

**A CLINICALLY CONTROLLED STUDY INVESTIGATING THE EFFECT
OF DRY NEEDLING MUSCLE TISSUE IN ASYMPTOMATIC SUBJECTS
WITH RESPECT TO POST-NEEDLING SORENESS**

By

Emile Ferreira

A dissertation submitted to the faculty of health in partial compliance with the requirements for the Masters Degree in Technology: Chiropractic, at the Durban Institute Of Technology.

I, Emile Ferreira, do declare that this dissertation represents my own work in both conception and execution.

Emile Ferreira

Date

Approved for final submission

Dr. A. Docrat
M.Tech: Chiropractic (TN), CCFC (TN)
Supervisor

Date

DEDICATION

This research is dedicated to my parents for their love and support over the years, this would not have been possible without you.

And to Michelle, your constant encouragement and never-ending support will always be remembered. You have been and always will be an inspiration to me.

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ABSTRACT

Myofascial pain syndrome is the second most common reason patients seek the help of health care workers. It costs billions of dollars each year in lost revenue due to loss of productivity and other costs.

The treatment of myofascial pain syndrome has been extensively researched and it appears that dry needling and medicinal injections of trigger points are some of the most effective modalities. However, an unwanted side effect common to both these therapies is post-needling soreness. Despite being mentioned in passing by many authors, very little detail is available regarding post-needling soreness.

It is unclear whether post-needling soreness arises from the trigger point itself, or whether the tissue damage caused by the needle insertion is responsible. Therefore, this study was aimed at investigating whether dry needling muscle tissue in asymptomatic subjects (i.e. subjects not suffering from myofascial pain syndrome) resulted in post-needling soreness. Two different dry needling techniques were also compared with a placebo group in order to determine which technique resulted in the least post-needling soreness.

This study was designed as a prospective, randomised, placebo controlled experimental investigation. Sixty subjects were randomly allocated into three equal groups. Group one received the single needle insertion technique and the second group received the fanning dry needling technique. The last group formed the control group and the subjects were treated using the Park Sham Device (placebo needles). All the subjects were between the ages of 18 and 50 and were required to be asymptomatic in the low back region.

Algometer readings were taken immediately before and after the dry needling procedure and again at the follow-up visit 24 hours later. Subjects were asked to rate, using the Numerical Pain Rating Scale 101, any post-needling soreness they might have

experienced. This was done immediately after the dry needling was completed and at the follow-up visit. A 24-hour pain diary was also provided to all the subjects, which they were required to complete at three-hour intervals following the dry needling.

SPSS version 11.5 was used for data analysis (SPSS Inc. Chicago, Ill, USA). Baseline demographics and outcome measurements were compared between the three groups using Pearson's chi square tests or ANOVA as appropriate.

An intra-group analysis revealed that, objectively, all groups experienced some degree of post-needling soreness. Subjectively however, the placebo group did not experience any post-needling soreness according to the findings from the NRS-101 and 24-hour pain diaries.

An inter-group analysis yielded no statistically significant results regarding the difference in which the single needle insertion group and the fanning dry needling group experienced post-needling soreness. However, both of these groups did develop a significantly greater level of post-needling soreness when compared to the placebo group.

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CHAPTER ONE

1.1 Introduction.

Myofascial Pain Syndrome, which results from myofascial trigger points, is a common source of frustration for both healthcare practitioners and patients. It is the second most common reason for patients visiting their health care practitioner and constitutes up to 85% of the reasons for visits to pain clinics (Han and Harrison, 1997). As muscle pain is the most common work-related injury (Hubbard, 1998), it costs billions of dollars in lost revenue every year due to lost productivity (Fricton, 1990).

Despite the high prevalence of myofascial trigger points, the pathophysiology of it is not appropriately emphasised in the training of healthcare practitioners (Gatterman and Goe, 1990). The treatment of Myofascial Pain Syndrome has been researched and discussed more extensively. This may be due to the fact that a wide range of treatment modalities exist, including massage, ischaemic compression, exercise, the application of heat or cold, ultrasonography, transcutaneous electrical nerve stimulation, Spray-and-Stretch technique, trigger points injection and dry needling (Wilks, 2003)(Cumming, 2002).

Trigger point injection, using saline, steroids or local anaesthetics is probably the most effective way of inactivating and relieving the painful symptoms of trigger points (Alvarez and Rockwell, 2002). However, studies have shown that dry needling is as effective as the injection of medication (Han and Harrison, 1997). Thus, it has been assumed that the therapeutic value of both dry needling and medicinal injections may actually be due to the effect of mechanical disruption by the needle (Alvarez and Rockwell, 2002). Therefore it is possible to avoid the development of unwanted side effects of medicinal injections such as allergic reactions, muscle necrosis (Travell, Simons and Simons,

1999), skin de-pigmentation and tendon atrophy, as well as syncope, apnoea and palpitations (Ruane, 2001).

A side effect common to both dry needling and the injection of medication is the development of post-needling soreness. Post-needling soreness appears to be worse after dry needling, with respect to both intensity and duration, when compared to trigger point injection (Alvarez and Rockwell, 2002). Although post-needling soreness is commented on by many authors (Han and Harrison, 1997, Lewit, 1979, Hubbard, 1998), its exact cause has not been documented. Travell, Simons and Simons (1999) noted that post-needling soreness experienced by patients was aggravated if bleeding occurred after trigger point injection or dry needling. Lewit (1979) noted that post-needling soreness resulted even when a trigger point was not precisely needled. It is thus unclear whether the pain arises from the trigger point itself, or whether the tissue damage caused by the needle insertion is responsible.

Therefore the aim of this study was to investigate whether dry needling muscle tissue in asymptomatic subjects (i.e. subjects not suffering from myofascial pain syndrome) resulted in post-needling soreness.

1.2 Aims and Objectives of the study.

The aim of this study was to determine whether applying dry needling to muscle tissue in asymptomatic subjects results in the development of post-needling soreness in terms of subjective and objective findings.

1.2.1 Objective one

To determine whether applying a single dry needle insertion, fanning dry needle insertion and placebo needling to muscle tissue of asymptomatic subjects result in the development of post-needling soreness in terms of subjective clinical findings.

1.2.2 Objective two

To determine whether applying a single dry needle insertion, fanning dry needle insertion and placebo needling to muscle tissue of asymptomatic subjects result in the development of post-needling soreness in terms of objective clinical findings.

