

THE THERAPEUTIC EFFICACY OF ACTION POTENTIAL  
THERAPY IN THE TREATMENT OF MYOFASCIAL PAIN  
SYNDROME.

By

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### **DEDICATION**

This dissertation is dedicated to my late dad Nelson Chettiar, my mom Pushpa and my wife Morgesh, for their continued sacrifice, support and encouragement and their constant belief in my ability to achieve my greatest ambitions.

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- Finally, all those patients who participated in this study, who through their contribution have made this study possible.

## **ABSTRACT**

The purpose of this investigation was to determine the relative efficacy of Action Potential Therapy (APT) as opposed to placebo Action Potential Therapy in the treatment of myofascial pain syndrome.

The study was a prospective, randomized, placebo controlled study. The study consisted of two groups of thirty subjects each, which were selected from the Durban Metropolitan area. Only subjects diagnosed as having active trigger points in either the trapezius or gluteus medius muscle were accepted into the study.

Each subject received four treatments over a period of seven to ten days. Group one received an active form of Action Potential Therapy while group two received placebo Action Potential Therapy.

Subjective assessment was by means of the short form McGill pain Questionnaire and the Numerical Pain Rating Scale-101. Objective assessment was by means of an algometer and the Myofascial Diagnostic Scale. Readings were taken twice for each patient. The first assessment was conducted at the initial consultation prior to the first treatment, and the second assessment was completed during the last consultation after the treatment.

Intra-group comparisons were made using the parametric two-sample paired t-test and the non-parametric Wilcoxon signed rank test. For the inter-group comparison, the parametric two-sample unpaired t-test and non-parametric Mann-Whitney unpaired U test were used. Statistical analysis was completed at a 5% significance level.

Statistical analysis of all subjective and objective measurements taken for the treatment group displayed a significant improvement. However, the control group only demonstrated significant differences for the myofascial diagnostic scale and the McGill measures. Therefore it may be concluded that improvement occurred in both groups between the first and fourth consultation, however the treatment group showed more favorable results.

The comparison of both subjective and objective data taken at the fourth consultation all indicated a statistically significant difference between the two groups. The data suggested that the treatment group responded more positively to the treatment protocol than the control group to the placebo intervention.

It was concluded that Action Potential Therapy was not only effective in treating patients with myofascial pain syndrome, but it was also more effective than placebo Action Potential Therapy in terms of both subjective and objective clinical findings.

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### **DEFINITION OF TERMS.**

**Action Potential:** Action potential is the propagation of a nerve impulse (Guyton, 1992:47).

**Action Potential Therapy:** Action Potential Therapy is a low-frequency current that simulates or mimics the naturally occurring action potential in a neuron. It is applied to the affected area via electrodes and is associated with pain alleviation, enhanced joint flexibility, a decrease in oedema due to improved circulation and possibly, reduced inflammation (Berger, 1999:11).

**Active locus (of a Trigger point):** A minute region in a muscle that exhibits spontaneous electrical activity and that may or may not also exhibit spike activity characteristic of single fibre action potentials. (Travell, Simons and Simons, 1999:1.)

**Active Myofascial Trigger point:** A myofascial trigger point that causes a clinical pain complaint. It is always tender, prevents full lengthening of the muscle, weakens the muscle, refers a patient-recognized pain on direct compression, mediates a local twitch response of muscle fibres when adequately stimulated, and, when compressed within the patient's pain tolerance, produces referred motor phenomena and often autonomic phenomena, generally in its pain reference zone, and causes tenderness in the pain reference zone. (Travell, Simons and Simons, 1999:1.)

**Latent Myofascial Trigger Point:** A myofascial trigger point that is clinically quiescent with respect to spontaneous pain; it is painful only when palpated. A latent trigger point may have all the other clinical characteristics of an active trigger point and always has a taut band that increases muscle tension and restricts range of motion. (Travell, Simons and Simons, 1999:4.)

**Local Twitch Response:** A transient contraction of a group of tense muscle fibres that traverse a trigger point. The contraction of the fibres is in response to stimulation of the same trigger point, or sometimes a nearby trigger point. (Travell, Simons and Simons, 1999:4.)

**Referred (Trigger-Point) Pain:** Pain that arises in a trigger point, but is felt at a distance, often entirely remote from its source. The pattern of referred pain is reproducibly related to its site of origin. The distribution of the referred trigger-point pain rarely coincides entirely with the distribution of a peripheral nerve or dermatomal segment. (Travell, Simons and Simons, 1999:6.)

**Taut Band:** The group of tense muscle fibres extending from a trigger point to the muscle attachments. The tension of the fibres is caused by contraction knots that are located in the region of the trigger point. Reflex contraction of the fibres in this band produces the local twitch response. (Travell, Simons and Simons, 1999:7.)



## CHAPTER 1

### INTRODUCTION

#### 1.1 THE PROBLEM AND ITS SETTINGS.

Myofascial pain syndrome is a regional muscular disorder that results from myofascial trigger points (Lee *et al.*, 1997). A trigger point is a hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. Snapping or palpation of the band may produce a local twitch response. The spot is painful on compression and can give rise to characteristic referred pain, referred tenderness, motor dysfunction, and autonomic phenomena (Travell, Simons and Simons, 1999:5).

Trigger points can be latent or active, depending on clinical characteristics. Latent trigger points result in muscle stiffness, weakness, limited range of motion, and dysfunction without persistent pain. In this situation, the body has adapted to the trigger point and thus the pain is not always apparent. In addition to the symptoms of latent trigger points, active trigger points cause pain and restricted motion and are associated with specific patterns of referred pain. (Han and Harrison, 1997.)

Myofascial pain syndrome has gone by a variety of names throughout the years. As early as the mid-1800's, reference to myofascial – type pain was recorded in medical journals. The condition has been known as muscular rheumatism, myalgia, myogelosis, interstitial myofibrositis, fibromyositis, myofasciitis and many others (Auleciems, 1995).

In 1990 Friction *et al.* reported that myofascial pain syndrome was regarded by some as a specific disease entity, by others as a wastebasket term for soft tissue complaints, and by others as simply non-existent. They suggest that the confusion regarding the syndrome may stem from lack of obvious organic findings, the lack of unified theory to explain it, and the

inconsistencies in the literature defining the syndrome. Adding to the problem, differences in terminology often made it difficult in knowing whether or not different investigators were examining patients with basically the same medical condition (Travell, Simons and Simons, 1999:57). Friction (1994) suggested that myofascial pain syndrome is frequently overlooked as a diagnosis because it is often accompanied by signs and symptoms in addition to pain, coincidental pathological conditions, and behavioural and psychosocial problems. } \* Q

It is the opinion of Hong (1999) that in the last 10 –15 years, many clinical and basic science research studies of myofascial trigger points have been published. He adds that the pathophysiology of a myofascial trigger point is now much clearer. Lee et al. (1997) state that through the recent efforts of several authors, myofascial trigger points have become widely accepted in the aspects of both clinical practice and research. } \* Q

Travell, Simons and Simons, (1999: 13) suggest that although muscles in general and trigger points in particular receive little attention as a major source of pain and dysfunction, its clinical importance to practitioners has been described in the literature for acupuncturists, anaesthesiologists, chronic pain managers, dentists, family practitioners, gynaecologists, neurologists, nurses, orthopaedic surgeons, paediatricians, physical therapists, physiologists, rheumatologists and veterinarians.


{ Myofascial pain syndrome is one of the most common painful muscular dysfunction found in patients (Hong et al., 1993). According to Travell, Simons and Simons, (1999:12) myofascial trigger points are extremely common and become a distressing part of nearly everyone's life at one time or another. 1

The syndrome is one of the least understood yet commonly encountered problems in the outpatient setting. Unfortunately, the condition often goes unrecognised, mis-diagnosed, mistreated, leading to unnecessary pain, suffering and disability (Auleciems, 1995). } \* Q

The disability that may result from unresolved myofascial pain is a self-limited phenomenon. In other words the patients functional capacities are secondary to the patients perception of pain and his or her interpretation of that perception. It is this perception that ultimately defines the person's ability to meet personal, social or occupational demands. (Rachlin, 1994: 97-99.)

Roth et al. (1998) examined patient knowledge of pain diagnosis and their satisfaction with pain treatment. They concluded that myofascial pain syndrome patients were significantly less accurate in identifying their diagnosis and believed that they suffered a physiological disturbance more serious and different than their physicians had suggested. They also expressed more dissatisfaction with physician's effort to treat their pain. Friction (1994) reports that the mean duration of pain is six years, with the mean of 4.5 clinicians seen for the condition.

According to Han and Harrison (1997) the four most frequently used modalities in the treatment of myofascial pain syndrome include trigger point injection; dry needling; spray and stretch and Transcutaneous electrical nerve stimulation (TENS). 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.

A handwritten bracket on the right side of the text, spanning from the sentence about Hong et al. (1993) down to the sentence about the management of myofascial pain syndrome. An asterisk is written next to the bracket.

The use of electricity as a therapeutic modality dates as far back as the Egyptian era; stone carvings in the tombs from the fifth dynasty (about 2500 BC) depict the use of a species of catfish found in the Nile for the treatment of painful conditions (Walsh et al., 1995). Despite this early interest in electroanaesthesia, it was only thirty years ago that Melzack and Wall's (1988: 98) gate control theory provided a neurophysiological mechanism for electrical stimulation analgesia. This theory acted as a catalyst in making electrical treatment modalities such as TENS a popular treatment regime for relief of pain.

The TENS modality has been successfully employed to treat trigger points as demonstrated by Hutchings (1998). Graff-Radford *et al.* (1989) found that TENS was effective in treating myofascial pain, however trigger point sensitivity was essentially unchanged and concluded that TENS therapy alone may not be sufficient to produce long term effect in treating myofascial pain syndrome.

Hsueh *et al.* (1997) studied the immediate effectiveness of electrotherapy on myofascial pain syndrome. They concluded that electrical nerve stimulation is more effective for immediate relief of myofascial trigger point pain than electrical muscle stimulation. The latter has better effect on immediate release of muscle tightness than electrical nerve stimulation.

Action Potential Therapy (APT) is a relatively new modality that was developed in South Africa in 1992. The modality has been used by both the lay public and the health profession as a stand-alone treatment of various musculoskeletal conditions (Berger, 1999:11). "The current emitted by the action potential unit causes cycle synchronous depolarisation of nerve fibres. It is postulated that the device may augment neuronal activity to areas where inflammatory processes occur, allowing biochemical wastes to be dispersed more effectively as well as facilitating lymph drainage. It is believed that action potential therapy may be useful in pain management, to restore mobility to stiff joint and muscles, to reduce swellings, to relieve tension and to improve blood circulation" (Berger and Matzner, 1999:27-28).

## **1.2 AIM OF THE STUDY.**

The aim of this investigation was to determine the efficacy of "Action Potential Therapy" in the treatment of myofascial pain syndrome.

### **1.3 OBJECTIVE OF THE STUDY.**

**1.3.1** The first objective was to evaluate the efficacy of “action potential therapy” in the treatment of myofascial pain syndrome in terms of subjective clinical findings.

**1.3.2** The second objective was to evaluate the efficacy of “action potential therapy” in the treatment of myofascial pain syndrome in terms of objective clinical findings.

### **1.4 HYPOTHESES**

#### **1.4.1 HYPOTHESIS ONE.**

It was hypothesised that “action potential therapy” would be effective in treating patients with myofascial pain syndrome.

#### **1.4.2 HYPOTHESIS TWO.**

It was hypothesised that “action potential therapy” would be more effective than placebo “action potential therapy” in the management of patients with myofascial pain syndrome.

### **1.5 BENEFITS OF THE STUDY.**

It is the opinion of Rachlin (1994:31) that much of the recommended treatment strategies for myofascial pain syndrome remains empirical and many often used modalities are essentially unproven. This has fostered the development of many disparate types of therapeutic interventions.

Since action potential therapy is a relatively new modality, most of the evidence for the use of this type of therapy is based on anecdotal information rather than randomised controlled clinical trials.

This study serves as a scientific investigation to establish if this modality can effectively treat myofascial pain syndrome, and not just be added to the list of unproven treatment interventions for the condition.

It is hoped that this investigation will add to the pool of knowledge regarding the conservative management of myofascial pain syndrome.

## CHAPTER 2

### 2.0 REVIEW OF THE LITERATURE.

#### 2.1 PREVALENCE AND INCIDENCE OF TRIGGER POINTS

It is the opinion of Friction (1994) that myofascial pain is the most common cause of persistent regional pain such as back pain, shoulder pain, tension-type headaches and facial pain.

In a study by Sola et al. (1954) which involved 200 unselected, asymptomatic basic airmen (100men and 100 women) with a mean age of nineteen, 99 (49.5%) were found to have one or more trigger points (active or latent) in the shoulder-girdle muscle. The female group showed somewhat of a higher incidence, with 55% of the females patients having positive findings compared to 45% of the male patients. Of the 99 subjects having trigger points 62 had multiple trigger points, with a slightly higher incidence in the male patients.

Skootsky et al. (1989) studied myofascial pain in a general internal medicine practice and found that among those patients that presented with pain, 29.6% were found to have myofascial pain as the cause of their pain.

According to Han and Harrison (1997), the incidence of myofascial pain syndrome (MPS) with associated trigger points (trps) appear to vary between 30 and 85% of the people presenting to pain clinics in America. Furthermore they add that although the condition is clearly found in both sexes, it is more prevalent in women.

Banks et al. (1998) reports that patients with this condition in the United States account for over 70 million visits to physicians and 425 million visits to Chiropractors.

A recent study by Chaiamnuay et al. (1998) examined and interviewed 2463 rural Thailand subjects and found that 36.2% had musculoskeletal pain of which MPS was the second most common diagnosis.

It is the opinion of Travell, Simons and Simons (1999: 12) that the wide range in the prevalence of myofascial pain that is reported in various studies is in part due to the following: differences in the patient populations examined and in the degree of chronicity; differences in criteria used to make the diagnosis of myofascial trigger points; and most important, differences in the training and skill level of the examiners.

## **2.2 AETIOLOGY OF TRIGGER POINTS**

Gatterman (1990: 291) states that many factors interact to create trigger points. Usually, one stress activates the trigger point, and then other factors perpetuate it.

According to Travell, Simons and Simons (1999: 110-112) acute events may precipitate a sudden onset of symptoms, while chronic stresses are likely to produce a gradual onset of trigger point symptoms. The latter has a tendency to perpetuate the activation of trigger points.

The mechanical stresses that tend to activate myofascial trps acutely include stresses such as a wrenching movement, automobile accidents, falls, fractures, joint sprains, dislocations, or a direct blow to the muscle. Acute onset may also be associated with an episode of excessive or unusual exercise.

Other examples of stresses that may activate myofascial trigger points are listed below:

-Travell, Simons and Simons (1999: 111) suggests that iatrogenic causes must not be excluded. Examples of these include: intramuscular injection of a medicinal substance at the site of a latent trigger point may activate the trp; therapeutic interventions such as spray and



stretch may activate latent trps in the antagonist muscle incidentally- this may occur, as one group of muscles is being passively stretched, its antagonist is shortened much more than normal; another example of this, is the application of needling therapy used to inactivate trigger points. This intervention usually causes referred pain in the reference zone. In some instances the pain may be so intense that it may activate trigger points in this zone.

-Myofascial trigger points may develop secondary to other conditions. An example of this is demonstrated by Chu (1997), who suggested that trigger points may develop in muscles innervated by a compressed nerve.

\* { -Kathleen et al. (1984) suggests that "nervous tension" associated with emotional stress or psychosocial tension can induce trigger points. *(emotional) stress*

-Direct cooling may activate -latent trigger points in a fatigued muscle as in a cold draft from an air conditioner.

It is the opinion of Travell, Simons and Simons (1999: 111), that in patients where the onset of symptoms is gradual, most of these patients cannot remember when or why the pain started. According to these authors it is imperative to establish the aetiology as chronic overload may perpetuate and intensify the trigger points symptoms. Examples of chronic stresses are discussed in more detail in section 2.3 of this chapter.

### **2.3 PERPETUATING FACTORS.**

According to Graff-Radford et al. (1987) pain associated with myofascial trigger points is perpetuated by factors that affect or stress the muscle containing the trigger point.

Travell, Simons and Simons (1999: 110-112) present a concise description of the perpetuating factors of myofascial trigger points. A summary of this description follows:

1. Mechanical stresses: Common sources include skeletal asymmetry and disproportion.

Skeletal asymmetry may include a short leg or a small hemi pelvis whereas disproportion

includes a long second metatarsal and short upper arms. Other significant contributing factors include misfitting furniture, poor posture and prolonged immobility.

