4 groups by choosing out of a hat a piece of paper with 1, 2, 3 or 4 on it. Two groups will receive treatment with the active oil and the others receive treatment with an oil of no known effects (this will be the control group) giving you a 50 % chance of being in the group receiving the active oil. Each subject will have the active trigger points located and marked with henna after which certain measurements will be taken. You will be handed your oil and given a five-day diary in which you will be required to note the application of the oil. A limit of four squirts of oil will be used in order for everyone to have the same dose of oil. You will return after the five-day period to hand in your diary and have the final measurements taken. Should you gain relief before the five-day period, please continue with the application making sure to record it on the diary. The development of any adverse reaction must be reported to the researcher immediately and no further applications of the oils should be made.

Exclusion or withdrawal from the study without your consent will occur if you:

- Take any kind of medication for this condition during the research period.
- Receive any other treatment for this condition.
- If you injure the area during the research.
- If you do not agree to comply with the research requirements.
- If you develop any undesired/ allergic reaction to the oil. In this case you will be referred to a medical doctor for a consultation at our cost.

Benefits:

Your participation in this study is voluntary and you may withdraw at any time. Feel free to contact the research faculty officer Mr. V. Singh at (031) 2042701 research faculty department, if you have any queries.

Thank you for participating in this study.  
Yours faithfully

-----  
Claudia Pedlar  
Chiropractic Intern/ Researcher

-----  
Dr. Junaid Shaik  
(Supervisor)

**APPENDIX: E            INFORMED CONSENT FORM**

Date: \_\_\_\_\_

To be completed in duplicate by patient.

**TITLE OF RESEARCH**

A comparative study to determine the efficacy of two different massage therapy oils in the treatment of chronic, active trapezius myofascial trigger points.

**NAME OF RESEARCH STUDENT**

Claudia Pedlar

**NAME OF SUPERVISOR**

Dr. Junaid Shaik

**PLEASE CIRCLE THE APPROPRIATE ANSWERE**

- 1. Have you read the research information sheet? Yes/No
- 2. Have you had an opportunity to ask questions? Yes/No
- 3. Have you received satisfactory answers to your questions? Yes/No
- 4. Have you had an opportunity to discuss this study? Yes/No
- 5. Have you received enough information about this study? Yes/No
- 6. Do you understand the implications of your involvement in this study? Yes/No
- 7. Do you understand that you are free to withdraw from this study? Yes/No
  - a) At any time.
  - b) Without having to give a reason for withdrawal, and
  - c) Without affecting your future health care.
- 8. Do you agree to voluntarily participate in this study? Yes/No

Please do not sign unless all your questions have been adequately answered by your researcher.

Fill in bellow in block letters

PATIENT/ SUBJECT            Name: \_\_\_\_\_            Signature: \_\_\_\_\_

WITNESS                            Name: \_\_\_\_\_            Signature: \_\_\_\_\_

RESEARCH STUDENT            Name: \_\_\_\_\_            Signature: \_\_\_\_\_

**APPENDIX: F**

**SUBJECTS NAME:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

	TIME	NUMERICAL PAIN RATING SCALE (0-10)										
<b>BREAKFAST</b>	6:00am	0	1	2	3	4	5	6	7	8	9	10
	7:00am	0	1	2	3	4	5	6	7	8	9	10
	8:00am	0	1	2	3	4	5	6	7	8	9	10
	9:00am	0	1	2	3	4	5	6	7	8	9	10
<b>LUNCH</b>	12:00am	0	1	2	3	4	5	6	7	8	9	10
	13:00am	0	1	2	3	4	5	6	7	8	9	10
	14:00am	0	1	2	3	4	5	6	7	8	9	10
	15:00pm	0	1	2	3	4	5	6	7	8	9	10
<b>SUPPER</b>	18:00pm	0	1	2	3	4	5	6	7	8	9	10
	19:00pm	0	1	2	3	4	5	6	7	8	9	10
	20:00pm	0	1	2	3	4	5	6	7	8	9	10
	21:00pm	0	1	2	3	4	5	6	7	8	9	10

**DATE:** \_\_\_\_\_

	TIME	NUMERICAL PAIN RATING SCALE (0-10)										
<b>BREAKFAST</b>	6:00am	0	1	2	3	4	5	6	7	8	9	10
	7:00am	0	1	2	3	4	5	6	7	8	9	10
	8:00am	0	1	2	3	4	5	6	7	8	9	10
	9:00am	0	1	2	3	4	5	6	7	8	9	10
<b>LUNCH</b>	12:00am	0	1	2	3	4	5	6	7	8	9	10
	13:00am	0	1	2	3	4	5	6	7	8	9	10
	14:00am	0	1	2	3	4	5	6	7	8	9	10
	15:00pm	0	1	2	3	4	5	6	7	8	9	10
<b>SUPPER</b>	18:00pm	0	1	2	3	4	5	6	7	8	9	10
	19:00pm	0	1	2	3	4	5	6	7	8	9	10
	20:00pm	0	1	2	3	4	5	6	7	8	9	10
	21:00pm	0	1	2	3	4	5	6	7	8	9	10

**APPENDIX: G**

**Numerical Rating Scale - 101 Questionnaire**

**Date:** \_\_\_\_\_ **File no:** \_\_\_\_\_ **Visit no:** \_\_\_\_\_

**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: H**

**ARE YOU BETWEEN 30 - 60 YEARS**

**ARE YOU SUFFERING FROM**

**CHRONIC NECK AND  
SHOULDER PAIN**

(Pain longer than three weeks duration)

Research is currently being conducted at the  
**DURBAN INSTITUTE OF TECHNOLOGY**

**CHIROPRACTIC DAY CLINIC**

If you qualify for the study, treatment will be  
**FREE** of charge. Should you be interested, please  
contact

**CLAUDIA**

At the D.I.T. Chiropractic Day Clinic

**Phone: (031) 2042205 / 2042512**