1.2.3 Objective three

To determine, through analysing the data from the subjective and objective findings, which application of dry needling resulted in the development of greater post-needling soreness.

1.3 The Hypotheses.

1.3.1 The First Hypothesis

It is hypothesized that the application of single dry needle insertion, fanning dry needle insertion and placebo needling to muscle tissue in asymptomatic subjects will result in the development of post-needling soreness in terms of subjective clinical findings.

1.3.2 The Second Hypothesis

It is hypothesized that the application of single dry needle insertion, fanning dry needle insertion and placebo needling to muscle tissue in asymptomatic subjects will result in the development of post-needling soreness in terms of objective clinical findings.

1.3.3 The Third Hypothesis

It is hypothesized that the application of fanning dry needle insertion will result in the development of greater post-needling soreness than the application of single dry needle insertion, and that both the afore mentioned applications will result in the development of greater post-needling soreness than the application of placebo needling in terms of subjective and objective clinical findings.

1.4 Rationale for this study.

From the variety of modalities available for the treatment of myofascial pain syndrome, dry needling appears to be one of the most effective forms of therapy (Alvarez and Rockwell, 2002). The development of post-needling soreness does, however, necessitate the avoidance of strenuous activity of the involved muscle and prevents any further needling of the same region for 3-4 days after, delaying follow-up treatment and

hence recovery (Travell, Simons and Simons, 1999). However, it is not known whether post-needling soreness is peculiar to trigger points or whether it occurs in muscle tissue of asymptomatic patients as well.

It is hoped that this investigation contributes to the limited literature available regarding post-needling soreness and that future studies can utilise this information in an attempt to limit or prevent the onset of post-needling soreness in order to hasten patient recovery in the future.

CHAPTER TWO

Review of the Related Literature

2.1 Introduction

Myofascial Pain Syndrome, as defined by Travell, Simons and Simons (1999: p5), refers to the motor, sensory and autonomic symptoms that are caused by myofascial trigger points. These trigger points may be either active or latent regarding the causation of spontaneous pain (Alvarez and Rockwell, 2002), with the latter occurring more commonly (Han and Harrison, 1997: p89).

Fischer and Chang (1986: p212) reported that Myofascial Pain Syndrome is the condition most often seen in general practice. Hubbard (1998: p16) stated that pain arising from muscle tissue is the most common work-related injury reported.

2.2 Incidence and prevalence of Myofascial Pain Syndrome

The statistics regarding the incidence and prevalence of MPS is significant. Travell, Simons and Simons (1999: p12) state that almost every single person will at one time or another suffer from this painful condition. Hubbard (1998: p16) states that 30% to 40% of those suffering from muscle strain will go on to experience pain of a chronic nature.

Voluntary muscle constitutes 40% to 50% of body weight (Travell, Simons and Simons, 1999: p13, Gatterman and Goe, 1990: p285). This means that there is a significant amount of muscle tissue in which myofascial trigger points can develop, thus constituting a large source of potential pain. Sola et al. (1955) found latent trigger points in the shoulder muscles in 54% of females and 45% of males upon examination of 200 asymptomatic young adults.

Whilst specific figures regarding the incidence and prevalence of MPS in South Africa are not yet known, a study conducted by Jansen (1998) revealed that 24.95% to 37.1% of 1441 high school pupils had active Trapezius MFTP's.

2.3 Pathophysiology of myofascial trigger points

The exact mechanism responsible for the development of trigger points has been a topic of discussion in the literature for many decades. Several theories have been expounded by many researchers in the field (Awad, 1973, Gatterman and Goe, 1990, Han and Harrison, 1997, Hubbard, 1998).

Travell, Simons and Simons (1999) described a tender nodule or trigger point as “a cluster of numerous microscopic loci of intense abnormality that are scattered throughout the nodule”. They concluded that dysfunction of the motor endplate of an extrafusal muscle fibre is the critical abnormality which best explains the longevity of trigger points. They thus classified myofascial pain syndrome as a neuromuscular disease.

Travell, Simons and Simons (1999) reached this conclusion after the review of two independent lines of investigation. The first line of investigation was the electrodiagnostic characteristics of trigger points and the second was the histopathological characteristics of trigger points.

1).The electrodiagnostic characteristics:

Travell, Simons and Simons (1999) referred to the study done by Travell and Weeks (1957) where they reportedly found that trigger points in the trapezius muscles exhibited electrical spikes during rest whilst adjacent sites in the very same muscle revealed no such electrical activity. They also reviewed the work of Berkoff and Hubbard (1993), whose study yielded similar results. Reference was also made to a study done by Hong, Simons and Simons in 1995 that found, in addition to the electrical activity, a noise-like component that they dubbed Spontaneous Electrical Activity (SEA). The term “active

locus” was given to sites where both SEA and electrical spikes were found. It was discovered that minor trauma causes changes in discharge patterns from normal to abnormal, brought about by increased levels of acetylcholine (ACh) release, and that the endplates fire so rapidly that it results in a noise-like component or SEA. Therefore, it led to the aforementioned conclusion that dysfunctional motor endplates, scattered among normal endplates, are responsible for development and persistence of trigger points.

2). The histopathological characteristics:

According to Travell, Simons and Simons (1999), contraction knots are a very common histopathological finding during biopsies of trigger points. They noted that in studies since 1951, these contraction knots have been showing up on longitudinal sections as segments of extremely contracted sarcomeres and on cross sections as darkly staining enlarged muscle fibres. It was noted that in these maximally contracted sarcomeres the sarcolemmas were found to be empty, possibly representing a non-reversible complication of sustained contraction knots.

Together, these two lines of investigation led Travell, Simons and Simons (1999) to form the Integrated Trigger Point Hypothesis.

2.3.1 The Integrated Trigger Point Hypothesis (Travell, Simons and Simons, 1999):

The concept of an energy crisis was formed approximately twenty years ago and thus far it appears to explain the development and perpetuation of trigger points.

It now appears that the initial insult, whatever it may be, causes the nerve terminal to malfunction and release acetylcholine indefinitely, leading to abnormal depolarisation of the post-junctional membrane. In turn, the sarcomeres contract maximally, due to the release of calcium, causing an increase in local metabolic demands. However, contraction of sarcomeres causes them to thicken, cutting off local blood capillaries.

Only a 30% to 50% maximal contraction is sufficient to cause local ischaemia. Therefore, the local increase in metabolic demands combined with the decreased blood supply results in a severe but local energy crisis.