2. Nutritional inadequacies: This includes abnormally low levels of the B vitamins (especially B1, B6, B12 and folic acid) and of vitamin C. Adequate calcium, potassium, iron and several trace minerals are essential for normal muscle functioning.
3. Metabolic and endocrine inadequacies: This includes Hypothyroidism, hypocalcaemia, hyperuricemia, hypoxia and anaemia. These impair muscle metabolism and perpetuate the symptoms of the trigger points.
4. Psychological factors: These include depression, sick behaviour, secondary gain, anxiety, and tension
5. Chronic infection and infestation: These include bacterial and viral infection and parasite infestation. Viral infection particularly herpes simplex, result in an increase in symptoms. Bacterial infections such as, an abscessed or impacted tooth, sinusitis and chronic urinary tract infections, are implicated.
6. Other factors: The authors list allergic rhinitis, impaired sleep and nerve impingement as other factors that may perpetuate trigger points.

Although Rachlin (1994: 20) agrees with Travell and Simons, he states that there are no data to support any of these claims. He suggests that it may be reasonable to suspect that mechanical factors (including trauma and abnormal posture), psychological distress, acute viral or bacterial infections, and non-restorative sleep would aggravate either regional or generalized musculoskeletal pain. He adds that no data are currently available to support the notion that vitamin or endocrine deficiencies perpetuate MPS.

According to Friction (1994) poor muscle health caused by lack of exercise, muscle disuse or poor posture can also predispose, or perpetuate, the muscle to the development of trigger points. He suggests that postural discrepancies may contribute to joint displacement and abnormal functional patterns, and both of these can contribute to abnormal proprioceptive input and sustained muscle contraction in an attempt to correct the poor postural relationship.

Produce  
\*

The most common cause for recurring pain and dysfunction according to Rosen (1994) is the inadequate or incomplete rehabilitation of a previously painful process, which has presumably resolved without the patient having achieved a normal range of motion or normal stretch.

## **2.4 CLINICAL FEATURES.**

### **2.4.1 SYMPTOMS.**

Patients with MPS complain of regional persistent pain, most frequently located in the head, neck, shoulder, upper and lower extremities, and lower back. The pain, ranging from a mild ache to excruciating pain, is either sharp or dull, and is often associated with general fatigue and decreased range of motion and muscle strength. (Han and Harrison, 1997.)

7

Friction et al. (1985) have quantitated pain and other symptoms among 164 patients diagnosed with MPS of the head and neck region. 36.6% of the patients reported fatigue, 19.5% reported stiffness, 12.5% reported swelling, and 17.7% demonstrated weakness of the muscle involved.

The pain was variously described as pressure (48%), dull (27%), throbbing (26%), sharp (18%), burning (26%), and heavy (14%).

Beside pain, several other musculoskeletal and non-musculoskeletal symptoms were also present, including poor sleep, 'swelling', stiff joints, tinnitus, fatigue, paraesthesia, nausea,

and constipation. Self reported depression and anxiety were present in 21% and 18%, respectively.

#### 2.4.2 SIGNS.


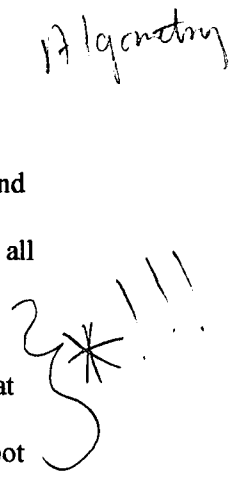
The most characteristic physical sign in MPS is the presence of trigger points (Friction et al., 1985; Travell, Simons and Simons, 1999: 21). Trigger points have been classified as either active or latent. An active trigger point has been defined as an area of tenderness on palpation in a taut band of a muscle, causing referred pain similar to the patient's spontaneous pain complaint. Additionally, a local twitch response should also be visible either to manual palpation to the tender spot or following a needle insertion into this spot. A latent trigger point has all of the above characteristics, except for absence of the referred pain similar to the patient's spontaneous pain symptom. (Travell, Simons and Simons, 1999: 22.)

Besides the presence of trigger points, the physical examination in MPS is normal, with an absence of objective joint swelling or neurological deficits. The range of motion in a joint may be decreased because of pain; similarly, the muscle strength may appear to be decreased secondary to pain.

x { Palpation of the affected muscle by applying sustained deep pressure is the method most frequently used in the diagnosis of trigger points (Han and Harrison, 1997). According to Travell, Simons and Simons (1999: 21), by gently rubbing across the direction of the muscle fibres of a superficial muscle containing the trigger points, a taut band containing hypersensitive muscle fibres of harder than normal consistency is a typical finding. *Diagnosis*

Palpation along the taut band usually reveals a nodule (2-5 mm in diameter) exhibiting a highly localized, exquisitely tender spot that is characteristic of a trigger point. This tenderness has been studied to determine its reliability, its presence in normal subjects, and its association with presenting symptoms. Gerwin et al. (1997) demonstrated that spot

tenderness is one of the most reliable features of a trigger point. Reeves et al. (1986) and

 Hong (1998) both have established the reliability and validity of pressure algometry in documenting myofascial trigger points. They found that by using the pressure algometer, tenderness scores at individual trigger points had moderate to good reliability of the head and neck sites tested. In addition they found MPS patients had significantly more tenderness at all sites tested as compared to normal. Travell, Simons and Simons (1999:22) agree that spot tenderness is a reliable sign of a myofascial trigger point, however these authors suggest that examiners should take into account that if the pressure is applied 1-2 mm adjacent to the spot at the trigger point, this can result in a markedly reduced pain response. 

Palpating the active trigger point with sustained, deep, single finger pressure increases the pain in the zone of reference (areas of pain complaint), which can be distant from the muscle with the trigger point. The patterns of referral are reproducible and consistent with patterns of other patients with similar trigger points. (Fricton, 1994.)

Travell, Simons and Simons (1999) presented the most definitive description of these patterns in their textbook. According to these authors, if the patient 'recognises' the elicited sensation as a familiar experience, this establishes the trigger point as being active and is one of the most important diagnostic criteria available when the palpating findings are also present.

Hong and Torigoe (1994) reports similar recognition is frequently observed when a needle penetrates the trigger point and encounters an active locus.

The patient's behavioural reaction to firm palpation of a trigger point is a distinguishing characteristic of MPS and is termed a "positive jump sign". This reaction may include withdrawing the head, wrinkling of the face or forehead, or a verbal response such as 'that's it' or 'oh, yes' (Fricton, 1990).

A 'local twitch response' can also occur with palpation. Weeks and Travell first reported this in 1957. Placing the muscle in moderate passive tension and snapping the band containing the trigger point briskly with a firm pressure from a palpating finger moving perpendicularly across the muscle band at its most tender point can elicit this response. This can produce a reproducible visible shortening of the muscle band characteristic of the local twitch response. It is now known that a local twitch response can also be reproduced when a needle penetrates the active loci of a myofascial trigger point (Simons and Dexter, 1995).

Muscles with active myofascial trigger points have a restricted range of motion because of pain, as demonstrated by Macdonald (1980). In this study patients were required to report any increase in pain when the muscle was either actively, passively or isometrically contracted. Macdonald suggested that if a muscle were passively stretched beyond the restricted range of movement, this would increase the pain as the involved muscle fibres are already under substantially increased tension at the rest length. Furthermore Macdonald reports that if the same muscle is strongly contracted against fixed resistance, the patient's pain will increase.

Although weakness is generally characteristic of muscles with active myofascial trigger points, the magnitude is variable from muscle to muscle and from subject to subject. Electromyographic studies indicate that, in muscles with active trigger points, the muscle starts out fatigued, it fatigues more rapidly, and it becomes exhausted sooner than normal muscles. (Travell, Simons and Simons, 1999: 22.)

## **2.5 DIAGNOSTIC CRITERIA.**

Four well-designed studies have recently evaluated the reliability of various myofascial trigger point examinations. In 1992 Wolf et al. reported a study in which four experienced physicians evaluated the following characteristics of trigger points: spot tenderness, pain recognition, palpable band, referred pain and local twitch response. Although the examiners

had many years of independent experience, the achieved poor interrater reliability. Findings of a similar nature were reported by Nice et al. in 1992 and Njoo and Van der Does in 1994. In 1997 Gerwin et al. reported a double study in which they demonstrated why such results were obtained in the previous investigations. The methodology of the first part of the study was similar to the previous three investigations and achieved the same poor interrater reliability. A second study was conducted using the same examiners, however this was done following a three hour training session. In addition an agreement pertaining to the examination technique among the doctors was assessed statistically and found to be reliable before proceeding with the study. This study showed good to excellent interrater reliability. According to Travell, Simons and Simons (1999: 33), the examiners conducting these studies have to be experienced and well trained in order to achieve good to excellent results.

Based on the above-mentioned studies, Travell, Simons and Simons (1999: 34) have compared the relative difficulty of performing the examinations, and estimated relative diagnostic value of each examination by itself, regardless of other findings. These authors have ranked the examinations of each sign from the easiest to the most difficult to elicit. These are listed as follows: spot tenderness, pain recognition, palpable band, referred pain and twitch response.

Spot tenderness or the jump sign is the easiest of the examinations to elicit. However these tenderness findings alone have a limited diagnostic value because the tenderness might be due to myofascial trigger points, fibromyalgia, enthesiopathy, bursitis, tenderness etc.

Pain recognition is a relatively reliable test, as long as the patient understands that the examiner is asking them if they recognise the pain as a familiar one that they have experienced recently. If the patient recognises the pain generated by pressure on a trigger point, then that tender spot can be considered a source that is contributing to the patient's pain. (Travell, Simons and Simons, 1999:34.)

Although a palpable taut band is one of the signs of a myofascial trigger point, it can be observed in pain free subjects without other clinical evidence of trigger point phenomena (Nice et al., 1992). The value of examining for a taut band alone is further limited by the inaccessibility of many muscles to satisfactory manual palpation. Travell, Simons and Simons (1999: 34) suggests that although never tested experimentally, the presence of a palpable band combined with spot tenderness should prove highly reliable.

Recognised referred pain that reproduces the patient's pain complaint identifies an active trigger point and adds greatly to the specificity of the diagnosis. Hong et al. (1996) suggests that unrecognised referred pain that corresponds to the known referred zones of the trigger point being examined is non-specific.

Hong and Torigoe (1994) reports that twitch responses are strongly associated with the presence of trigger points and this finding is probably the most specific single clinical test of a trigger point.

Travell, Simons and Simons (1999: 34) agree that the local twitch response is highly specific. Furthermore they add although the local twitch response is readily elicited by needle penetration of the trigger point, it is the most difficult of the diagnostic signs to elicit reliably manually.

These authors have concluded that no one diagnostic examination alone is a satisfactory criterion for identification of a trigger point. Rather the combination of spot tenderness in a palpable band and subject recognition of the pain are minimum acceptable criteria. (Travell, Simons and Simons, 1999:35.)



## 2.6 CONFIRMATORY OBSERVATIONS.

Routine laboratory tests, including complete blood count, ESR, liver and renal function tests are normal. Routine thyroid function tests or determination of serum vitamin levels are not recommended as this will only establish two possible causative factors that contribute to the development of myofascial trigger points, and therefore cannot serve as confirmatory tests. (Rachlin, 1994: 20.)

Simons (1999) reports that three recently identified confirmatory findings characteristic of an active myofascial trigger point are completely objective and can be recorded. Although not used routinely for clinical applications, it is of much use for research studies of myofascial trigger points. The first finding is electromyographic readings and ultrasound imaging of the local twitch response (LTR). Electromyographic recordings of the local twitch response have been reported when the LTR was elicited by snapping palpation (Chu, 1998; Hong and Torigoe, 1994) or by needling (Simons and Dexter, 1995). The LTR may also be visualized by ultrasound imaging, which was first described and reported by Gerwin and Duranleau in 1997. The second confirmatory test is the demonstration of spontaneous electrical activity (SEA) in the clinically identified trigger point. This was first reported by Weeks and Travell in 1957 and later described in more detail by Hubbard and Berkoff in 1993. Simons *et al.* (1995) showed that this SEA is characteristic of endplate noise and often exhibit the end plate spikes. The above is described in detail later in this chapter under 'nature of trigger points'.

The third finding is the histopathological demonstration of contraction knots. These knots are seen in longitudinal section as fusiform enlargements filled with greatly shortened sarcomeres, and in cross section appear as exceptionally large round, densely staining muscle fibres (Simons and Stalov, 1976). Although Simons and Stalov (1976) reported on canine muscle observations, similar findings were observed by Reitingner *et al.* (1996). In addition these researchers found an excess of the A-band and lack of the I-band configuration in cross sections under electronic microscopy.

According to Travell, Simons and Simons (1999:22) there has not been a sufficient number of well-controlled studies to establish the clinical reliability of these tests, but the few reports of these testing techniques are very promising. It is the opinion of these authors that these tests have much potential for the clinical application in the diagnosis and assessment of therapeutic interventions of myofascial trigger points.

## 2.7 TREATMENT OF MYOFASCIAL PAIN SYNDROME.

Myofascial pain syndrome can range from simple cases with transient single muscle syndromes to complex cases involving multiple muscles and many interrelating contributing factors. It is the opinion of Friction (1994) that simple cases with minimal behavioural and psychosocial involvement can be managed by a single clinician, however complex patients should be managed within an inter-disciplinary pain clinic setting that uses a team of clinicians to address different aspects of the problem.

Friction (1994) suggests that the treatment of myofascial pain syndrome should consist of short term and long-term goals. These can be summarized as follows:

### Short-term goals

- Reduce pain.
- Restore muscle to normal length with full joint range of motion.
- Restore muscle to normal posture.
- Reduce sustained muscle activity.

### Long-term goals

- Restore normal life style activities.
- Reduce contributing factors.
- Regular stretching, postural and conditioning exercises.
- Proper use of muscles.

Many authors have found success in the treatment of myofascial pain syndrome using a wide variety of techniques. Han and Harrison (1997) reports that the four most frequently used treatment modalities include, stretch and spray, trigger point injection, dry needling, and transcutaneous electrical nerve stimulation. Travell, Simons and Simons (1999: 27) 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. These authors suggest another non-invasive technique called ischaemic compression in which digital pressure is sustained to a trigger point with sufficient force for long enough duration to inactivate it. Three variations of the needling technique are found in the literature, these include dry needling (Friction, 1994), injection of saline and injection of local anaesthetic (Hameroff et al., 1981). Studies have indicated that all three techniques are effective in the treatment of myofascial pain syndrome (Broome, 1996 and Hameroff et al., 1981.) The decision whether to treat trigger points by non-invasive methods or by injection depends strongly on the training and skill of the practitioner. Ideally, all approaches should be equally available to the patient and used when indicated. (Travell, Simons and Simons, 1999:151.)

Treatment

Friction (1994) describes a few treatment techniques and their possible mechanisms of action.

These are summarized as follows:

- Massage, acupressure and ultrasound provide non-invasive mechanical disruption to inactivate the trigger point.
- Moist heat applications, ice packs, fluorimethane and diathermy provide skin and muscle temperature changes as a form of counter stimulation. Transcutaneous electrical nerve stimulation, electroacupuncture and direct current stimulation provides electric currents to stimulate the muscle and trigger points.
- Acupuncture and trigger point injections of local anaesthetic, corticosteroids or saline cause direct mechanical or chemical alteration of trigger points (Friction, 1994).

### 2.7.1 ELECTROTHERAPEUTIC MODALITIES.

Rachlin (1994: 473) suggests that the advantages of electrical stimulation are: relatively weight free exercise, increase fibre recruitment, enhanced reticuloendothelial waste removal, increased circulation, and endorphin release analgesia.

Lee *et al.* (1997) adds that electrical stimulation causes an immediate depolarisation of the membranes surrounding nerve and muscle fibres. High intensity electrical stimulation may directly stimulate the small nociceptive sensory fibres and offers counter – irritation affect to control pain. Low intensity electrical stimulation may stimulate the large sensory fibres and causes a pain control effect through the 'gate control' mechanism (Melzack and Wall, 1988: 98). In addition, the rhythmic muscle activity caused by the electrical current may improve local circulation, and subsequently cause the breakdown of the trigger point vicious cycle, to facilitate muscle relaxation.

Hong (1996) reports that electrotherapy may inactivate trigger points by stimulating muscle fibres around trigger points and may facilitate relaxation of the taut band and improve local circulation.