Calcium is normally returned to the sarcoplasmic reticulum via the calcium pump. This process is dependent on adenosine triphosphate (ATP) in order to function normally. However, due to the energy crisis, sufficient amounts of ATP are not available, leaving the contractile elements exposed to free calcium. The absence of ATP also leaves the myosin heads firmly attached (the myosin heads fail to recock) and thus the muscle stiffens as in rigor mortis. Furthermore, the severe local hypoxia and the energy crisis stimulate production of vasoreactive substances that could sensitise nociceptors.

Other authors (Gatterman and Goe, 1990, Han and Harrison, 1997, Simons, 1980) suggest that trigger points form as a result of an initial insult that damages the sarcoplasmic reticulum, leaving the contractile elements exposed to free calcium. This again causes the local energy crisis. However, this theory fails to explain the self-perpetuation and chronicity of some trigger points that remain active for extended periods (Simons, 1981: p106).

Hubbard (1998: p17) described trigger points as being “hyperactive muscle spindles with intrafusal muscle fibres that are in spasm secondary to sympathetic stimulation.” As a result he attributed the cause of trigger points to the combination of sympathetically mediated tension and the overstretching of muscle spindles, either traumatic or repetitive.

2.4 Management of Myofascial Pain Syndrome

The particular modality chosen when treating a myofascial trigger point depends greatly on the presentation of the patient. Certain key factors must be taken into account when deciding on the form of treatment that is to be used, such as the chronicity of the disease process as well as possible psychological and physiological stressors (Han and

Harrison, 1997: p95). The location of the trigger point in the muscle must also be considered. If the trigger point is located in the endplate region of a muscle it is referred to as a central trigger point. If the trigger point is located near the region where the muscle attaches to its tendon, bone or aponeurosis, it is referred to as an attachment trigger point. Central trigger points respond better to the application of warmth, whereas attachment trigger points respond better to cold. Stretching potentially inactivates central trigger points, but could aggravate attachment trigger points, thus attachment trigger points must be inactivated before stretching the involved muscle. Attachment trigger points also respond well to the application of manual therapy, especially when it is directed toward the central trigger point (Travell, Simons and Simons, 1999: p126-127).

Various forms of treatment for myofascial pain syndrome exist, including the Spray and Stretch technique, ischaemic compression, massage, osteopathic manual medicine techniques, application of heat or cryotherapy, ultrasound, diathermy, Transcutaneous Electrical Nerve Simulation (TENS), acupressure, acupuncture, trigger point injection and dry needling (Alvarez and Rockwell, 2002).

However, for the purposes of this study, only dry needling and trigger point injection will be discussed further.

2.4.1. Dry needling and trigger point injection

Dry needling involves the insertion of a thin gauge needle, usually an acupuncture needle, into the most painful spot in the tender nodule. Immediate analgesia can be expected, termed the 'needle effect', if local twitch responses are elicited (Lewit, 1979, Travell, Simons and Simons, 1999: p 151).

According to Han and Harrison (1997: p95), the proposed mechanisms through which injections inactivate trigger points are as follows:

- The needle causes mechanical disruption of muscle fibres and nerve endings.
- Mechanical disruption of muscle fibres causes increased levels of extracellular potassium, which in turn leads to the depolarisation of nerve fibres.
- The positive feedback mechanism that perpetuates pain (the pain-spasm-pain cycle) is interrupted through the use of hyperstimulation analgesia (Gatterman and Goe, 1990: p296).
- Injection of local anaesthetics or saline solutions causes dilution of nociceptive substances.
- Injection of local anaesthetics causes vasodilation locally, thus increasing the removal of metabolites.

In a study done by Hong (1994), it was found that subjects injected with lidocaine experienced no greater relief than those treated with dry needling and thus, the critical therapeutic value of trigger point injection and dry needling appears to be the mechanical disruption of local nerve endings or contractile tissue caused by the needle.

As such, the proposed mechanisms through which dry needling inactivates trigger points are as follows:

- The needle causes disruption of the contraction knot in the muscle. This in turn terminates the basis for the sensitisation of local nerve endings and the local energy crisis, which is responsible for the perpetuation of trigger points (Travell, Simons and Simons, 1999).
- Mechanical disruption of muscle fibres also causes increased levels of extracellular potassium, which leads to the depolarisation of nerve fibres (Han and Harrison, 1997: p95).
- The needle causes mechanical disruption of local nerve endings (Han and Harrison, 1997:p95).
- Dry needling utilises hyperstimulation analgesia to interrupt the positive feedback mechanism that perpetuates pain (the pain-spasm-pain cycle). The

three major properties of hyperstimulation analgesia are a) a moderate to severe sensory input in order to alleviate pain, b) a sensory input sometimes applied to a site distant from the site of pain and c) the sensory input, applied briefly up to 30 minutes, may relieve chronic pain for a short period of time or even permanently (Gatterman and Goe, 1990: p296). Levine (1976) also stated that counter-irritation is the possible explanation for the efficacy of dry needling.

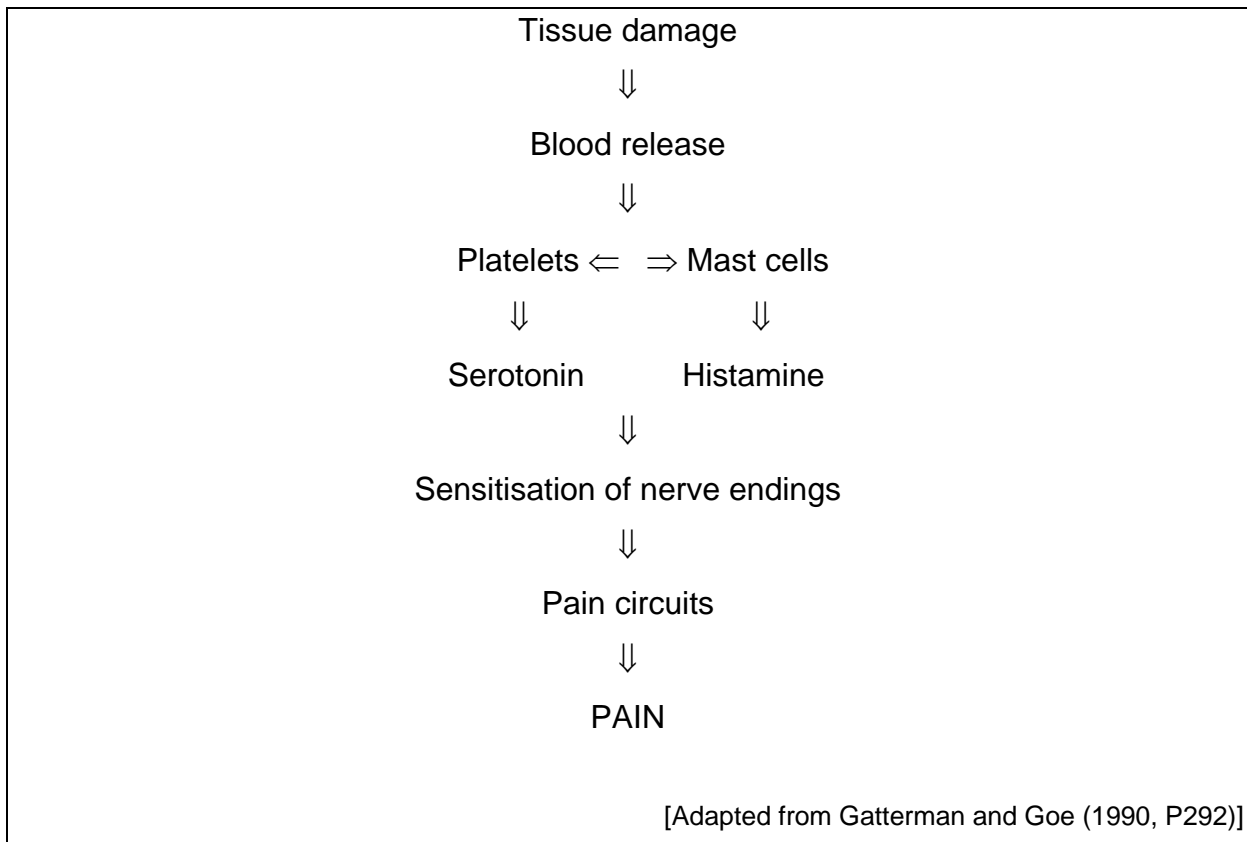
Baldry (1989) described various different techniques with which one can stimulate the needle once it has penetrated the trigger point. These include rotation, vibration, twirling and twisting, lifting and thrusting and snapping. Although all these techniques exist, the single needle insertion technique utilising twirling or rolling as stimulation was selected for this study. This technique will be compared to the fanning dry needling technique, which involves withdrawing the needle and redirecting it in a fan-like manner, without withdrawing it from the skin, in order to inactivate all active loci (Travell, Simons and Simons, 1999: p161).

2.4.1.1. Post-needling soreness

Post-needling/post-injection soreness is a phenomenon that is commented on in the literature (Alvarez and Rockwell, 2002, Lewit, 1979, Travell, Simons and Simons, 1999). It is described as a completely separate entity and is not the same as myofascial pain (Lewit, 1979).

The soreness experienced by patients following dry needling is reported to be longer lasting and more intense than the soreness experienced by patients following lidocaine injections (Alvarez and Rockwell, 2002). Travell, Simons and Simons (1999) noted that post-needling soreness is worse if bleeding occurs whilst injecting or needling a trigger point. Rowley (2000) found that subjects receiving the fanning dry needling technique experienced greater levels of post-needling soreness when compared to subjects receiving the single needle insertion technique. Gatterman and Goe (1990: P292)

displayed the following flow diagram in order to explain how a tissue damage leads to the development of pain:



Travell, Simons and Simons (1999) reported that post-needling soreness is worse if a local twitch response is elicited during dry needling or trigger point injection, however Lewit (1979) noted that post-needling soreness developed even when a trigger point was not precisely needled. Accordingly it is unclear whether post-needling soreness is a phenomenon peculiar to dry needling or injection of trigger points due to the already sensitised nociceptors, or whether it will occur when normal muscle tissue is needled also.

Travell, Simons and Simons (1999: p165) recommends applying moist heat to the area that was needled immediately following the procedure in order to limit the development

of post-needling soreness, as well as applying some pressure to the area for haemostasis.

2.5 Placebo needling

A placebo treatment is defined as a physiologically inert procedure (Streitberger and Kleinhenz, 1998). In order to provide a convincing placebo treatment, the procedure should mimic the active treatment in every respect, except for the physiological effects.

Thus far, two forms of placebo treatment are available for needling/acupuncture. Sham needling/acupuncture is invasive and involves inserting a needle into a non-acupoint or merely varying the depth of needle penetration. Placebo needling/acupuncture is considered non-invasive and can be performed by using a retractable needle or a needle with a blunted tip. It has however been suggested that the insertion of a needle into the skin can still activate noxious inhibitory control and as such, placebo needling/acupuncture appears to be the modality of choice (Goddard et al., 2005).

2.6 Conclusion

Myofascial Pain Syndrome is a common disorder that almost every person will suffer from and as a result its treatment is the topic of many research studies. Dry needling appears to be the most effective way of inactivating myofascial trigger points, but the development of post-needling soreness remains to be a major drawback when contemplating its use. Very little has been written regarding the causes of, and the limitation of, post-needling soreness and whether it is a normal reaction to the tissue damage that occurs during dry needling or if it is a phenomenon peculiar to the dry needling of trigger points only. This research is thus aimed at providing some insight into the response, regarding the development of post-needling soreness, of asymptomatic muscle tissue to two forms of dry needling therapy.

CHAPTER THREE

Materials and Methods

3.1 Design

This study was designed as a prospective, randomised, placebo controlled experimental investigation. The effect of applying two different techniques of dry needling to muscle tissue in asymptomatic subjects was tested with respect to the development of post-needling soreness in each group. The two techniques were investigated against placebo needling and between the two techniques themselves.

3.2 Sampling

3.2.1 Subject recruitment

Subjects were recruited by means of convenience sampling. Advertisements were placed at the Durban Institute of Technology's Chiropractic Day Clinic to obtain volunteers for the study. This study was conducted using asymptomatic subjects only and all volunteers were screened prior to their acceptance into the study based on the inclusion and exclusion criteria (discussed later in this chapter).

3.2.2 Sample size and randomisation

A sample size of 60 subjects was used for this study and all were randomly allocated to one of the three groups containing 20 subjects each. Randomisation was ensured by using 60 slips of paper, 20 from each of the treatment protocols, drawn from a box by the subjects until two of the groups contained 20 subjects each. The remainder of the subjects were allocated to the group that was not filled (Mouton, 1996).

Group 1 received dry needling using the single needle insertion technique. Group 2 received dry needling using the fanning dry needling technique and group 3 was the placebo group in which needling was done using the placebo needle.