Murphy (1989) states that trigger points can be treated with various electrotherapeutic devices, these include high – voltage electrical stimulation, interferential current therapy, Transcutaneous Electrical Nerve Stimulation (TENS), micro current and ultrasound. He experienced best results with a combination of electrotherapeutic modalities and the spray and stretch technique.

Lee *et al.* (1997) investigated the effectiveness of ultrasound-compared to electrotherapy compared to combined electrotherapy and ultrasound in the treatment of myofascial trigger points. The electrotherapy current was a combination of medium frequency AC current (80%) and galvanic current (20%) at a frequency of 50-100 Hz. The effectiveness of treatment was

assessed by conducting three measurements on each patient, before and immediately after treatment, i.e. subjective pain intensity, pain threshold and range of motion. They found that ultrasound therapy increased range of motion, while subjective pain intensity was reduced by electrotherapy treatment. They concluded that a combination of ultrasound and electrotherapy should be used to treat myofascial trigger points.

Hsueh *et al.* (1997) compared electrical nerve stimulation (ENS) to electrical muscle stimulation (EMS) in the treatment of myofascial trigger points. The study consisted of 3 groups namely: group A (n=18) given placebo treatment, group B (n=20) treated with ENS, and group C (n=22) treated with EMS. When the effectiveness of treatment was compared with that of the placebo group (group A) there was a significant improvement in pain intensity and pain threshold in group B but not in group C. The improvement of range of motion was significantly more in group C as compared with that in-group A or group B.

The researchers concluded that ENS is more effective for immediate relief of myofascial trigger point pain than EMS, and EMS has a better effect on immediate release of muscle tightness than ENS.

It is the opinion of Travell, Simons and Simons (1999:146) that although micro amperage therapy for myofascial trigger points has been promoted by manufactures, no well controlled experimental studies that demonstrate efficacy have been conducted, nor is there a convincing rationale at this time for its use in the treatment of trigger points.

Christie (1995) conducted a controlled study involving 30 patients with myofascial trigger points of the shoulder girdle muscle. The aim of the study was to determine whether the use of interferential current provided a non-invasive alternative to dry needling agitation in the treatment of myofascial pain syndrome. No statistical difference was noted between the two groups. Comparison of subjective and objective data within the each group showed a

significant improvement in both groups. Thus Christie concluded that interferential current is an effective and viable alternative treatment to dry needling in the treatment of myofascial trigger points. More conclusive results could have been obtained if the sample size was increased, and secondly if the researcher chose one of the shoulder girdle muscles and compared the relative effectiveness of the two modalities in the treatment of myofascial pain syndrome.

Although transcutaneous electrical nerve stimulation (TENS) is not classified as a specific treatment modality for MPS, it has been successfully employed to treat trigger points (Han and Harrison, 1997).

Graff – Radford et al. (1989) conducted a double blind study involving 60 patients with active myofascial trigger points. Four modes of the TENS modality and a no stimulation control were compared. Subjects were instructed that the study was a double-blind trial and that they would randomly receive one of five treatment protocols. The study design included two examiners. The first examiner recorded the measurements, and was unaware of the treatment protocol the patient received, while the second examiner administered the treatment intervention. The study demonstrated that high frequency and high intensity electrical stimulation was effective in decreasing myofascial pain. They concluded from their study that high frequency electrical stimulation may reduce myofascial pain without affecting the trigger point sensitivity. Since trigger point sensitivity was essentially unchanged, TENS therapy alone may not be sufficient to produce a long-term effect in treating MPS.

## **2.8 ACTION POTENTIAL THERAPY.**

### **2.8.1 INTRODUCTION**

Action potential therapy was developed in South Africa in 1992 and has been used as a stand-alone treatment by both layman and by health professionals since 1994 (Berger, 1999:11).

The modality produces a low frequency current that simulates the naturally occurring action potential found in a neuron. The current mimics the body's natural electrical impulse, which then causes cycle synchronous depolarisation of nerve fibres. (Berger and Matzner, 1999.)

### **2.8.2 ACTION POTENTIAL.**

The principle way neurons communicate is by generating and propagating action potentials.

An action potential is a brief reversal of membrane potential with a total amplitude (change in voltage) of 100 mV (from -70 mV to +30 mV). (Marieb, 1998:377.)

In a neuron, a transmitted action potential is called a nerve impulse. A neuron transmits a nerve impulse only when it is adequately stimulated. The stimulus changes the permeability of the neuron's membranes by opening specific voltage gated channels that are located on axons. These channels open and close in response to changes in the membrane potential and are activated by local currents that spread toward the axon along the dendritic and cell body membranes.

The action potential is divided into three successive stages namely (Guyton, 1992:47):

Resting stage: this is the resting membrane potential. The membrane is polarized, that is, there is a very large negative membrane potential. This is the stage before the action potential occurs. Depolarisation stage: The membrane of the nerve fibre contains voltage gated activated ion channels. These channels are sensitive to voltage across the membrane and when the voltage reaches a critical point, the gates open allowing the passage of specific ions through the channels. At this stage the membrane becomes permeable to sodium ions, which flow through the channels into the axons. The nerve fibre depolarises moving away from its

depolarised state of  $-90\text{mV}$ , with the potential approaching the zero level. In large fibres the membrane potential may 'overshoot' beyond the zero level, with a momentary reversal in polarity. Repolarisation stage: After a few 10,000ths of a second after becoming permeable to sodium ions, the sodium channels begin to close with the potassium channels opening. The diffusion of potassium ions externally re-establishes the normal negative resting potential of the nerve fibre. Thus the nerve fibre is repolarised. (Guyton, 1992:48.)

### **2.8.3 ACTION POTENTIAL CURRENT THERAPY.**

Action potential therapy is a low frequency current that simulates or mimics the naturally occurring action potential in a neuron. It is applied to the affected area via electrodes and is associated with pain alleviation, enhanced joint flexibility, and decrease in oedema due to improved circulation and possibly, reduced inflammation. (Berger, 1999:11.) If a neuron is not producing action potentials, owing to interference with the electrons within or outside the cell membrane, which could be due to inflammatory or anti-analgesic substances, or oedema, then transmission along the neuron is either reduced or ceases. The next synapse along the neuron may be another neuron, a gland or a muscle. Thus interference in transmission of action potential along the neuron may result in the homeostatic and regenerative mechanisms being disturbed. If the action potential mechanism can be restored to normal, injury and disease can be affected at a cellular level and the health of the organism improved. This is the action of action potential therapy. (Berger, 1999:31.)

The current created by the 'action potential therapy' modality is stronger than the normal current required to produce the action potential in the neuron and as a result depolarisation takes place (Berger, 1999:31). Stimulation by action potential therapy current creates a normal action potential, which restores the inherent biochemical processes in the region (Berger and Matzner, 1999).



Berger (1999:33-34) lists the following possible physiological effects of action potential therapy (APT):

1. Electrolytic effects in the treated area, it is postulated that there is a break down of biochemical waste from uric acid, inflammation and excess fluid.
2. Leu-enkephalin, a pain-modulating hormone, levels are increased.
3. Melatonin levels are increased. Melatonin is an anti-anxiolytic that induces relief from anxiety and has beneficial effects on muscle spasm.
4. Circulation improves resulting in increased transportation of antibodies, enzymes, neurotransmitters and hormones toward the area.
5. Improved circulation may positively effect lymph drainage in the area or the limb.

De Wet et al. (1999) in their study on the neurohormonal consequences of APT report the possibility of the following beneficial effects:

1. Analgesia due to more effective utilization of the endogenous opioids and the inhibition of pain transmission.
2. Reduced anxiety and a more realistic self-assessment of pain.
3. Limitation of tissue damage at the site of inflammation and or hypoxia due to local vasodilation and better perfusion of the affected areas.
4. Anti-inflammatory effects due to beneficial influences on the prostaglandin mechanisms.

It is the opinion of Berger (1999:11) that APT may have beneficial effects on many conditions such as any inflammatory joint diseases, including osteoarthritis, rheumatoid arthritis, gout and ankylosing spondilitis. Furthermore he suggests that the modality may be used to reduce pain caused by fractures from trauma or osteoporosis, nerve root compression, phantom limb pain, post-herpetic and trigeminal neuralgia, sinusitis, fibrositis, sport injuries, headaches, epicondylitis, bursitis, parasthesia, including that of diabetic neuropathy, varicose ulcers, and circulatory disorders.

#### **2.8.4 A COMPARISON OF THE ACTION POTENTIAL THERAPY WAVEFORM TO OTHER LOW FREQUENCY WAVEFORMS.**

The use of low frequency electrical currents (1 – 1000Hz) has been an established part of physical therapy for many years (Prentice, 1994:10). Faradism, galvanism, sinusoidal and interrupted direct current are examples of low frequency waveforms.

Direct current refers to a current passing continuously in the same direction and is referred to as galvanism. The general result is the formation of acids at the positive electrode and bases at the negative electrode. Direct current therefore produces electrochemical reactions that could possibly cause depolarization with electrolysis. However, this may cause chemical injury to the skin. Therefore the majority of these direct currents are not well tolerated by most patients (Nightingale, 1959:88).

A sinusoidal current is an evenly alternating low frequency current. In an alternating current the direction of the electron flow periodically changes in a rhythmic manner. Thus there is no net ion transfer. The effects of a sinusoidal current are to assist in the absorption of exudate, and to cause superficial vasodilatation. Surged sinusoidal currents produce muscle-stimulating effects. (Forster and Palastanga, 1985:38.)

Rectified sinusoidal current consists of a series of half sine wave pulses with intervals of full waves. This type of waveform is monophasic and is known as didynamic current. These currents besides causing sensory and motor stimulation, increase circulation and decreases inflammation. Although didynamic current has beneficial effects, the current is difficult to sustain, as it is markedly uncomfortable. (Forster and Palastanga, 1985:243.)

A faradic-type current is a short duration, interrupted direct current with a frequency of 50-70Hz. These muscle-stimulating currents act directly on nerve fibers and are used therapeutically for stimulating muscles with an intact nerve supply.

The action potential therapy current is a simulated action potential, with a waveform that is a monophasic square pulse with an exponential decay. The current is neither direct, interrupted direct, alternating nor rectified alternating. It is, in fact, a combination of direct and alternating current (Odendaal and Joubert, 1999). The pulse duration is between 800 microseconds to 6.6 milliseconds and the frequency is 150Hz (Berger, 1999:20). The South African Research council did a Fast Fourier Transform of the pulse at different frequencies. They concluded that a pulse frequency of 150Hz was 30% more effective at reducing the unwanted polarization effects than other frequencies tested. As a result of a current that is monophasic, with an exponential decay, and with a negative uneven balance between polarities, depolarization is facilitated. This appears to be the major difference between action potential therapy current and the low frequency currents previously described.

The action of depolarization also occurs with direct current. However, this type of current has unpleasant sensory effects with resultant cauterisation and damage to the skin could possibly even occur (Prentice, 1995:89-90). Due to the nature of the waveform of action potential therapy, these unpleasant sensory effects are not associated with the use of this modality.

Since the current is a square wave with an exponential decay, the current is turned on abruptly, kept constant for the duration of the stimulus, and turned off abruptly. It is continuous and modulated and thus theoretically accommodation should not develop (Berger, 1999:25). In contrast slow rising triangular, saw tooth or trapezoidal pulses, where the peak intensity is reached slowly and reduced slowly or abruptly, more accommodation occurs and higher intensities are needed to excite the nerve membrane. The absence of accommodation when using action potential therapy may attributed to the speed of the fast-rising square wave and then a drop into a continuous exponential decay, which prevents the nerve membrane from adapting to the impulse. According to Berger (1999:20), this type of waveform cannot be compared to any other waveform in use at present.

### **2.8.5 A COMPARISON OF ACTION POTENTIAL THERAPY TO TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION THERAPY.**

Transcutaneous electrical nerve stimulation is designed to block the pain sensation's pathway along the ascending neural tracts and stimulating large low threshold sensory nerve fibres (Rachlin, 1994:479). According to the gate control theory by Melzack and Wall (1988:98), this would inhibit cells, which transmit injury signals.

The pulses produced by TENS are balanced biphasic pulses with equal electron flow above and below the baseline. As such, they produce no net unbalanced ionic shift in the tissues (Graff-Radford, 1989). In contrast the action potential therapy unit produces a current that is monophasic, with an exponential decay, with a negative balance produced between the polarities, therefore, facilitating depolarisation of the nerve. This is the major difference between TENS and APT.

### **2.8.6 CLINICAL TRIALS ON ACTION POTENTIAL THERAPY.**

Action potential therapy is a relatively new modality aimed at the treatment of various musculoskeletal conditions. Although much of the evidence for the use of this type of therapy is anecdotal, it seems that the device may augment neuronal activity to areas where inflammatory processes occur, allowing biochemical wastes to be dispersed more effectively as well as facilitating lymph drainage.

Although the exact mechanisms are yet unknown a number of studies have shown clinical efficacy (Berger 1999:11). The original prototype of action potential current therapy was tested at various universities in South Africa, with promising results.

A double blind, placebo controlled, randomised study was executed on 20 patients in the Pain Control Unit, National Hospital, University of Orange Free State, Bloemfontein, by De Wet *et al.* (1999). The study was aimed at evaluating the neurohormonal effects of APT in patients

with chronic back pain due to osteoporosis. Blood samples were taken and radio-immune essays were used to determine hormone concentrations after APT. The results demonstrated an increase in the serum concentration of melatonin (endogenous anxiolytic) after the second treatment and in leu-enkephalin (endogenous peripheral analgesic) after the fourth treatment. Beta-endorphin (endogenous central analgesic) concentrations decreased after 5 treatments. Serotonin (endogenous anti-depressant) and cortisol (endogenous anti-inflammatory) levels remained within normal limits after 6 treatments.

These effects are believed to benefit the patient by increasing analgesia, reduction of anxiety with a more realistic self-assessment of pain, anti-inflammatory effects and limitation of tissue damage at the site of inflammation or hypoxia (De Wet *et al.*, 1999).

A randomised, single blinded, placebo controlled study involving 33 patients with chronic backache owing to osteoporosis was conducted at the Pain Control Unit, Department of Anaesthesiology, University of the Orange Free State, Bloemfontein, by Odendaal and Joubert (1999). Patients received 6 treatments consisting of 32 minutes each, on every second day. The data indicated a statistical significant result in the Action Potential Therapy group ( $p = 0.0001$ ). The researches concluded that clinically the effect of treatment was very successful. However, inter-group analysis of the data indicated no statistical difference between the two groups.

It is important to note that the study was of a poor quality. The sample size was too small and the respective groups were not equally weighted, i.e. placebo group- $n = 12$  and the treatment group-  $n = 21$ . Secondly, the Hawthorne effect (Fox, 1969:470) may have occurred, as most of the patients who participated in the study came from old age homes and may have received more attention in the study than they were use to. Lastly, only the visual analogue scale was used as a measurable tool to assess effectiveness of the treatment protocol. These factors may

have influenced the results of the study, and therefore be a possible explanation for no differences noted between the two groups.

A randomised, single blinded, placebo study was conducted at the Pain Relief and Research Unit, Department of Anaestheology, Baragwanath Chris Hani Hospital, University of Witwatersrand, by Berger and Matzner (1995). The aim of the study was to compare the effectiveness of APT to TENS and Placebo, on 99 patients with osteoarthritis of the knee. The visual analogue scale was used to assess the patient's self reported pain. Objective assessment was means of the goniometer, which measured knee flexion. In addition a tape measure was used to assess change in swelling above and below the patella. The data demonstrated that APT was able to improve mobility, decrease night pain as well as joint stiffness. It was concluded that APT was statistically proven to be effective in the treatment of patients with osteoarthritis of the knee. There was no statistical difference between the groups, thus APT, TENS and placebo were equally effective.

As in the previous study the discrepancies in the findings may be attributed to the poor study design and methodology. Patients were not restricted from taking analgesics or anti-inflammatory medication for the duration of their participation in the study. Secondly, some patients reported administering 'self massage' to reduce pain and swelling. Thirdly, strapping was used to apply the electrodes firmly to the skin. All the above are examples of therapeutic interventions on their own, and therefore may have affected treatment outcome and the findings of the study.

A more recent study by Goldberg (2000), with methodological improvements and superior study design showed more conclusive results than the two previous studies. The aim of the study was to determine the relative effectiveness of combined 'action potential therapy' and patella mobilization versus combined placebo 'action potential therapy' and patella mobilization in the treatment of patellofemoral pain syndrome. Both treatments were found

to be effective, with the treatment group showing a statistically significant improvement in the objective measure when compared to the control group. Goldberg concluded that APT is effective in the treatment of Patellofemoral pain syndrome. She also suggests that this modality has the potential of being an important adjunct to chiropractic management of patellofemoral pain syndrome. High quality studies similar to that of Goldberg (2000) are currently being carried out in South Africa, which are showing promising results.