3.3 Clinical procedure

Volunteers who showed an interest in participating in the study were given a description of the study (Letter of Information) (Appendix A) containing all the relevant information regarding the procedure that was to be followed. Participants who accepted the terms were requested to complete an indemnity form (Informed Consent Form) (appendix B) and their details were recorded for future reference.

At the initial consultation, performed at the Chiropractic Day Clinic at the Durban Institute of Technology, prospective subjects underwent a full case history, a revised physical examination and a lower back regional examination in order to determine whether or not they met the inclusion and exclusion criteria set forth for this study.

3.3.1 Inclusion criteria

1. Subjects between the ages of 18 and 50 were selected for this study.
2. All subjects were required to be asymptomatic in the low back pain region.
3. Subjects were only accepted once they had read and signed the Informed Consent form and had undergone a complete case history, a revised physical examination and a lower back regional examination.

3.3.2 Exclusion criteria

1. Subjects with contra-indications to dry needling were excluded. These were:
 - Subjects under the influence of alcohol or those suffering from systemic illness, fever, bleeding disorders, anxiety or syncopial reactions (Travell and Simons, 1999). Subjects who report initially being adverse to the thought of dry needling were excluded. All smokers were also excluded as tobacco causes low vitamin C levels which can lead to increased fragility of capillaries, possibly resulting in unsightly ecchymoses and altered development of post-needling soreness.

2. Subjects taking, or those who have taken, analgesic or anti-coagulant medication during the three days prior to the initial consultation were excluded from the study.
3. Subjects receiving or those who had received dry needling in the three months prior to the initial consultation were excluded, as maximal naivety regarding the onset of post-needling soreness was desired (Mouton, 1996).
4. Subjects with a confirmable diagnosis of a lumbar radiculopathy or myelopathy based on the neurological examination were not considered.
5. Subjects suffering from Primary Fibromyalgia Syndrome were not allowed to participate in the study (Han and Harrison, 1997).
6. Subjects found to have either active or latent myofascial trigger points in the Quadratus Lumborum, Gluteus Medius or Iliopsoas muscles were excluded from the study due to their referral pattern to the low back (Travell, Simons and Simons, 1999).

3.4 Intervention

Once the subject had undergone a full case history, revised physical examination, low back regional examination, including screening the Quadratus Lumborum muscles for active and latent trigger points, and had read and signed the Informed Consent form (Appendix B), patients were positioned prone for the duration of the procedure. An algometer reading was obtained from the exact area that was to be needled prior to the commencement of dry needling.

Group 1 received the single needle insertion technique. The needle was inserted into the muscle until roughly only one quarter of the needle shaft was still showing. The needle was left in place for five minutes, after which it was rolled clockwise and anti-clockwise, using the thumb and forefinger, for up to one minute. The needle was again left in place for a further five minutes and again stimulated as before. The same procedure was repeated three times and lasted approximately 20 minutes. After the third manipulation of the needle, it was left in place for five minutes and withdrawn (Rowley, 2000).

Group 2 received the fanning dry needling technique. The needle was inserted into the muscle as above and repeatedly withdrawn and redirected to another position ten times, without withdrawing the needle from the skin completely. For the sake of homogeneity the needle was stimulated at the same time intervals as Group 1.

Group 3 received the placebo needle and stimulation of the needle was repeated as for Group 1.

For the purposes of this study the Park Sham Device was selected in order to administer the application of placebo needling: Acuprime, 33 Southerhay East, Exeter, EX1, 1NX, UK.

The Park Sham Device consists of a base, two clear tubes (a “double tube”) and an acupuncture needle with a blunt tip.

The base has a hole in the centre and the bottom is covered with sticky tape, which allows the examiner to stick the device onto the skin and leave it in place without having to hold it for the entire duration of the procedure. The hole is continuous with the double tube making it possible to pass a needle from the top, through the double tube and the base to the skin. At insertion, the tubes are extended, allowing the needle to be tapped into the skin. The tubes slide inside one another, allowing more of the needle to be exposed if manipulation of the needle is required. The placebo needle itself slides inside its own handle, increasing the appearance that the skin is being penetrated.

In both Group 1 and 2, 0, 25 x 25mm acupuncture needles were used. The Quadratus Lumborum muscles were needled in all instances and all sites that were needled were marked with henna in order to ensure that all measurements were obtained from the exact area that was needled.

Needling precaution: All acupuncture needles were used only once (not including the placebo needles). The needles were opened in full view of the subjects. The area that was to be needled was cleaned with alcohol before and after treatment. Once used, the needles were discarded in the medical waste bins provided in accordance with normal clinical procedure. The examiner wore surgical gloves throughout the entire procedure.

3.5 Outcome measures

3.5.1 Subjective data

3.5.1.1 Numerical Pain Rating Scale 101 (NRS-101)

The NRS-101 was used in order to monitor the development, if any, of post-needling soreness as perceived by the patient.

The NRS-101 involves asking the subject to rate his or her pain intensity on a

numerical scale from a score of 0 to 100, with 0 representing the subject experiencing no pain and 100 representing the subject experiencing the pain at its worst.

In a study conducted by Jensen et al. (1986) using 75 subjects, all suffering from chronic pain, the NRS-101 proved to be the most precise, replicable, predictive and valid measurement.

Subjects were required to complete the NRS-101 immediately following the first consultation and again at the second consultation, which took place 24 hours after the first.

3.5.1.2 Pain Diary

Owing to the uncertainty regarding the time period pertaining to the onset of post-needling soreness, all subjects were required to complete a 24-hour pain diary (Appendix C) in order to monitor the onset, if any, of post-needling soreness following the treatment. The pain diary is divided into three-hour periods, commencing immediately after the treatment, and subjects were required to either tick 'yes' or 'no' to whether or not they were experiencing pain at that point. The pain diary also required subjects to record at which time, in hours, they experienced the most pain.

3.5.2 Objective data

3.5.2.1 Pressure Threshold Algometry

The algometer was used in this study in order to measure the subjects' pressure pain threshold (ppt), defined as "the minimum pressure (force) that induces pain or discomfort" (Fischer, 1987). In a study performed by Nussbaum et al. (1998) it was concluded that the non-electronic algometer is a reliable way of measuring pressure pain threshold over three consecutive days, especially if the same examiner obtains the measurements.