To date there are no literature or studies available regarding the use of Action Potential Therapy in the treatment of myofascial pain syndrome.

#### **2.8.7 CONTRAINDICATIONS TO ACTION POTENTIAL THERAPY.**

According to manufactures' guidelines APT should not be used:

- By patients with any electrical medical implants.
- By patients predisposed to thrombolytic episodes.
- By patients with epilepsy.
- Over the abdominal area of pregnant women.
- In the vicinity of a malignant tumour.
- Directly over the eye.
- In children under the age of 12 and persons with a body mass of less than 30 kilograms.

#### **2.8.8 TECHNICAL SPECIFICATIONS OF THE ACTION POTENTIAL**

**RECTIFICATION THERAPY DEVICE** (Medi Pulse Pty Ltd, Private Bag X1116,  
Halfwayhouse, 1685, South Africa)

- |                  |  |
|------------------|--|
| - Wave form name | Action Potential Current                           |
| - Wave type      | Positive pulse with exponential decay.             |
| - Pulse rate     | 166Hz  |
| - Amplitude      | Adjustable between a to 5mA peak in 1000 ohm load. |
| - Voltage        | 0 – 48 volts (open circuit).                       |

## **2.9 OVERVIEW OF MUSCLES.**

Patients diagnosed with active trigger points in either the trapezius or gluteus medius muscle were accepted into the study. An overview of each muscle follows:

### **2.9.1 GLUTEUS MEDIUS MUSCLE**

The gluteus medius muscle attaches proximally, along the anterior three-fourths of the iliac crest and, distally to the greater trochanter. According to Travell, Simons and Simons (1999:150) trigger points found in this muscle causes referred pain that is commonly identified as low back pain or lumbago. Its three trigger point regions together refer pain and tenderness primarily along the posterior crest of the ilium, to the sacrum, and to the posterior and lateral aspect of the buttock. Pain and tenderness may extend to the upper thigh.

Activities such as walking, lying on ones back or on the affected side, or sitting slouched down in a chair may exacerbate the pain (Travell, Simons and Simons, 1999: 154). The main function of the muscle is to stabilize the pelvis during single-limb stance. The muscle also plays a role in thigh abduction. Spinal roots L4, L5, and S1 via the superior gluteal nerve innervate the gluteus medius muscle.

### **2.9.2 TRAPEZIUS MUSCLE (Travell and Simons, 1999:278).**

The paired trapezii muscle forms a diamond shape that extends in the midline from the occiput above to the twelfth thoracic vertebrae below. The muscle reaches anteriorly on either side to include the lateral one third of the clavicle. Laterally the muscle extends to include the acromion, and posteriorly throughout the length of the spine of the scapular. The trapezius muscle is tripartite, that is it is made up of the upper, middle and lower fibres. Each of which has different fibre directions and often-different functions. The trigger points in the upper trapezius fibres characteristically refer pain and tenderness along the posterolateral aspect of the neck, behind the ear and to the temple. The trigger points in the lower trapezius refer pain and tenderness mainly to the posterior neck and adjacent mastoid area, suprascapular region, and interscapular region. The less common middle trapezius trigger points project pain towards the vertebrae and to the interscapular region. The muscle is innervated by the spinal



division of the eleventh cranial nerve, which supplies mainly motor fibres. The second to fourth cervical nerves supply mainly sensory fibres to the muscle. The main function of the upper trapezius is to draw the clavicle and indirectly the scapular backwards and raise them by rotating the clavicle at the sternoclavicular joint. The upper trapezius also complements the serratus anterior in rotating the scapular so that the glenoid fossa faces upward. The lower trapezius stabilizes the scapular for this rotation. The middle trapezius strongly adducts the scapular, stabilizing traction forces.

## **CHAPTER 3**

### **METHODOLOGY**

#### **3.1 INTRODUCTION**

The details of the research study undertaken are discussed in this chapter. This involves a detailed description of the study, the subjects used and the intervention utilized.

Measurements obtained and the statistical analyses for evaluation of data are also discussed.

The objective of this study was to determine the efficacy of action potential therapy in the treatment of myofascial pain syndrome.

3.1.1 The first objective was to evaluate the efficacy of APT in the treatment of MPS in terms of subjective clinical findings.

3.1.2 The second objective was to evaluate the efficacy of APT in the treatment of MPS in terms of objective clinical findings.

#### **3.2 STUDY DESIGN AND PROTOCOL.**

The design was that of a prospective, single blinded, randomised, placebo controlled study. Subjects were informed of the study via local notice boards, flyers and newspapers. The study incorporated 60 patients who were accepted according to inclusion and exclusion criteria. Patients were randomly assigned to either the treatment group (group A), or the control group (group B). Each group consisted of 30 patients. As there are no guidelines as to the natural history of myofascial trigger points in different areas of the body, a collection of the most common trigger points from the upper and lower extremities were chosen (Travell, Simons and Simons, 1999:12). Each group was therefore subdivided into 2 muscle subgroups (trapezius muscle – treatment group 1 or control group 1; gluteus medius muscle – treatment group 2 or control group 2).

### **3.2.1 STANDARD OF ACCEPTANCE.**

At the initial consultation the patient underwent a full case history (Appendix A), physical examination (Appendix B) and a regional examination (appendix C). During this process the patient was screened for myofascial pain syndrome and to assess if the candidate met the inclusion and exclusion criteria. Only if the patient met these criteria were they accepted into the study.

### **3.2.2 INCLUSION AND EXCLUSION CRITERIA OF PATIENTS.**

1. The patient's condition had to comply with the following criteria for the diagnosis of active myofascial trigger points as described by Travell and Simons (1983:18-19).
  - Either a history of rapid onset during, or shortly following acute overload stress, or a history of gradual onset with chronic overload of the affected muscle.
  - A pattern of pain referred from the trigger point that is characteristic for that muscle in which it is located.
  - A taut palpable band in the affected muscle.
  - Intense focal tenderness of the taut band to applied pressure.
  - A local twitch response produced by needling or snapping palpation of the trigger point.
  - Reproduction of the characteristic pain patterns by needling or palpating the trigger point.
  - Elimination of the clinical presentation by specific trigger point therapy
2. Patients had to be between the ages of 18 and 60 years old.
3. Patients were not allowed to take any allopathic or homeopathic medication for the condition, nor receive any manual therapy for the duration of their participation in the study. Manual therapy includes chiropractic adjustments, any electrotherapies other than the treatment interventions of the study, any other myofascial therapy or soft tissue therapies.

4. Only patients diagnosed by the researcher as having active myofascial trigger points in either the trapezius or gluteus medius muscle were considered. This was confirmed by the consulting clinician.
5. The APT manufacturers' (Medi Pulse Pty Ltd, Private Bag x116, Halfway House, 1685, South Africa) guidelines further precluded usage in the following situations:
  - Pregnancy
  - Patients with body mass of less than 30 kg
  - Patients predisposed to thrombolytic episodes
  - Patients with any electrical implanted devices e.g. pacemaker.
6. Patients with concomitant facet syndrome were included in the study but were not treated for the facet syndrome.

### **3.2.3 INTERVENTIONS.**

At the initial consultation the researcher explained the nature and importance of the study to the subjects found suitable for the study. In addition each patient was given a letter of information (Appendix H) and was asked to complete an informed consent form (Appendix I).

#### **3.2.3.1 RANDOMIZATION AND BLINDING**

Patients were randomly assigned to one of the two groups each consisting of 30 patients. Four treatment units labelled 'A, B, C and D' were used for the study. Two units were active and two units were placebo. Each patient was randomly assigned to a unit. This was done by having 60 pieces of paper marked either A, B, C or D (representing a unit) placed in a box. An independent observer then drew a letter out of the box. The letter chosen was recorded next to the patient's name. In so doing, the patient was treated with the same unit on each visit.

Both groups were informed as to how action potential therapy might be effective in treating their condition. However for blinding purposes, patients were not told to which group they

were assigned. Patients received four treatments sessions over a period of 7 to 10 days, with a maximum of one treatment per day. At each consultation the respective unit was set at 8 minutes treatment time. The intensity depended on individual response, however it did not exceed 2.0 mA. The electrode placement was according to the manufacture's guidelines.

### **3.2.4 ETHICAL CONSIDERATIONS.**

- The rights and welfare of the patients were protected.
- Informed consent was made.
- Patients were not coerced into participating in the study.
- Information was given to the patient in an understandable language.
- Confidentiality was maintained.
- Participation was voluntary and did not involve financial benefits.
- Patients were free to withdraw from the study at any stage. (Pak and Adams, 1994:37.)

## **3.3 MEASUREMENTS.**

### **3.3.1 THE DATA.**

The study incorporated both primary and secondary data as mentioned below.

Primary data:

- Case history (Appendix A)
- Physical examination (Appendix B)
- Regional examination (appendix C)
- Numerical Pain Rating Scale (Appendix D)
- Short Form McGill Pain Questionnaire (Appendix E)
- Algometer reading for pressure pain threshold (Appendix F)
- Myofascial Diagnostic Scale (Appendix G)

Secondary data: The secondary data was collected from current journals, textbooks, Internet and CD-medline at the Technikon Natal Library. If the literature was unavailable at the campus library, inter-library loans were used.

### 3.3.2 METHOD OF MEASUREMENT.

The subjective and objective measurements were taken at the initial consultation prior to the first treatment and were repeated at the fourth consultation after the treatment.

#### 3.3.2.1 SUBJECTIVE MEASUREMENTS

##### 1. The Numerical Pain Rating Scale-101 (NRS-101).

The NRS-101 assesses the perceived level of pain intensity of the patient (Jensen et al., 1986). The questionnaire consists of a numerical scale from 0 to 100, with the 0 representing one extreme (e.g. no pain), and the 100 representing the other extreme (e.g. pain at its worst). The patient indicates their intensity of pain by means of a percentage, both at its least and its worst. Jensen et al. (1986) examined the usefulness of six different pain intensity measures in a group of 75 chronic pain patients. This scale was found to be the most practical index when measuring clinical pain intensity compared to the other five scales. It can be administered in written or verbal form and is extremely simple to score. In addition, it has 101 response categories and thus is more likely to be accepted by researchers concerned with limited response options of the other measures. The NRS-101 does not appear to be associated with incorrect responding more than any other scale and the difficulty of the scale is not associated with age.

##### 2. The Short Form McGill Pain Questionnaire.

The data obtained with the Short form McGill Pain Questionnaire provides valuable information on the patient's sensory, affective and overall intensity of pain (Melzack, 1987). It was derived from the standard McGill Pain Questionnaire for the use in specific research settings when time, for the capture of patient information regarding the sensory dimension of pain, was limited. The Short Form McGill Pain Questionnaire consists of 15 descriptors (representative words). Descriptors 1 to 11 represent the sensory dimension of pain experience and descriptors 12 to 15 represent the affected dimension. Combining the sensory

and affective dimensions of pain represent the overall pain score. Each descriptor is ranked on an intensity scale of zero = none, one = mild, two = moderate, three = severe.

### 3.3.2.2 OBJECTIVE MEASURES.

#### 1. Algometer.

Since Fischer (1986) developed a pocket-sized pressure algometer, this convenient tool has been widely used to document the tenderness of myofascial trigger points (Hong, 1998). According to Fischer (1987), evaluation of the therapeutic efficacy in myofascial pain syndromes is based primarily on the subjective assessment of local tenderness, but there are certain methods, such as pressure threshold measurement that are particularly useful in the objective assessment of treatment results.

Pressure threshold is the minimum pressure inducing pain or discomfort (Fischer, 1986). Fischer (1987) performed a study on the pressure threshold measurement for diagnosis and evaluation of treatment results of trigger points. He concluded that algometry is a useful method for diagnosis of tender spots and trigger points and particularly useful in their clinical management and assessment of treatment results.

Reeves et al. (1986) demonstrated the reliability and validity of the pressure algometer in measuring myofascial trigger point sensitivity. The algometer used in this study was the force dial manufactured by Wagner Instruments: P.O. Box 1217, Greenwich CT 06836. The pressure range of the algometer was 11 kilograms.

The algometer was used as follows:

- The dial on the gauge was set to zero
- The 1cm rubber disc was applied to the point of maximum tenderness by placing the gauge perpendicular to the surface.
- The patient was told to say 'now' at the point at which they first perceived pain.

- The pressure was gradually increased at a rate of 1kg/ second, as recommended by Fischer (1986).
- The researcher stopped applying pressure as soon as the patient indicated discomfort.
- The reading on the dial was immediately recorded on the algometer form.

## 2. The Myofascial Diagnostic Scale.

The myofascial diagnostic scale assesses the extent to which the patient suffers from myofascial pain syndrome. This scale was developed by the researcher, as there are no satisfactory laboratory tests or imaging techniques currently available that may be clinically utilized as objective tools when assessing efficacy of treatment interventions.

Notwithstanding this, two new tests namely surface EMG and ultrasound imaging are able to substantiate objectively the presence of the characteristic trigger point phenomena. However, to date there has not been a sufficient number of well-controlled studies to establish the clinical reliability and application of these tests, but the few reports of these testing techniques are very promising. It is the opinion of Travell and Simons (1999:22) that these tests have much potential for the clinical application in the diagnosis and assessment of therapeutic interventions of myofascial trigger points.

The myofascial trigger point is the hallmark physical finding of the myofascial pain syndrome (Fricton, 1994). The signs of a myofascial trigger point were used as indicators in the Myofascial Diagnostic Scale. According to Travell and Simons (1983:12-16) the signs of a trigger point are the following: referred pain in the zone of reference, local twitch response, palpable taut band, and focal tenderness.

Melzack et al. (1976), Hameroff et al. (1981), Hong et al. (1993), Simons and Dexter (1995), Bendtsen et al. (1996), Gerwin et al. (1997), Hsueh et al. (1997), Lee et al. (1997) and Banks et al. (1998), are researchers who have all reported using these criteria to identify trigger



points in order to conduct their respective investigations. Notwithstanding this, of the four recent studies on interrater reliability of trigger point examinations, the first three reported unsatisfactory to marginal interrater reliability. The fourth study by Gerwin *et al.* (1997) demonstrated why such results were obtained. Gerwin *et al.* (1997) reported that these physical features are reproducible among different examiners, thereby establishing the reliability of these physical signs in the diagnosis of the myofascial pain syndrome. Since then no studies have been reported that evaluate the discriminative power of each of the clinical characteristics of trigger points. Simons (1999) suggests that one can only estimate their likely diagnostic value based on the information now available.

It is the opinion of Travell and Simons (1999:34-35) that no one diagnostic examination alone is a satisfactory criterion for the identification of a trigger point, rather a combination of these signs would be more specific. Furthermore these authors suggest that referred pain is the strongest indicator of an active trigger point, whilst a local twitch response, focal tenderness and a palpable taut band are associated signs of equal importance.

The Myofascial Diagnostic Scale was made up of four indicators. The first indicator consisted of five grades of soft tissue tenderness. Each grade was scored as follows: grade 0 - no tenderness = 0, grade 1 - tenderness to palpation without grimace or flinch = 1, grade 2 - tenderness with grimace and/or flinch to palpation = 2, grade 3 - tenderness with withdrawal = 3, grade 4 - withdrawal to non-noxious stimuli = 4. The second and third indicators represented the presence of the local twitch response and the taut band respectively. These indicators were given a value of 4 each. The fourth indicator was the presence of referred pain. Since this sign is the strongest indicator of an active trigger point, this indicator was given a value of 5. These signs were assessed and scored by the researcher at the initial and last consultations. Total values of 9 or more were indicative of an active trigger point and were used to standardize the inclusion of patients. The data also enabled the researcher to establish intra-group and inter-group change in terms of clinical signs.

### **3.4 TREATMENT OF DATA.**

The subjective data was treated as follows:

- After the questionnaires were completed by the patient, they were checked to ensure that they were completed correctly.
- The scores obtained from the NRS-101 were expressed as percentages
- The scores obtained from the McGill Pain Questionnaire were recorded as whole numbers (The sum of the value of 'ticks' ascribed to each column i.e. 0 = none, 1 = mild, 2 = moderate, 3 = severe) with the highest possible score being 45.
- The data was then statistically analysed.

The objective data was treated as follows:

- The algometric readings were recorded in kg/cm squared.
- The scores obtained from the myofascial diagnostic scale were recorded as whole numbers, with the highest possible score being 17.
- The data was then statistically analysed.