Once the target point, the exact point where the needle was inserted, was marked the subject was instructed to say “yes” when pain was first felt. Pressure was then gradually applied until the subject said “yes” and the reading was recorded. This procedure was performed three times and the average reading was calculated. Readings were obtained immediately following the treatment and at the second consultation 24 hours later.

The algometer chosen for this study is the force dial manufactured by Wagner Instruments: P.O. Box 1217 Greenwich CT 06836 as its pressure range measures kilograms as opposed to Newton meters which is preferable for this study.

Statistical Analysis

SPSS version 11.5 was used for data analysis (SPSS Inc. Chicago, Ill, USA). Baseline demographics and outcome measurements were compared between the three groups using Pearson’s chi square tests or ANOVA as appropriate.

For the evaluation of the treatment effect for the outcomes of the NRS and algometer readings, repeated measures ANOVA procedure was used. Time by group interactions were reported overall and for each two-way comparison of treatment group. Proportions of participants reporting pain at various time points post treatment, as well as duration of pain were compared cross-sectionally, by group, with chi square tests. A Kruskal-Wallis test was used to compare time since treatment at which worst pain was experienced between groups. P values of <0.05 were considered as statistically significant.

3.7 Definitions of tests used

3.7.1. Analysis of variance (ANOVA): This is a statistical technique for analysing data that tests for a difference between two or more means by comparing the variances within and between groups. ANOVA determines an overall p value and does not determine differences between specific groups (www.isixsigma.com, 2005).

3.7.2. Bonferroni multiple comparison post hoc test: This test is done following the ANOVA in order to determine whether or not a statistically significant difference exists between specific groups. It is harder to achieve statistical significance with Bonferroni adjustment but it is more accurate (www.isixsigma.com, 2005).

3.7.3. Kruskal-Wallis Test: Kruskal-Wallis performs a hypothesis test of the equality of population medians for a one-way design (two or more populations). This test is a generalisation of the procedure used by the Mann-Whitney test and offers a non-parametric alternative to the one-way analysis of variance. This test looks for differences among the population medians (www.bmj.com, 2005).

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

3.8 Abbreviations

N = Number

% = Percentage

CI = Confidence interval

SD = Standard Deviation

P = Probability value

df = Degrees of freedom

Std = Standard

CHAPTER FOUR

Results

4.1 Demographics by group

Table 1: Descriptive statistics for age by group.

GROUP	Mean (Years)	N	Std. Deviation
Single needle insertion	19.15	20	5.344
Fanning dry needling	24.00	20	7.056
Placebo	25.70	20	9.476
Total	22.95	60	7.873

Table 1 depicts that sixty participants were randomized into 3 equal groups (n=20). The mean age of the sample was 22.95 years (SD 7.9 years). It also reflects the mean age of each group. It is clear that the subjects in the single needle insertion group were on average younger than the other two groups. This was a random event as subjects were allocated to their groups according to the randomization process.

4.2 Demographics by gender

Table 2: Comparison of gender by group.

		GROUP			Total
		Single needle insertion	Fanning dry needling	Placebo	
GENDER	Male	8(29.6%)	12(44.4%)	7(25.9%)	27(100.0%)
	Female	12(36.4%)	8(24.2%)	13(39.4%)	33(100.0%)
Total		20(33.3%)	20(33.3%)	20(33.3%)	60(100.0%)

P=0.243

Table 2 reflects that there was no significant difference in gender distribution between the groups ($p=0.243$). There was a slight preponderance of males in the fanning dry needling group and of females in the placebo group, but the difference in proportions was not significant.

4.3 Baseline outcomes

Only the algometer measurements were obtained at baseline (before any treatment). There was a significant difference in mean baseline algometer measurements between the groups ($p=0.024$). Many studies have noted that ppt's (pressure pain threshold) vary significantly between individuals and therefore, to prevent this factor from determining the outcome, it was controlled for in subsequent analysis (Farasyn and Meeusen, 2005).

Table 3: Descriptive statistics for mean algometer baseline measurement by group.

GROUP	Mean Kg/cm ²	N	Std. Deviation
Single needle insertion	14.28	20	3.806
Fanning dry needling	16.97	20	3.733
Placebo	17.65	20	4.455
Total	16.30	60	4.208

Table 3 shows that the single needle group had a lower mean algometer measurement than the placebo group. This means that prior to the treatment the subjects in the single needle insertion group had, on average, a lower pressure pain threshold than the subjects in the placebo group. However, this factor was controlled for in the final analysis.

Table 4: ANOVA test for the comparison of mean algometer baseline by group.

	Sum of Squares	df	Mean Square	F	P value
Between Groups	127.575	2	63.787	3.965	0.024
Within Groups	917.025	57	16.088		
Total	1044.600	59			

Table 4 shows that the ANOVA test revealed a statistically significant difference between the groups ($p=0.030$) regarding the baseline algometer readings. This means that prior to treatment a difference existed between the groups regarding the amount of pressure they could tolerate per cm^2 . The ANOVA test however does not reveal which groups differed; therefore the Bonferroni post hoc test was done in order to establish which groups differed significantly from each other.

Table 5: Bonferroni multiple comparison post hoc tests for the comparison of mean algometer baseline by group.

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	P value
Single needle insertion	Fanning dry needling	-2.70	1.268	0.113
	Placebo	-3.37(*)	1.268	0.030
Fanning dry needling	Single needle insertion	2.70	1.268	0.113
	Placebo	-.67	1.268	1.000
Placebo	Single needle insertion	3.37(*)	1.268	0.030
	Fanning dry needling	.67	1.268	1.000

* The mean difference is significant at the .05 level.

Table 5 therefore depicts that the statistically significant difference existed between the single needle insertion group and the placebo group at baseline. This means that prior to the treatment it was the subjects in the single needle insertion group that could tolerate less pressure per cm^2 than the subjects in the placebo group. As stated earlier,

this factor was controlled for in the subsequent analyses in order to avoid it affecting the results.

4.4 Effect of the treatment

4.4.1 Algometer:

Table 6: Inter- and intragroup effects for the algometer readings.

Effect	Statistic	p value
Time	Wilk's lambda 0.637	<0.001
Time*group overall	Wilk's lambda 0.853	0.062
Time*group single needle vs. placebo	Wilk's lambda 0.811	0.021
Time*group single needle vs. fanning dry needling	Wilk's lambda 0.982	0.712
Time*group fanning dry needling vs. placebo	Wilk's lambda 0.818	0.024

Table 6 shows that there was a significant time effect regarding the algometer readings, thus regardless of which treatment group the subject was in, there was a significant change in mean algometer readings over time ($p < 0.001$).

A borderline significant interaction existed ($p = 0.062$) between time and group. This means that not all the groups experienced the same change in algometer readings over time. The interaction was significant between the single needle insertion group and the placebo group, and the fanning dry needling group and the placebo group, but not

between the single needle insertion group and the fanning dry needling group (p=0.712).

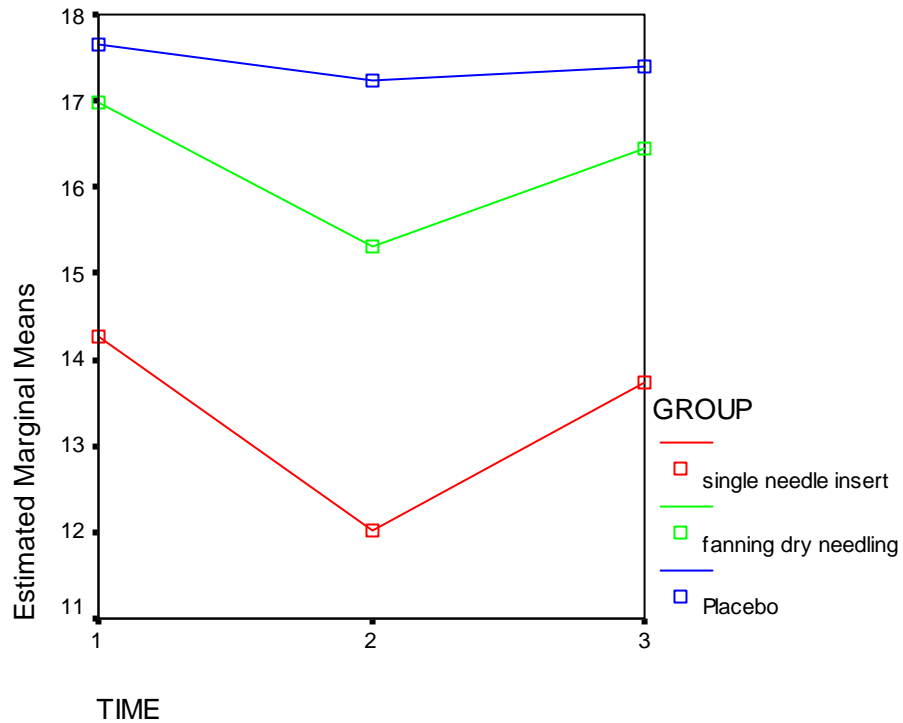


Figure 1: Profile plot (by intervention group) of mean algometer over time.

When looking at Figure 1 it is clear that the profiles of the single needle insertion group (red line) and the fanning dry needling group (green line) are parallel over time. Thus both treatment groups reacted significantly differently over time when compared to the placebo group; however they were not different from each other.

4.4.2 NRS-101:

The differences between the groups in baseline algometer measurements were controlled for as a covariate in the analysis.

Table 7: Inter- and intragroup effects for the NRS-101.

Effect	Statistic	p value
Time	Wilk's lambda 0.973	0.219
Time*group overall	Wilk's lambda 0.946	0.078
Time*group single needle vs. placebo	Wilk's lambda 0.963	0.240
Time*group single needle vs. fanning dry needling	Wilk's lambda 0.996	0.708
Time*group fanning dry needling vs. placebo	Wilk's lambda 0.839	0.011

Table 7 indicates that a statistically significant interaction existed between time and group in the fanning dry needling group versus the placebo group ($p=0.011$). This means that there was a difference in the levels of pain reported by the subjects in the fanning dry needling group when compared to those in the placebo group. This table merely indicates that a difference existed and that the difference was statistically significant. Figure 2 indicates these differences clearly.

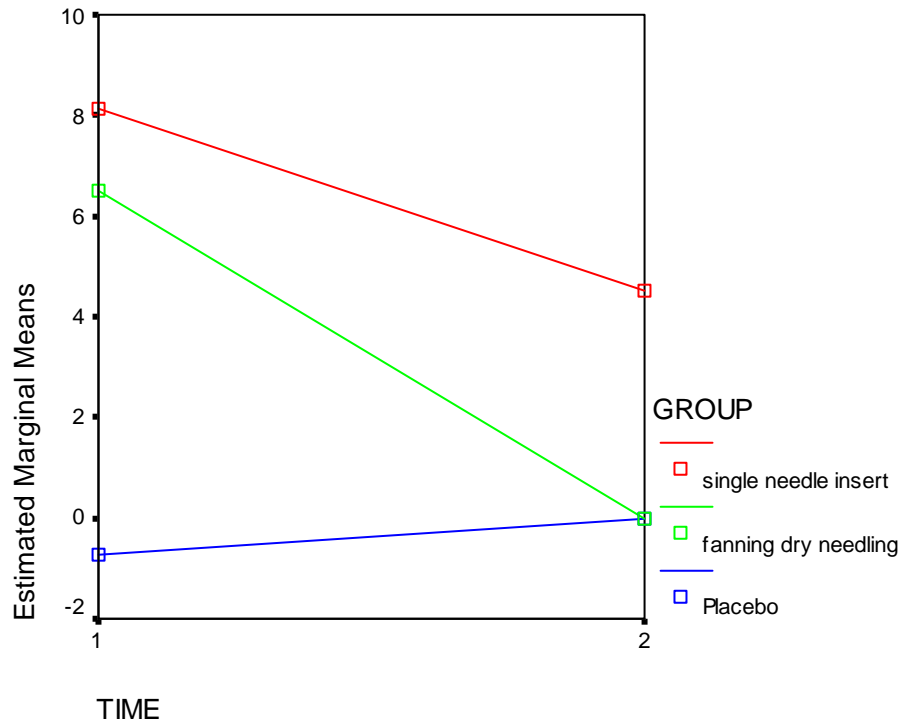


Figure 2: Profile plot (by intervention group) of mean NRS-101 over time.

Figure 2 reveals that the fanning dry needling group (green line) reached the mean pain level of the placebo group at time 2, but the single needle insertion group (red line) experienced a higher mean pain level than both groups both immediately following the needling and at the follow-up visit 24 hours later. The fanning dry needling group and the single needle insertion group showed no difference over time when compared to each other ($p=0.708$). Therefore, the fanning dry needling technique and single needle technique both showed a similar decrease in pain over time, however, compared to the placebo (blue line), the fanning dry needling showed a significantly steeper rate of decrease in pain.