As there were two muscle 'subgroups' within group A and B, both subjective and objective data was recorded separately for each subgroup.

### **3.5 STATISTICAL ANALYSIS**

The SPSS statistical package (as supplied by SPSS Inc., Marketing Department, 444 North Michigan Avenue, Chicago, Illinois, 60611) was utilized for data analysis. The statistical evaluation was aimed at measuring any significant inter or intra-group changes that occurred between the first and last consultation.

The Mann-Whitney Test (non-parametric test) was used to determine whether any significant differences occurred between the two groups with respect to the categorical variables. The categorical variables included the Short Form McGill Pain Questionnaire and the Myofascial Diagnostic Scale (MDS).

The two-sample unpaired t-test (parametric test) was used to determine whether any significant differences occurred between the two groups with respect to the continuous variables. The continuous variables include the NRS-101 and the algometer. The Wilcoxon Sign Rank Test (non-parametric test) was used to determine whether any significant changes occurred within each study group with respect to the categorical variables. The categorical variables included the Short form McGill Pain Questionnaire and the Myofascial Diagnostic Scale. The two-sample paired t-test (parametric test) was used to determine whether any significant changes occurred within each study group with respect to continuous variables. The continuous variables were the NRS-101 and the algometer.

Descriptive statistics were used, incorporating mean, standard deviation and standard error to analyse the P value (levels of statistical significance) acquired in order to further interpret the results from data collected once in a spread sheet format. The mean value (Me) was calculated in order to interpret the measurement of the central tendency found within the raw data. The mean values were calculated by summing the values of several observations. This provided a practical quantitative summary of each group's characteristics. The reliability of the mean was measured using the standard deviation, which measures the spread of the data around the mean. The bigger the value, the bigger the spread of values and hence the less reliable the data. The results of these tests were then used to discuss and draw conclusion as to the efficacy of action potential therapy in the treatment of myofascial pain syndrome.

## **CHAPTER 4**

### **THE RESULTS**

#### **4.1 INTRODUCTION.**

This chapter covers the results obtained from the statistical analysis of the data collected from the following measurements criteria:

- The Numerical Pain Rating Scale-101
- The Short Form McGill Pain Questionnaire
- The Algometer readings
- The Myofascial Diagnostic Scale

The age and gender distributions are tabulated.

The results obtained for the inter and intra-group data analysis are tabulated. The tables for statistical results include the mean (ME.), standard deviation (SD.) and the level of significance (P-value). Results for subjective and objective findings are tabulated separately. The mean value of each variable is represented graphically for both groups.

#### **4.2 CRITERIA GOVERNING THE ADMISSIBILITY OF DATA.**

Data collected and used was only taken from those patients who participated for the full duration of the programme, and who met the inclusion and exclusion criteria. Objective measures, that is, the Algometer readings and the Myofascial Diagnostic Scale scores taken only by the researcher were utilized. Responses to the NRS-101 and McGill Pain Questionnaire were completed under the researcher's supervision.

#### **4.3 THE HYPOTHESIS.**

The null hypothesis (Ho) was the same for group A and B, it is stated below:

Ho: On analysis of the intra-group data there would be no statistical improvement in the subjective and objective findings, indicating that the treatment was statistically insignificant.

The alternative hypothesis (H1) is the same for both groups and is described below:

H1: On analysis of the intra-group data there would be a statistical improvement in the subjective and objective findings, indicating that the treatment was statistically significant.

A further null hypothesis and an alternative hypothesis were required in order to integrate the data from the two groups.

Ho: On analysis of the inter-group data there would be no statistical difference in the objective and subjective findings indicating that the two treatments were equally effective.

H1: On analysis of the inter-group data there would be a statistical difference in the objective and subjective findings indicating that the two treatments were not equally effective.

#### 4.4 THE ANALYSED DATA.

##### 4.4.1 P-value.

The data was analysed at the  $\alpha = 0.05$  level and the decision rule was applied as follows:

Reject the null hypothesis if the P-value is  $\leq \alpha / 2$

Accept the null hypothesis if the p-value is  $\geq \alpha / 2$ , ( $\alpha / 2 = 0.025$ ).

In order to conclude that there is a statistically significant improvement at the  $\alpha = 0.05$  level, the P-value would have to be  $\leq 0.025$ .

**4.5 TABLES OF DEMOGRAHPIC DATA.**

Table 4.1 Age distribution.

<u>Age</u>	<u>Treatment group</u>	<u>Control group</u>	<u>Total % of patients</u>
20 – 25	8	9	28
26 – 31	4	5	15
32 – 37	2	5	11
38 – 43	7	3	16
44 – 49	7	5	20
50 – 55	1	2	5
56 – 61	3	1	6

Table 4.2. Gender distribution.

<u>Gender</u>	<u>Treatment group</u>	<u>Control group</u>	<u>Total</u>
Male	11	14	25
female	19	16	35

#### **4.6 TABLES OF STATISTICAL RESULTS.**

Significant P-values are highlighted.

##### **4.6.1 STATISTICAL RESULTS COMPARING THE SUBJECTIVE MEASURES OF THE TREATMENT GROUP.**

Table 4.3

Statistical results of the NRS-101 and the Short form McGill Pain Questionnaire comparing the first and fourth visits of the treatment group 1.

	N	Treatment group 1		P-value	Treatment group 1	
		Visit 1			Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	15	52.16	14.10	0.000	16.13	14.10
McGill	15	12.53	7.43	0.01	2.73	2.10

The Wilcoxon's signed rank test was used to compare results within each group for the categorical variables, i.e.: McGill. The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: NRS-101.

The null hypothesis was rejected for the McGill and NRS-101 questionnaires, indicating a significant subjective improvement between the first and fourth visits in the treatment group

1.

Table 4.4

Statistical results of the NRS-101 and the Short form McGill Pain Questionnaire comparing the first and fourth visits of the treatment group 2.

	N	Treatment group 2 Visit 1		P-value	Treatment group 2 Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	15	41.66	13.58	<b>0.000</b>	12.70	9.95
McGill	15	15.80	9.13	<b>0.001</b>	4.26	3.89

The Wilcoxon's signed rank test was used to compare results within each group for the categorical variables, i.e.: McGill. The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: NRS-101.

The null hypothesis was rejected for the McGill and NRS-101 questionnaires, indicating a significant subjective improvement between the first and fourth visits in the treatment group 2.



Table 4.5

Statistical results of the NRS-101 and the Short form McGill Pain Questionnaire comparing the first and fourth visits of the treatment group overall.

	N	Treatment group overall		P-value	Treatment group overall	
		Visit 1			Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	30	46.91	14.61	0.000	14.41	12.12
McGill	30	14.16	8.35	0.000	3.50	3.18

The Wilcoxon's signed rank test was used to compare results within each group for the categorical variables, i.e.: McGill. The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: NRS-101.

The null hypothesis was rejected for the McGill and NRS-101 questionnaires, indicating a significant subjective improvement between the first and fourth visits in the treatment group overall.

#### 4.6.2 STATISTICAL RESULTS COMPARING THE SUBJECTIVE MEASURES OF THE CONTROL GROUP.

Table 4.6

Statistical results of the NRS-101 and the Short form McGill Pain Questionnaire comparing the first and fourth visits of the control group 1.

	N	Control group 1 Visit 1		P-value	Control group 1 Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	15	49.66	11.56	0.603	48.16	13.96
McGill	15	14.06	8.21	0.106	12.93	8.40

The Wilcoxon's signed rank test was used to compare results within each group for the categorical variables, i.e.: McGill. The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: NRS-101.

The null hypothesis was accepted for the NRS-101 and McGill questionnaires, indicating no significant improvement between the first and fourth visits in the control group 1.

Table 4.7

Statistical results of the NRS-101 and the Short form McGill Pain Questionnaire comparing the first and fourth visits of the control group 2.

	N	Control group 2 Visit 1		P-value	Control group 2 Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	15	39.16	15.63	0.127	36.36	16.82
McGill	15	8.20	5.75	0.063	5.86	3.35

The Wilcoxon's signed rank test was used to compare results within each group for the categorical variables, i.e.: McGill. The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: NRS-101.

The null hypothesis was accepted for the NRS-101 and McGill questionnaires, indicating no significant improvement between the first and fourth visits in the control group 2.

Table 4.8

Statistical results of the NRS-101 and the Short form McGill Pain Questionnaire comparing the first and fourth visits of the control group overall.

	N	Control group overall Visit 1		P-value	Control group overall Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	30	44.41	14.52	0.198	42.26	16.33
McGill	30	11.13	7.58	<b>0.013</b>	9.40	7.24

The Wilcoxon's signed rank test was used to compare results within each group for the categorical variables, i.e.: McGill. The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: NRS-101.

The null hypothesis was accepted for the NRS-101 questionnaire, indicating no significant improvement between the first and fourth visits in the control group overall.

However, the null hypothesis was rejected for the McGill questionnaire, indicating a significant improvement over the same time interval.

#### 4.6.3 STATISTICAL RESULTS COMPARING THE OBJECTIVE MEASURES IN THE TREATMENT GROUP.

Table 4.9

Statistical results of the algometric measurements and Myofascial Diagnostic Scale scores, comparing the first and fourth visits of the treatment group 1.

	N	Treatment group 1 Visit 1		P-value	Treatment group 1 Visit 4	
		M.E	S.D		M.E	S.D
ALG	15	1.62	0.55	<b>0.000</b>	2.20	0.68
MDS	15	14.00	1.88	<b>0.001</b>	6.80	2.54

The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: Algometer. The Wilcoxon's Rank test was used to compare results within each group for the categorical variables, i.e.: Myofascial Diagnostic Scale.

The null hypothesis was rejected for the algometric measurements and the myofascial diagnostic scale scores, indicating a significant objective improvement between the first and fourth visits in the treatment group 1.

Table 4.10

Statistical results of the algometric measurements and Myofascial Diagnostic Scale scores,  
comparing the first and fourth visits of the treatment group 2.

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	N	Treatment group 2 Visit 1		P-value	Treatment group 2 Visit 4	
		M.E	S.D		M.E	S.D
ALG	15	1.69	0.69	<b>0.000</b>	2.39	0.65
MDS	15	13.20	2.04	<b>0.001</b>	6.40	1.80

The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: Algometer. The Wilcoxon's Rank test was used to compare results within each group for the categorical variables, i.e.: Myofascial Diagnostic Scale.

The null hypothesis was rejected for the algometric measurements and the myofascial diagnostic scale scores, indicating a significant objective improvement between the first and fourth visits in the treatment group 2.

Table 4. 11

Statistical results of the algometric measurements and Myofascial Diagnostic Scale scores, comparing the first and fourth visits of the treatment group overall.

	N	Treatment group overall		P-value	Treatment group	
		Visit 1			Visit 4	
		M.E	S.D		M.E	S.D
ALG	30	1.65	0.61	0.000	2.29	0.66
MDS	30	13.60	1.97	0.000	6.60	2.17

The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: Algometer. The Wilcoxon's Rank test was used to compare results within each group for the categorical variables, i.e.: Myofascial Diagnostic Scale.

The null hypothesis was rejected for the algometric measurements and the myofascial diagnostic scale scores, indicating a significant objective improvement between the first and fourth visits in the treatment group overall.

**4.6.4 STATISTICAL RESULTS COMPARING THE OBJECTIVE MEASURES IN THE CONTROL GROUP.**

Table 4.12

Statistical results of the algometric measurements and Myofascial Diagnostic Scale scores, comparing the first and fourth visits of the control group 1.

	N	Control group 1		P-value	Control group 1	
		Visit 1			Visit 4	
		M.E	S.D		M.E	S.D
ALG	15	1.77	0.45	0.120	1.82	0.40
MDS	15	13.26	1.98	0.034	12.66	1.79

The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: Algometer. The Wilcoxon’s Rank test was used to compare results within each group for the categorical variables, i.e.: Myofascial Diagnostic Scale.

The null hypothesis was accepted for the algometric measurements and the myofascial diagnostic scale scores, indicating no significant objective improvement between the first and fourth visits in the control group 1.



Table 4.13

Statistical results of the algometric measurements and Myofascial Diagnostic Scale scores, comparing the first and fourth visits of the control group 2.

	N	Control group 2 Visits 1		P-value	Control group 2 Visit 4	
		M.E	S.D		M.E	S.D
ALG	15	1.77	0.62	0.610	1.76	0.59
MDS	15	12.53	1.35	0.059	12.13	1.50

The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: Algometer. The Wilcoxon's Rank test was used to compare results within each group for the categorical variables, i.e.: Myofascial Diagnostic Scale.

The null hypothesis was accepted for the algometric measurements and the myofascial diagnostic scale scores, indicating no significant objective improvement between the first and fourth visits in the control group 2.

Table 4.14

Statistical results of the algometric measurements and Myofascial Diagnostic Scale scores, comparing the first and fourth visits of the control group overall.

	N	Control group overall Visit 1		P-value	Control group overall Visit 4	
		M.E	S.D		M.E	S.D
ALG	30	1.77	0.54	0.351	1.79	0.50
MDS	30	12.90	1.70	<b>0.005</b>	12.40	1.65

The two-sample paired t-test was used to compare results within each group for the continuous variables, i.e.: Algometer. The Wilcoxon's Rank test was used to compare results within each group for the categorical variables, i.e.: Myofascial Diagnostic Scale.

The null hypothesis was accepted for the algometric measurements, indicating no significant objective improvement between the first and fourth visits in the control group overall.

However the null hypothesis was rejected for the myofascial diagnostic scale scores, indicating a significant improvement over the same time interval.

#### 4.6.5 STATISTICAL RESULTS COMPARING THE TREATMENT AND CONTROL GROUP IN TERMS OF SUBJECTIVE MEASUREMENTS, FOR THE FIRST VIST.

Table 4.15

Statistical results of the Numerical Pain Rating Scale –101 and the Short Form McGill Pain Questionnaire, comparing the first visit for the treatment group 1 and the control group 1.

	N	Treatment group 1 Visit 1		P-value	Control group 1 Visit 1	
		M.E	S.D		M.E	S.D
NRS-101	15	52.16	14.10	0.600	49.66	11.56
McGill	15	12.53	7.43	0.561	14.06	8.21

The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: McGill. The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: NRS-101.

The null hypothesis was accepted for the NRS-101 and the McGill questionnaires, indicating no significant difference between the treatment group 1 and the control group 1 at the first visit.

Table 4.16

Statistical results of the Numerical Pain Rating Scale –101 and the Short Form McGill Pain Questionnaire, comparing the first visit for the treatment group 2 and the control group 2.

	N	Treatment group 2		P-value	Control group 2	
		Visit 1			Visit 1	
		M.E	S.D		M.E	S.D
NRS-101	15	41.66	13.58	0.644	39.16	15.63
McGill	15	15.80	9.13	<b>0.012</b>	8.20	5.75

The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: McGill. The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: NRS-101.

The null hypothesis was accepted for the NRS-101, indicating no significant difference between the treatment group 2 and the control group 2 at the first visit.

However the null hypothesis was rejected for the McGill questionnaire, indicating a significant difference between the treatment group 2 and the control group 2, at the first visit.

Table 4.17

Statistical results of the Numerical Pain Rating Scale –101 and the Short Form McGill Pain Questionnaire, comparing the first visit for the treatment group overall and the control group overall.

	N	Treatment group overall		P-value	Control group overall	
		Visit 1			Visit 1	
		M.E	S.D		M.E	S.D
NRS-101	30	46.91	14.61	0.509	44.41	14.52
McGill	30	14.16	8.35	0.129	11.13	7.56

The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: McGill. The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: NRS-101.

The null hypothesis was accepted for the NRS-101 and the McGill questionnaires, indicating no significant difference between the treatment group overall and the control group overall, at the first visit.

**4.6.6 STATISTICAL RESULTS COMPARING THE TREATMENT AND CONTROL GROUPS IN TERMS OF SUBJECTIVE MEASUREMENTS, FOR THE FOURTH VISIT.**

Table 4.18

Statistical results of the Numerical Pain Rating Scale –101 and the Short Form McGill Pain Questionnaire, comparing the fourth visit for the treatment group 1 and the control group 1.

	N	Treatment group 1 Visit 4		P-value	Control group 1 Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	15	16.13	14.10	<b>0.000</b>	48.16	13.96
McGill	15	2.73	2.12	<b>0.000</b>	12.93	8.40

The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: NRS-101. The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: McGill.

The null hypothesis was rejected for the NRS-101 and McGill Pain Questionnaire, indicating a significant subjective improvement between the treatment group 1 and the control group 1, at the fourth visit.

Table 4.19

Statistical results of the Numerical Pain Rating Scale –101 and the Short Form McGill Pain Questionnaire, comparing the fourth visit for the treatment group 2 and the control group 2.

	N	Treatment group 2 Visit 4		P-value	Control group 2 Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	15	12.70	9.95	0.000	36.36	16.82
McGill	15	4.26	3.89	0.175	5.86	3.35

The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: McGill. The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: NRS-101.

The null hypothesis was accepted for McGill Pain Questionnaire, indicating no significant differences between the treatment group 2 and the control group 2, at the fourth visit.

However the null hypothesis was rejected for the NRS-101, indicating a significant subjective improvement between the treatment group 2 and the control group 2, at the fourth visit.

Table 4.20

Statistical results of the Numerical Pain Rating Scale –101 and the Short Form McGill Pain Questionnaire, comparing the fourth visit for the treatment group overall and the control group overall.

	N	Treatment group overall		P-value	Control group overall	
		Visit 4			Visit 4	
		M.E	S.D		M.E	S.D
NRS-101	30	14.41	12.12	0.000	42.26	16.33
McGill	30	3.50	3.18	0.000	9.40	7.24

The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: McGill. The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: NRS-101.

The null hypothesis was rejected for the NRS-101 and McGill Pain Questionnaire, indicating a significant subjective improvement between the treatment group and the control group overall, at the fourth visit.



#### 4.6.7 STATISTICAL RESULTS COMPARING THE TREATMENT AND CONTROL GROUPS IN TERMS OF OBJECTIVE MEASUREMENTS, FOR THE FIRST VISIT.

Table 4.21

Statistical results of the Algometric measurements and the Myofascial Diagnostic Scale scores, comparing the first visit of the treatment group 1 and the control group1.

	N	Treatment group 1		P-value	Control group I	
		Visit 1			Visit 1	
		M.E	S.D		M.E	S.D
ALG	15	1.62	0.55	0.413	1.77	0.45
MDS	15	14.00	1.88	0.422	13.26	1.98

The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: Algometer. The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: Myofascial Diagnostic scale.

The null hypothesis was accepted for the Algometric measures and Myofascial Diagnostic Scale scores, indicating no significant difference between the treatment group 1 and control group 1, at the first visit.

Table 4.22

Statistical results of the Algometric measurements and the Myofascial Diagnostic Scale scores, comparing the first visit of the treatment group 2 and the control group2.

	N	Treatment group 2		P-value	Control group 2	
		Visit 1			Visit 1	
		M.E	S.D		M.E	S.D
ALG	15	1.69	0.69	0.744	1.77	0.62
MDS	15	13.20	2.04	0.412	12.53	1.35

The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: Algometer. The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: Myofascial Diagnostic scale.

The null hypothesis was accepted for the Algometric measures and Myofascial Diagnostic Scale scores, indicating no significant difference between the treatment group 2 and control group 2, at the first visit.

Table 4.23

Statistical results of the Algometric measurements and the Myofascial Diagnostic Scale scores, comparing the first visit of the treatment group overall and the control group overall.

	N	Treatment group overall		P-value	Control group overall	
		Visit 1			Visit 1	
		M.E	S.D		M.E	S.D
ALG	30	1.65	0.61	0.440	1.77	0.54
MDS	30	13.60	1.97	0.390	12.90	1.70

The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: Algometer. The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: Myofascial Diagnostic scale.

The null hypothesis was accepted for the Algometric measures and Myofascial Diagnostic Scale scores, indicating no significant difference between the treatment group overall and control group overall, at the first visit.

#### 4.6.8 STATISTICAL RESULT COMPARING THE TREATMENT AND CONTROL GROUPS IN TERMS OF OBJECTIVE MEASUREMENTS, FOR THE FOURTH VISIT.

Table 4.24

Statistical results of the Algometric measurements and the Myofascial Diagnostic Scale scores, comparing the fourth visit of the treatment group 1 and the control group1.

	N	Treatment group 1 Visit 4		P-value	Control group 1 Visit 4	
		M.E	S.D		M.E	S.D
ALG	15	2.20	0.68	0.080	1.82	0.40
MDS	15	6.80	2.54	<b>0.000</b>	12.66	1.79

The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: Algometer. The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: Myofascial Diagnostic scale.

The null hypothesis was accepted for the Algometric measures, indicating no significant difference between the treatment group 1 and control group 1, at the fourth visit.

However the null hypothesis was rejected for the Myofascial Diagnostic Scale scores, indicating a significant difference between the treatment group 1 and control group 1, at the fourth visit.

Table 4.25

Statistical results of the Algometric measurements and the Myofascial Diagnostic Scale scores, comparing the fourth visit of the treatment group 2 and the control group2.

	N	Treatment group 2 Visit 4		P-value	Control group 2 Visit 4	
		M.E	S.D		M.E	S.D
ALG	15	2.39	0.65	<b>0.010</b>	1.76	0.59
MDS	15	6.40	1.80	<b>0.000</b>	12.13	1.50

The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: Algometer. The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: Myofascial Diagnostic scale.

The null hypothesis was rejected for the Algometric measures and Myofascial Diagnostic Scale scores, indicating a significant objective improvement between the treatment group 2 and control group 2, at the fourth visit.

Table 4.26

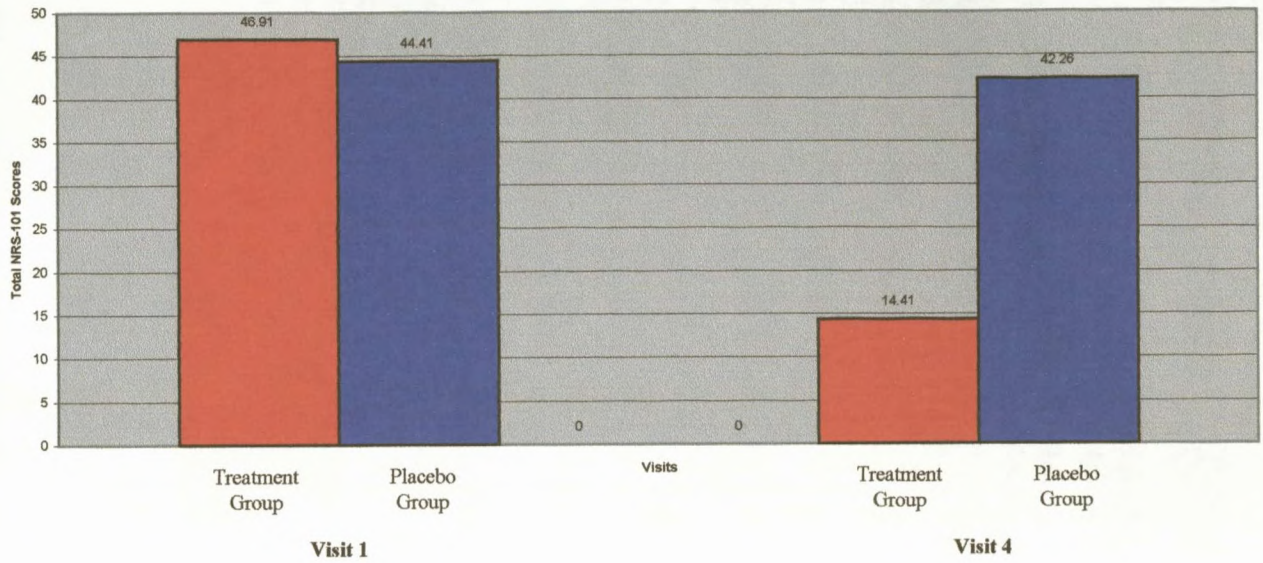
Statistical results of the Algometric measurements and the Myofascial Diagnostic Scale scores, comparing the fourth visit of the treatment group overall and the control group overall.

	N	Treatment group overall		P-value	Control group overall	
		Visit 4			Visit 4	
		M.E	S.D		M.E	S.D
ALG	30	2.29	0.66	<b>0.002</b>	1.79	0.50
MDS	30	6.60	2.17	<b>0.000</b>	12.40	1.65

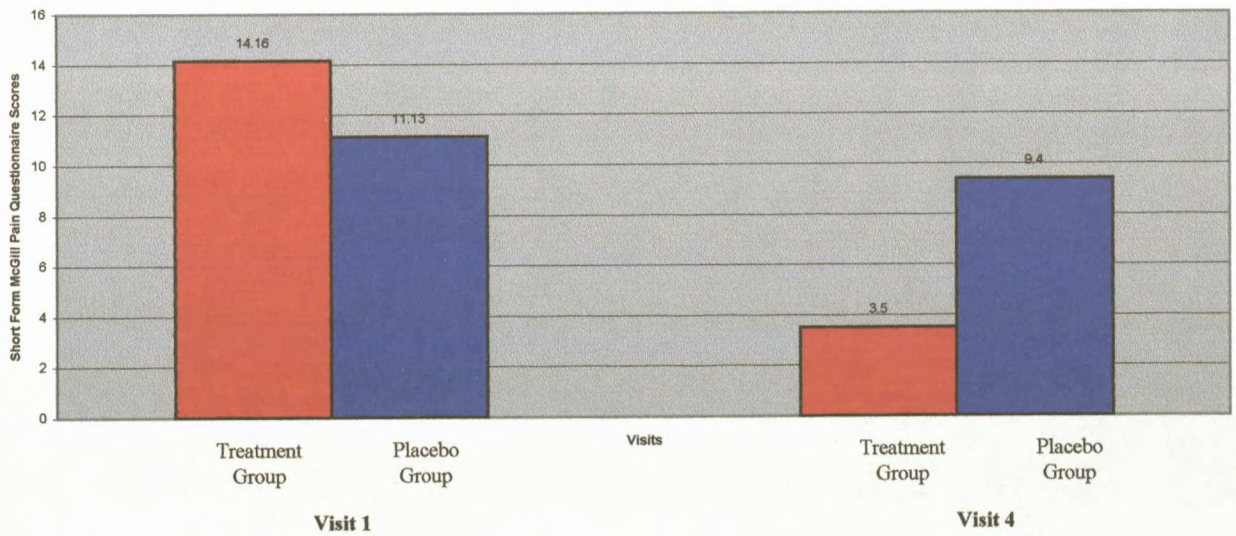
The two-sample unpaired t-test was used to compare the two groups with respect to the continuous variable, i.e.: Algometer. The Mann-Whitney unpaired U test was used to compare the two groups with respect to the categorical variable, i.e.: Myofascial Diagnostic scale.

The null hypothesis was rejected for the Algometric measures and Myofascial Diagnostic Scale scores, indicating a significant objective improvement between the treatment group overall and control group overall, at the fourth visit.

**Figure 4.1 Mean Values of the total NRS-101 Pain Questionnaires Scores at the 1st and 4th visits comparing the treatment and control groups.**

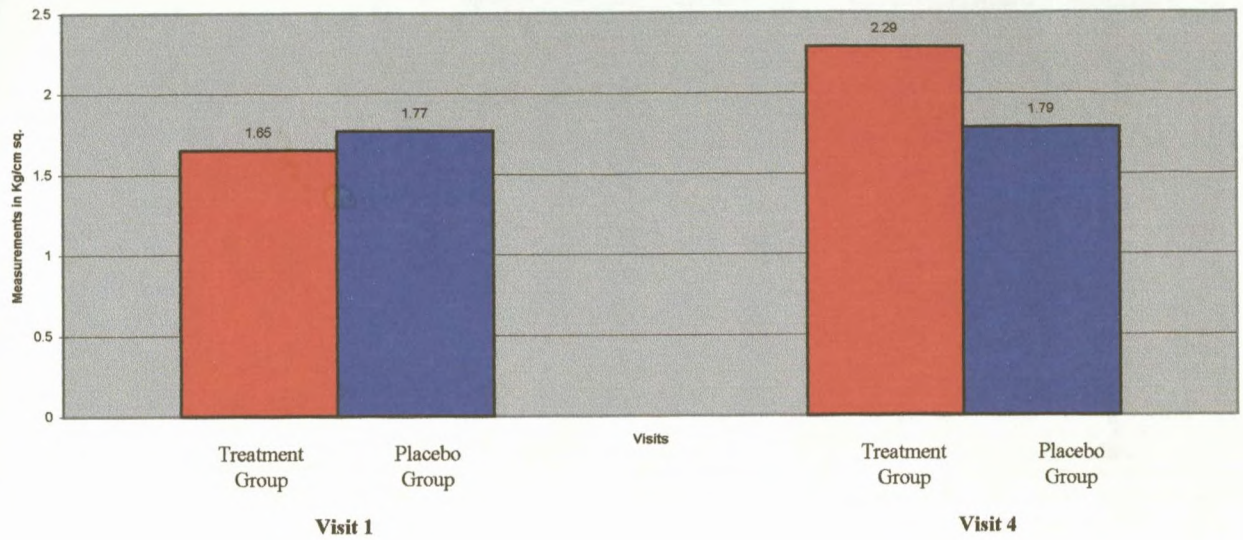


**Figure 4.2 Mean values of the Short Form McGill Pain Questionnaire at the 1st and 4th visits comparing the treatment and control groups**

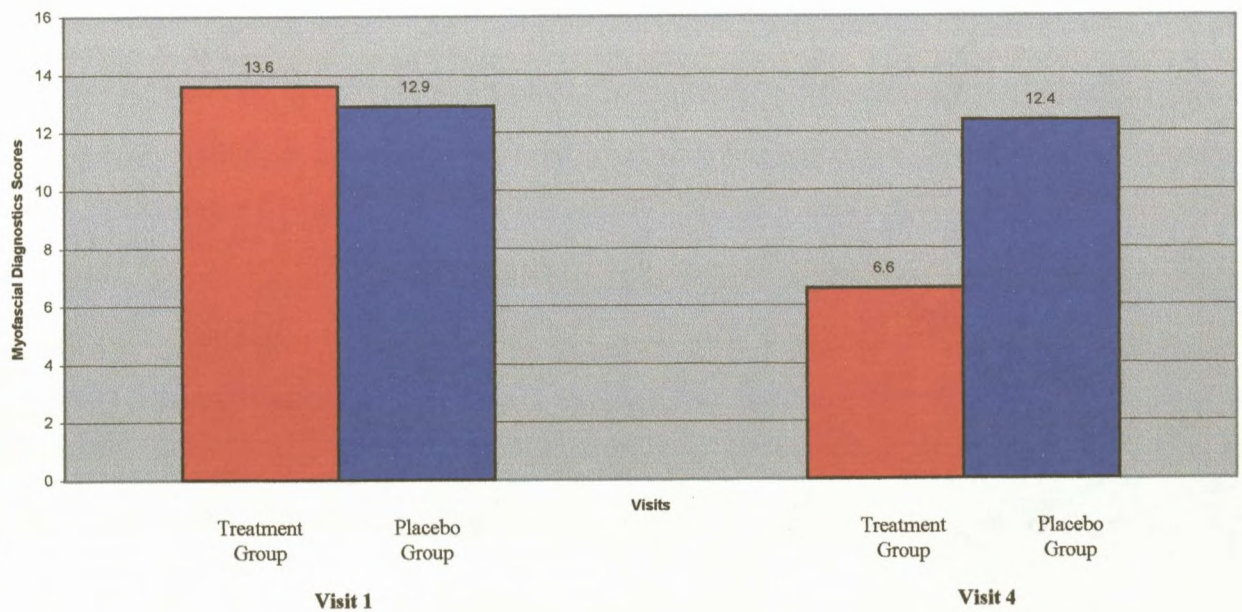




**Figure 4.3 Mean values of the Algometric measurements at the 1st and 4th visits comparing the treatment and control groups.**



**Figure 4.4 Mean values of the Myofascial Diagnostic Scale at the 1st and 4th visits comparing the treatment and control groups**





## **CHAPTER 5**

### **DISCUSSION OF THE RESULTS.**

#### **5.1 INTRODUCTION**

This chapter involves the discussion of the results obtained from the subjective and objective data. The results are discussed in two parts, that is, the objective and subjective results. Each measurement parameter is discussed and involves intra and inter-group comparisons.

The ranges of age distribution are tabulated in table 4.1. Of the patients who were accepted into the study and whom had completed the programme, 41% were males and 59% were females. These findings support Han and Harrison's(1997) opinion that, although the condition is prevalent in both sexes, it is more common in females.

#### **5.1.2 INTRA-GROUP COMPARISON.**

The assessment of the subjective and objective intra-group results of the first to fourth consultations represents the effectiveness of the treatment regime.

The results obtained from the respective 'muscle groups' were also evaluated. This gave an indication of whether or not the treatment regime was effective in treating myofascial trigger points in the trapezius muscle and or the gluteus medius muscle.

#### **5.1.3 INTER-GROUP COMPARISONS.**

Evaluation of the inter-group results of the first visit revealed any variance in the subjective and objective findings between the two groups, which presented at the start of the study. The comparison of the data collected at the fourth consultation indicated whether or not the treatment regime was more effective than placebo.

## **5.2 OBJECTIVE DATA.**

### **5.2.1 ALGOMETER READINGS.**

#### **5.2.1.1 INTRA-GROUP COMPARISONS.**

Two-sample paired t-test.

Upon evaluation of the overall measurement interval, that is the first to fourth consultation, there was a statistically significant improvement in the treatment group (overall) with respect to algometric measurements (Table 4.11). Both 'muscle groups' showed similar findings (Tables 4.9 and 4.10). In contrast no statistically significant improvement was seen in the control group (overall) nor the respective 'muscle groups' (Tables 4.12, 4.13 and 4.14). These findings suggest that while the treatment group was successful in terms of increasing the pressure pain threshold as measured by the algometer, the control group was unable to do so. The findings of only the treatment group support hypothesis one.

#### **5.2.1.2 INTER-GROUP COMPARISONS.**

Two-sample unpaired t-test.

Statistical comparison of the first visit showed no significant differences between the groups (Table 4.23). A significant difference was found at the fourth visit (Table 4.26).

This suggests that at visit four there was a significant difference with regards to the algometric measures between the two groups, that is the treatment group (overall) showed a greater improvement in pressure pain threshold. This supports hypothesis two.

Data analysis comparing the trapezius muscle treatment group with the control group resulted in a P-value of 0.080. This value approaches a level of statistically significant difference and therefore indicates that the treatment group responded more favourably than the control group even though not statistically significant.

## **5.2.2 THE MYOFASCIAL DIAGNOSTIC SCALE.**

### **5.2.2.1 INTRA-GROUP COMPARISON.**

Wilcoxon Signed Ranks test.

Statistical assessment of the mean values of the Myofascial Diagnostic Scale for the first to fourth consultation period depicted a statistically significant improvement in both groups (Tables 4.11 and 4.14). These findings support hypothesis one.

Evaluation of the respective muscle groups of the control group revealed no statistical differences (Tables 4.12, 4.13). The P-values of control group 1 and control group 2 were 0.034 and 0.059 respectively, which approaches a level of statistically significant difference. Thus statistical assessment of the control group as a whole showed a significant difference.

### **5.2.2.2 INTER-GROUP COMPARISON.**

Mann Whitney U test.

Statistical comparison of the first visit showed no significant differences between the groups (Table 4.23).

Data analysis of the Myofascial Diagnostic Scale scores for the fourth consultation revealed a statistically significant difference between the groups, indicating that one group responded more favourably than the other group (Table 4.26). Analysis of the mean values of the overall treatment group as well as the respective muscle treatment groups showed statistical significant improvement (Tables 4.24 and 4.25). These findings support hypothesis two.

## **5.3 SUBJECTIVE DATA.**

### **5.3.1 NUMERICAL PAIN RATING SCALE – 101**

#### **5.3.1.1 INTRA-GROUP COMPARISON.**

Two sample paired t-test.

Comparison of the first and fourth consultations revealed a statistically significant difference in the treatment group, indicating that the treatment regime used reduced the amount of pain experienced by the patients (Table 4.5).

In contrast the control group demonstrated no significant differences over the same treatment interval (Table 4.8). The results obtained from the treatment group supports hypothesis one.

#### **5.3.1.2 INTER-GROUP COMPARISON.**

Two sample unpaired t-test.

Statistical comparison of the first consultation of the two groups revealed no significant difference in terms of degree of pain intensity (Table 4.17). This suggests a similarity between the two groups with respect to pain perception as evaluated by the NRS-101.

Analysis of the data obtained from the fourth consultation disclosed a significant statistical difference between the two groups (Table 4.20). These findings suggest that the treatment group responded more favourably than the control group. The results obtained support hypothesis two.

#### **5.3.2 SHORT FORM MCGILL PAIN QUESTIONNAIRE.**

##### **5.3.2.1 INTRA-GROUP COMPARISON.**

Wilcoxon Signed Rank test

Comparative statistical analysis of the mean values of each group between the first and fourth consultation showed a statistically significant improvement in both groups (Tables 4.5 and 4.8). Although the control group as a whole demonstrated a statistical improvement, the two 'muscle' control groups respectively did not display similar findings (Tables 4.6 and 4.7). The data indicates that overall both the treatment group and control group was effective in terms of decreasing pain perception as shown by the McGill questionnaire. This supports hypothesis one.

### **5.3.2.2 INTER-GROUP COMPARISON.**

Mann Whitney U test.

Comparison of the first consultation of both groups showed no statistically significant difference, indicating that both groups as a whole were relatively homogenous with respect to pain perception (Table 4.17). However it is important to note that there was a statistically significant difference between the gluteus medius treatment group and the control group at the first consultation. This may be a possible explanation for the absence of statistical difference noted between the gluteus medius treatment group and control group at the fourth consultation.

In contrast data analysis of the fourth consultation comparing the treatment group and control group as a whole revealed a statistically significant difference between the two groups. This may be in part due to the relatively homogenous nature of the two groups as a whole with respect to pain perception. The data indicated that the treatment group as whole responded better than the control group in terms of pain perception (Table 4.20). These findings support hypothesis two.

## **5.4 INTERPRETATION OF CLINICAL FINDINGS.**

### **INTRA-GROUP HYPOTHESIS.**

It was hypothesised that 'Action Potential therapy' would be effective in treating patients with myofascial pain syndrome in terms of subjective and objective clinical findings.

Statistical analysis of the NRS-101, McGill, Myofascial Diagnostic Scale and Algometric measures all displayed significant improvement for the treatment group. These findings support the above-mentioned hypothesis. The control group demonstrated significant differences for the Myofascial Diagnostic Scale and the McGill measures, but not for the NRS-101 or Algometric readings. Therefore it can be said that improvement occurred in both

groups between the first and fourth consultations, however the treatment group showed more favourable results.

#### INTER-GROUP HYPOTHESIS.

It was hypothesised that 'Action Potential therapy' would be more effective than placebo 'Action Potential therapy' in the management of patients of myofascial pain syndrome.

Analysis of NRS-101, McGill Pain Questionnaire, Myofascial Diagnostic Scale and Algometric measures taken at the fourth consultation all indicate a statistically significant difference between the two groups. This data suggests that the treatment group responded more positively to the treatment protocol, than the control group to the placebo intervention. The results obtained from the inter-group analysis support the above hypothesis in terms of both subjective and objective clinical findings.

### **5.5 PROBLEMS ENCOUNTERED WITH THE DATA.**

#### **5.5.1 THE OBJECTIVE DATA.**

Algometer.

Three problems were encountered with the use of the algometer as an objective tool.

- Some patients did not understand the instruction clearly, and therefore did not respond by saying "now" at the point at which they first perceived pain.
- Some patients responded to lower pressure in order to prevent themselves from feeling the pain.
- It was felt that although the same trigger point was used to take algometric readings on the first and last consultations, certain factors could affect the outcome namely direction of pressure applied through the shaft of the algometer, skin slack and the emotional state of the patient.

#### Myofascial Diagnostic Scale:

Many patients who were part of the gluteus medius muscle group presented with active trigger points in the posterior trigger point one region, as described by Travell and Simons (1983:150). The accuracy of refinding and re-evaluating these trigger points on subsequent visits were difficult.

#### **5.5.2 THE SUBJECTIVE DATA.**

- Misunderstanding of the questionnaires by the patients may have affected their response, and therefore the outcome of the results.
- Patients may also have recorded improvements, which were beyond those actually felt in order to please the researcher.
- Patients may have answered the questionnaires based on what they recalled filling in on previous questionnaires.

## CHAPTER 6

### CONCLUSION AND RECOMMENDATIONS.

#### 6.1 CONCLUSION.

The study comprised of 60 patients, all of which were diagnosed with active trigger points in either the trapezius or gluteus medius muscle. All patients underwent a full case history, physical examination and a regional examination. The patients were randomly allocated to either the treatment group (Group A) or the control group (Group B). Each group consisted of 30 patients, 15 of which had trigger points in the trapezius muscle and 15 in the gluteus medius muscle. Patients attended the clinic four times over a period of 7 to 10 days. At each consultation, group A received 'Action Potential therapy' for 8 minutes, while group B received placebo 'Action Potential therapy'. The data was captured at the initial and final consultations.

It was evident from the data that patients in the treatment group responded favourably to the treatment intervention, in terms of both subjective and objective clinical findings. The control group showed a significant statistical improvement in terms of the McGill and Myofascial Diagnostic Scale scores. However patients in this group demonstrated no improvement of pressure pain threshold (Algometer) and pain perception (NRS-101). Significant differences were found for all measures taken at the final consultation between the two groups. The data indicate that the treatment intervention was more effective than placebo in the management of myofascial pain syndrome, in terms of both subjective and objective clinical findings. This study therefore supports the use of Action Potential therapy in the short-term treatment of myofascial pain syndrome.



## 6.2 RECOMMENDATIONS.

The following recommendations are made for future studies.

X Inclusion and exclusion criteria:

-Stricter inclusion and exclusion criteria with regards to onset and duration of the condition, perpetuating factors, amount of dysfunction, concomitant and associated complaints, will enhance the strength of the study.

✓ Independent observers:

-It is recommended that if a study of a similar nature is conducted, a double blind procedure should be implemented. This could be done by having an unbiased independent observer administer the treatment or placebo intervention.

-A researcher may be influenced by the results obtained from previous measures. It is therefore recommended that an independent observer should conduct assessments such as the Myofascial Diagnostic Scale.

Data measurement:

-The data was captured at the initial consultation prior to the first treatment and was repeated at the fourth consultation immediately after the last treatment. It is the opinion of the researcher that the readings taken at the fourth consultation could have been affected by the patient's response to the stimulatory effects of the treatment intervention. It is therefore recommended that a window period be allowed after the last treatment before the readings are taken again.

-When utilizing objective tools such as the algometer, make sure that the participants clearly understand the instructions.

-If a study is conducted in which a new scale is developed and used, such as the Myofascial Diagnostic Scale, it is recommended that a pilot study be carried out first. In addition when utilizing such a scale for the first time, it is suggested that one area be assessed. In this case, just one muscle.

Treatment time and the number of treatments:

-From the data it is evident that Action Potential therapy is effective in treating myofascial pain syndrome. Further studies may be carried out to assess the relative effectiveness of this modality compared to others in the treatment of myofascial pain syndrome. However, before these comparisons are made, a study should be conducted to evaluate the most effective treatment time and number of treatments needed to treat patients with myofascial pain syndrome using this modality.

Intensity of treatment:

-Berger (1999:63) states that the higher the intensity, the greater the improvement of the condition, with the objective being to encourage as high as intensity as possible always allowing the comfort of the patient. In this study the current intensity was not allowed to exceed 2 mA. Some patients receiving active form of the treatment intervention felt no sensation even at 2 mA. Thus usage of a current as high as the patient's comfort will allow is recommended.

Follow up consultation:

The inclusion of a follow up consultation, a few weeks after the final treatment is recommended, to assess the long-term effects of 'Action Potential therapy'.

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Appendix A

**TECHNIKON NATAL CHIROPRACTIC DAY CLINIC**  
**CASE HISTORY**

Patient: \_\_\_\_\_ Date: \_\_\_\_\_  
file #: \_\_\_\_\_ X-Ray#: \_\_\_\_\_  
Age: \_\_\_\_\_ Sex: \_\_\_\_\_ Occupation: \_\_\_\_\_  
Intern: \_\_\_\_\_ Signature: \_\_\_\_\_

**FOR CLINICIAN'S USE ONLY**

Initial visit clinician: \_\_\_\_\_ Signature: \_\_\_\_\_

**Case History:**

**Examination:**

Previous: \_\_\_\_\_

Current: \_\_\_\_\_

**X-Ray Studies:**

Previous: \_\_\_\_\_

Current: \_\_\_\_\_

**Clinical Path. lab:**

Previous: \_\_\_\_\_

Current: \_\_\_\_\_

**Case Status:**

PTT: \_\_\_\_\_ Conditional: \_\_\_\_\_ Signed Off: \_\_\_\_\_ Final Sign out: \_\_\_\_\_

Recommendations: \_\_\_\_\_

**Intern's Case History**

1. Source of History:
2. Chief Complaint: (patient's own words)

3. Present Illness:

- ▶ Location
- ▶ Onset
- ▶ Duration
- ▶ Frequency
- ▶ Pain (Character)
- ▶ Progression
- ▶ Aggravating Factors
- ▶ Relieving Factors
- ▶ Associated S & S
- ▶ Previous Occurrences
- ▶ Past Treatment and 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
- ▶ Environmental Hazards (Home, School, Work)
- ▶ Safety Measures (seat belts, condoms)
- ▶ Exercise and Leisure
- ▶ Sleep Patterns
- ▶ Diet
- ▶ Current Medication
- ▶ Tobacco
- ▶ Alcohol
- ▶ Social Drugs

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

**TECHNIKON NATAL CHIROPRACTIC DAY CLINIC**

**PHYSICAL EXAMINATION**

Patient: \_\_\_\_\_ File#: \_\_\_\_\_ Date: \_\_\_\_\_  
 Clinician: \_\_\_\_\_ Signature: \_\_\_\_\_  
 Intern: \_\_\_\_\_ Signature: \_\_\_\_\_

**1. VITALS**

Pulse rate:

Respiratory rate:

Blood pressure:      R                      L

Temperature:

Height:

Weight:

**2. GENERAL EXAMINATION**

General Impression:

Skin:

Jaundice:

Pallor:

Clubbing:

Cyanosis (Central/Peripheral):

Oedema:

Lymph nodes            - Head and neck:  
                                  - Axillary:  
                                  - Epitrochlear:  
                                  - Inguinal:

Urinalysis:

**3. CARDIOVASCULAR EXAMINATION**

1) Is this patient in **Cardiac Failure** ?

2) Does this patient have signs of **Infective Endocarditis** ?

3) Does this patient have **Rheumatic Heart Disease** ?

**Inspection**   - Scars  
                   - Chest deformity:  
                   - Precordial bulge:  
                   - Neck -JVP:

**Palpation:**   - Apex Beat (character + location):  
                   - Right or left ventricular heave:  
                   - Epigastric Pulsations:  
                   - Palpable P2:  
                   - Palpable A2:



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

Percussion:        - borders of heart

Auscultation:        - heart valves (mitral, aortic, tricuspid, pulmonary)  
                         - Murmurs (timing, systolic/diastolic, site, radiation, grade).

#### 4.     RESPIRATORY EXAMINATION

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

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

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

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

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

#### 5.     ABDOMINAL EXAMINATION

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

Inspection    - Shape:  
                 - Scars:  
                 - Hernias:

Palpation     - Superficial:  
                 - Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

**Percussion** - Rebound tenderness:  
 - Ascites:  
 - Masses:

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

**Rectal Examination**      - Perianal skin:  
                                      - Sphincter tone & S4 Dermatome:  
                                      - Obvious masses:  
                                      - Prostate:  
                                      - Appendix:

## 6. G.U.T EXAMINATION

External genitalia:  
 Hernias:  
 Masses:  
 Discharges:

## 7. NEUROLOGICAL EXAMINATION

**Gait and Posture** - Abnormalities in gait:  
                              - Walking on heels (L4-L5):  
                              - Walking on toes (S1-S2):  
                              - Rombergs test (Pronator Drift):

**Higher Mental Function** - Information and Vocabulary:  
                                      - Calculating ability:  
                                      - Abstract Thinking:

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

**Evidence of head trauma:**

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

**Cranial Nerves:**

I      Any loss of smell/taste:  
        Nose examination:

II      External examination of eye:      - Visual Acuity:  
    - Visual fields by confrontation:

- Pupillary light reflexes      = Direct:
- = Consensual:

- Fundoscopy findings:

III    Ocular Muscles:  
       Eye opening strength:

IV    Inferior and Medial movement of eye:

- V    a.    Sensory      - Ophthalmic:  
                          - Maxillary:  
                          - Mandibular:
- b.    Motor        - Masseter:  
                          - Jaw lateral movement:
- c.    Reflexes    - Corneal reflex  
                          - Jaw jerk

VI    Lateral movement of eyes

- VII   a.    Motor - Raise eyebrows:  
                  - Frown:  
                  - Close eyes against resistance:  
                  - Show teeth:  
                  - Blow out cheeks:
- b.    Taste - Anterior two-thirds of tongue:

VIII   General Hearing:  
       Rinnes = L:                      R:  
       Webers lateralisation:  
       Vestibular function - Nystagmus:  
    - Rombergs:  
    - Wallenbergs:  
       Otoscope examination:

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

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

XII   Inspection of tongue (deviation):

### Motor System:

- a.    Power
- Shoulder    = Abduction & Adduction:  
                          = Flexion & Extension:
  - Elbow        = Flexion & Extension:
  - Wrist        = Flexion & Extension:

- Forearm = Supination & Pronation:
  - Fingers = Extension (Interphalangeals & M.C.P's):
  - Thumb = Opposition:
  - Hip = Flexion & Extension:
  - = Adduction & Abduction:
  - Knee = Flexion & Extension:
  - Foot = Dorsiflexion & Plantar flexion:
  - = Inversion & Eversion:
  - = Toe (Plantarflexion & Dorsiflexion):
- b. Tone
- Shoulder:
  - Elbow:
  - Wrist:
  - Lower limb - Int. & Ext. rotation:
  - Knee clonus:
  - ankle clonus:
- c. Reflexes
- Biceps:
  - Triceps:
  - Supinator:
  - Knee:
  - Ankle:
  - Abdominal:
  - Plantar:

### Sensory System:

- a. Dermatomes
- Light touch:
  - Crude touch:
  - Pain:
  - Temperature:
  - Two point discrimination:
- b. Joint position sense
- Finger:
  - Toe:
- c. Vibration:
- Big toe:
  - Tibial tuberosity:
  - ASIS:
  - Interphalangeal Joint:
  - Sternum:

### Cerebellar function:

Obvious signs of cerebellar dysfunction:

- = Intention Tremor:
- = Nystagmus:
- = Truncal Ataxia:

Finger-nose test (Dysmetria):

Rapid alternating movements (Dysdiadochokinesia):

Heel-shin test:

Heel-toe gait:

Reflexes:

Signs of Parkinsons:

8. SPINAL EXAMINATION:(See Regional examination)

Obvious Abnormalities:

Spinous Percussion:

R.O.M:

Other:

9. BREAST EXAMINATION:

Summon female chaperon.

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

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

## Appendix C

### TECHNIKON NATAL CHIROPRACTIC DAY CLINIC REGIONAL EXAMINATION - *CERVICAL SPINE*

Patient: \_\_\_\_\_ File: \_\_\_\_\_

Date: \_\_\_\_\_ Intern/Resident: \_\_\_\_\_

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

#### OBSERVATION:

Posture  
Swellings  
Scars  
Discolouration  
Hair Line  
Bony & Soft Tissue Contours

Shoulder position:

Left:

Right:

Muscle spasm  
Facial expression

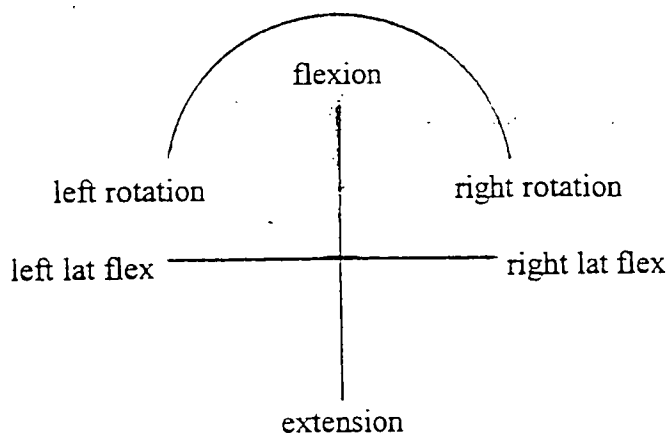
#### RANGE OF MOTION:

Flexion (45'):

L/R Rotation (70'):

Extension (70'):

L/R Lat Flex (45'):



#### PALPATION:

Lymph Nodes  
Thyroid Gland

Trachea

#### ORTHOPAEDIC EXAMINATION:

Tenderness

Trigger Points:

SCM

Scalenii

Post Cervicals

Trapezius

Lev Scap

Doorbell sign

Kemp's test

Cervical distraction

Halstead's test

Hyperabduction test

Shoulder abduction test

Cervical compression

Lateral compression

Adson's test

Costoclavicular test

Eden's test

Shoulder depression test

Dizziness rotation test  
Brachial plexus tension

Lhermitte's sign

**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					

**VASCULAR:**

	Left	Right
Blood Pressure		
Carotid arts.		
Subclavian arts.		
Wallenberg's test		

**MOTION PALPATION & JOINT PLAY:**

Left: Motion Palpation:  
Joint Play:

Right: Motion palpation:  
Joint Play:

Basic Exam: Shoulder:  
Case History:

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

Upper Thoracics:  
Motion Palpation:  
Joint Play:

Basic Exam: Thoracic Spine:  
Case History:

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

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC  
REGIONAL EXAMINATION - LUMBAR SPINE AND PELVIS.

PATIENT: \_\_\_\_\_

FILE #: \_\_\_\_\_

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

INTERN/RESIDENT: \_\_\_\_\_

SUPERVISING CLINICIAN: \_\_\_\_\_

STANDING:

Posture  
Minor's Sign  
Skin  
Scars  
Discoloration  
Muscle Tone  
Bony & Soft Tissue Contours

Spinous Percussion  
Schober's Test (6cm)  
Treadmill  
Body Type  
Attitude

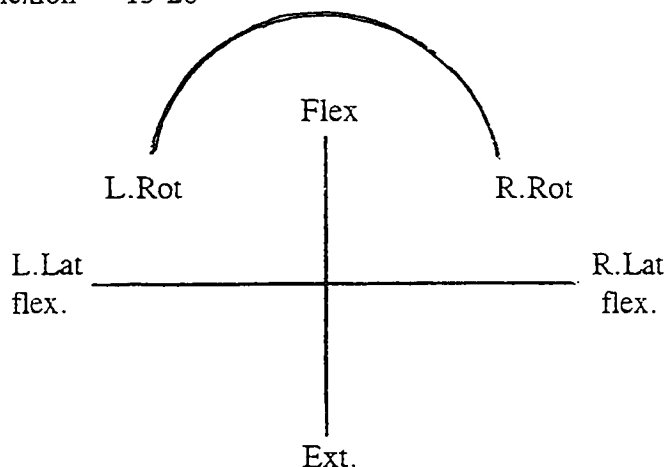
RANGE OF MOTION

Forward Flexion = 40-60° (15cm from floor)

Extension = 20-35°

L/R Rotation = 3-18°

L/R Lateral Flexion = 15-20°



SUPINE:

Skin  
Hair  
Nails  
Palpate Abdomen/groin  
Pulses (abdomen)

Observe abdomen  
Fasciculations  
Abdominal Reflexes



Pulses (extremities)  
SLR  
Bowstring  
Plantar Reflex  
Circumference (thigh, calf)  
Leg Length:  
    actual  
    apparent  
Sciatic Notch  
Patrick FABERE  
Gaenslen's Test  
Gluteus Maximus Stretch  
Hip Medial rotation  
Psoas Test  
Thomas' Test:  
    hip joint  
    Rectus Femoris

#### LATERAL RECUMBENT

S-I Compression  
Ober's Test  
Femoral Nerve stretch  
Myotomes:  
    QL  
    Gluteus Medius

#### NON ORGANIC SIGNS

Pin Point Pain  
Axial Compression  
Trunk Rotation  
Burn's Bench Test  
Flip Test  
Hoover's Test  
Ankle Dorsiflexion Test.

#### GAIT

Rhythm  
On toes (standing)  
On Heels (standing)  
Half squat on one leg

#### PRONE

Gluteal skyline  
Skin rolling  
Iliac crest compression  
Facet joint challenge  
S-I tenderness  
Erichson's Test  
Pheasant's Test  
Myotome:  
    Glut. Max  
Active MF Trigger Pts:  
    QL  
    Glut. Med  
    Glut. Min  
    Glut. Max  
    Piriformis  
    Hamstrings  
    TFL

NEUROLOGICAL EXAMINATION

DERMATOMES			MYOTOMES			REFLEXES		
	L	R		L	R		L	R
T12			Hip Flex			Pat.		
L1			Hip int rot			Achil		
L2			Hip ext rot			H/S		
L3			Hip abd					
L4			Hip add					
L5			Knee flex					
S1			Knee ext					
S2			Dorsiflex					
S3			Plantarflex					
			Eversion					
			Ext.hal.long					

Tripod  
Kemp's Test

MOTION PALPATION and JOINT PLAY:

LEFT:      Upper Thoracics:  
             Lumbar Spine:  
             Sacroiliac Joint:

RIGHT:     Upper Thoracics:  
             Lumbar Spine:  
             Sacroiliac Joint:

Basic Exam: Hip  
Case History:

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

Observ/Palpation:

Basic Exam: Thoracic Spine  
Case History:

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

Observ/Palpation:

## Appendix D

### NUMERICAL RATING SCALE – 101

Please indicate on the line below the number between 0 and 100 that best describes the pain of your major problem at this point, when it is at its worst. A zero (0) would mean “no pain at all” and a hundred (100) would mean “pain as bad as it could be”. Please write only one number.

---

Please indicate on the line below the number between 0 and 100 that best describes the pain of your major problem at this point, when it is at its least. A zero (0) would mean “no pain at all” and a hundred (100) would mean “pain as bad as it could be”. Please write only one number.

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Appendix E

**Short-form McGill Pain Questionnaire (SF-MPQ)**

Ronald Melzack (1984)

Date: \_\_\_\_\_ File no.: \_\_\_\_\_ Visit no: \_\_\_\_\_

Patient name: \_\_\_\_\_

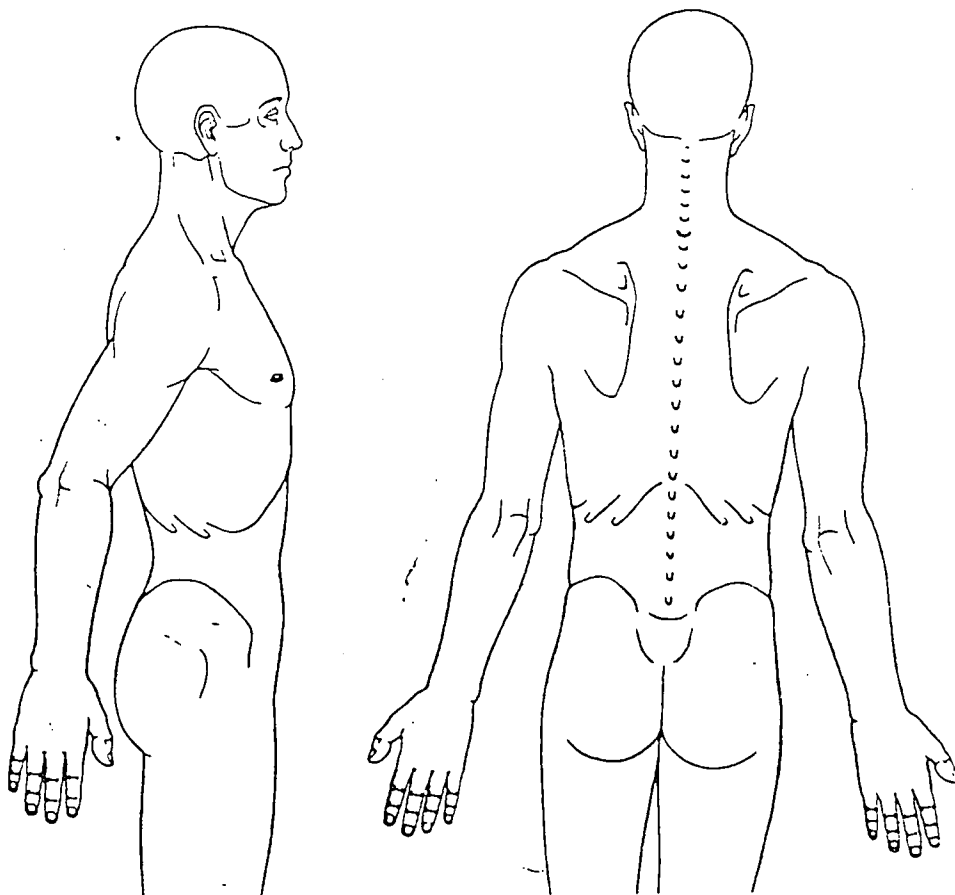
	NONE 0	MILD 1	MODERATE 2	SEVERE 3
THROBBING				
SHOOTING				
STABBING				
SHARP				
CRAMPING				
GNAWING				
HOT-BURNING				
ACHING				
HEAVY				
TENDER				
SPLITTING				
TIRING-EXHAUSTING				
SICKENING				
FEARFUL				
PUNISHING-CRUEL				

Adapted from the Short-form McGill Pain Questionnaire. Copyright 1984 Ronald Melzack

## Appendix F

Name: \_\_\_\_\_

Group: A B C D



### ALGOMETER READINGS

READING NO. 1	READING NO. 2

## Appendix G

### Myofascial Diagnostic Scale

Patient's Name:  
Treatment No. \_\_\_\_\_

Muscle: \_\_\_\_\_

Circle the appropriate  
Letter A B C D

#### Signs:

- |     |  |   |
|-----|--|---|
| 1)  | Soft tissue tenderness   |   |
|     | Grade  |   |
| 0   | No tenderness  | 0 |
| i   | Tenderness to palpation WITHOUT<br>Grimace or flinch   | 1 |
| ii  | Tenderness WITH grimace and/or<br>Flinch to palpation  | 2 |
| iii | Tenderness with WITHDRAWAL<br>(+"Jump sign")   | 3 |
| iv  | Withdrawal (+"Jump sign")<br>To non-noxious stimuli (ie. Superficial<br>palpation, pin prick, gentle percussion) | 4 |
| 2)  | Snapping palpation of the trigger point evokes a<br>local twitch response.                                       | 4 |
| 3)  | The trigger point is found in a palpable taut band.  | 4 |
| 4)  | Moderate, sustained pressure on the trigger point<br>Causes or intensifies pain in reference zone.               | 5 |

Total

## Appendix H

### TECHNIKON NATAL CHIROPRACTIC

### CHIROPRACTIC RESEARCH ON THE USE OF ACTION POTENTIAL THERAPY IN THE MANAGEMENT OF MUSCULAR PAIN.

#### Letter of information:

Dear patient,

You are invited to participate in a research study to examine the efficacy of a new pain relief modality called Action potential therapy (APT). It will be used to treat muscular pain in this study.

The study will allow the researcher to determine whether or not the device is effective in reducing pain of a muscular origin.

There will be two groups within the study, one will receive an active form of APR therapy, whilst the other group will receive a placebo treatment. Free chiropractic treatment will be available once the study is completed to those participants placed in the placebo group and do not have any relief of symptoms. The study is designed so that neither the researcher nor the patient knows the true nature of the device being used (i.e. active or placebo).

The importance of this research is that it allows the profession to develop new strategies to treat muscular pain more effectively.

Treatment will be free of charge and will be performed under supervision of a qualified chiropractor.

Your involvement is voluntary and confidentiality will be ensured.

You are asked for the duration of the study to avoid the use of any pain relieving medication.

Thank you for your interest and support.

Yours sincerely,

Amaran Chettiar.  
Chiropractic resident.

## INFORMED CONSENT FORM

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

Title of research project ; THE THERAPEUTIC EFFICACY OF "ACTION  
POTENTIAL THERAPY" IN THE TREATMENT OF  
MYOFASCIAL PAIN SYNDROME.

Name of supervisor : Dr. MyburghName of research student ; Amaran chettiarPlease circle the appropriate answer

YES NO

- |    |   |     |    |
|----|---|-----|----|
| 1. | Have you read the research information sheet?                         | Yes | No |
| 2. | Have you had an opportunity to ask questions regarding this study?    | 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. | Who have you spoken to? _____   |     |    |
| 7. | Do you understand the implications of your involvement in this study? | Yes | No |
| 8. | Do you understand that you are free to withdraw from this study?      | Yes | No |
|    | a) at any time  |     |    |
|    | b) without having to give any a reason for withdrawing, and           |     |    |
|    | c) without affecting your future health care.                         |     |    |
| 9. | Do you agree to voluntarily participate in this study                 | Yes | No |

If you have answered no to any of the above, please obtain the information before signing

Please Print in block letters:

Patient /Subject Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Witness Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Research Student Name: \_\_\_\_\_

Signature: \_\_\_\_\_