4.4.3 Post-needling soreness as reported in the 24-hour pain diaries:

Post-needling soreness was reported very infrequently by diary assessment. Cross-sectional analysis of pain at each time point (every three hours following the treatment) revealed no significant differences between the groups. At 3 hours 15% of the single needle insertion group had pain and 5% of the fanning dry needling group had pain. At no time did any participant from the placebo group report pain. At 6 hours only one subject had pain (single needle group). At 9 hours post-treatment only 2 subjects had pain, one in each of the single needle and fanning dry needle groups. No participants experienced pain at 12 and 24 hours following the treatment.

Table 8: Proportions of participants per group who reported experiencing post-needling soreness at 3, 6 and 9 hours post treatment.

GROUP	Diary 3		Diary 6		Diary 9	
	Yes	No	Yes	No	Yes	No
Single needle insertion	3 (15%)	17(85%)	1(5%)	19(95%)	1(5%)	19(95%)
Fanning dry needling	1(5%)	19(95%)	0(0%)	20(100%)	1(5%)	19(95%)
Placebo	0(0%)	20(100%)	0(0%)	20(100%)	0(0%)	20(100%)
Total	4(6.7%)	56(93.3%)	1(1.7%)	59(98.3%)	2(3.3%)	58(96.7%)

P=0.153

Table 8 reveals that 3 participants (15%) in the single needle insertion group experienced post-needling soreness 3 hours after the receiving dry needling. It also

shows that only 1 participant (5%) in the group that received fanning dry needling, and none of the participants in the placebo group, experienced post-needling soreness.

Table 8 indicates that only one of the participants from the single needle insertion group experienced post-needling soreness 6 hours after the treatment and that none of the participants from neither the fanning dry needling group nor the placebo group experienced any post-needling soreness at the same time interval.

Table 8 also shows that only one participant from each of the treatment groups experienced post-needling soreness 9 hours after receiving dry needling therapy, and that none of the participants from the placebo group experienced any post-needling soreness.

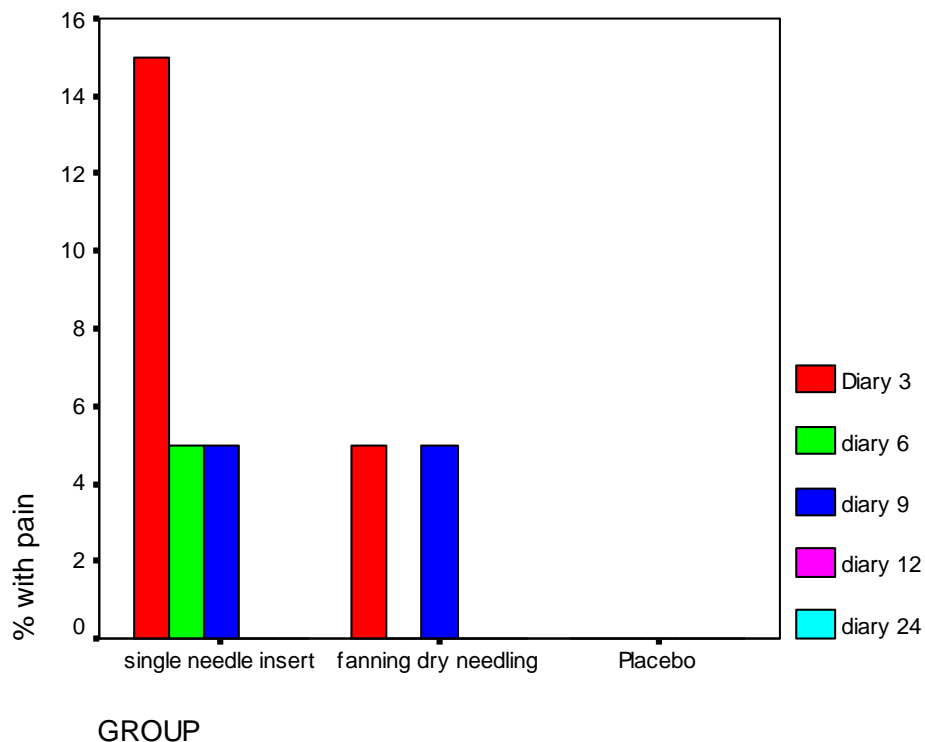


Figure 3: Percentage of participants (by intervention group) with pain at each time point.

Figure 3 indicates that the single needle insertion group was the group that experienced the most post-needling soreness at 3 hours and 6 hours following the treatment, although this slight difference was not statistically significant.

Table 9: Comparison of duration of pain by group.

Participants who did not experience any post-needling soreness were given a score of zero for this variable.

		Duration of pain (Hours)			Total
		0	3	6	
GROUP	Single needle insertion	16 (80.0%)	3 (15.0%)	1 (5.0%)	20(100.0%)
	Fanning dry needling	18 (90.0%)	2 (10.0%)	0 (0%)	20 (100.0%)
	Placebo	20 (100.0%)	0 (0%)	0 (0%)	20 (100.0%)
Total		54 (90.0%)	5 (8.3%)	1 (1.7%)	60 (100.0%)

P=0.263

The duration of post-needling soreness was calculated from the diary assessments for each participant. Table 9 shows that most participants indicated that they had experienced no pain, 5 participants reported experiencing post-needling soreness over

a 3 hour duration and 1 participant reported pain over a 6 hour duration. This was compared by group and was not found to be significant.

4.4.3.1 Worst pain as reported in 24-hour pain diary

The 24-hour pain diary required the participants to record at which point in time they had experienced their worst pain, if any, following the treatment. The subjects were asked to only consider pain experienced in the region that was treated.

Table 10: Comparison (by group) of any worst pain reported.

		Worst pain reported		Total
		No	Yes	
GROUP	Single needle insertion	10 (50.0%)	10 (50.0%)	20 (100.0%)
	Fanning dry needling	12 (60.0%)	8 (40.0%)	20 (100.0%)
	Placebo	18 (90.0%)	2 (10.0%)	20 (100.0%)
Total		40 (66.7%)	20 (33.3%)	60 (100.0%)

P=0.020

There was a statistically significant difference in the proportion of subjects reporting any pain and those reporting no pain between the groups, as indicated by Table 10. In the single needle insertion group 50% of the subjects indicated that they had noted a point in time when their post-needling soreness was at its worst. This is compared to only 40% in the fanning dry needling group and 10% in the placebo group.

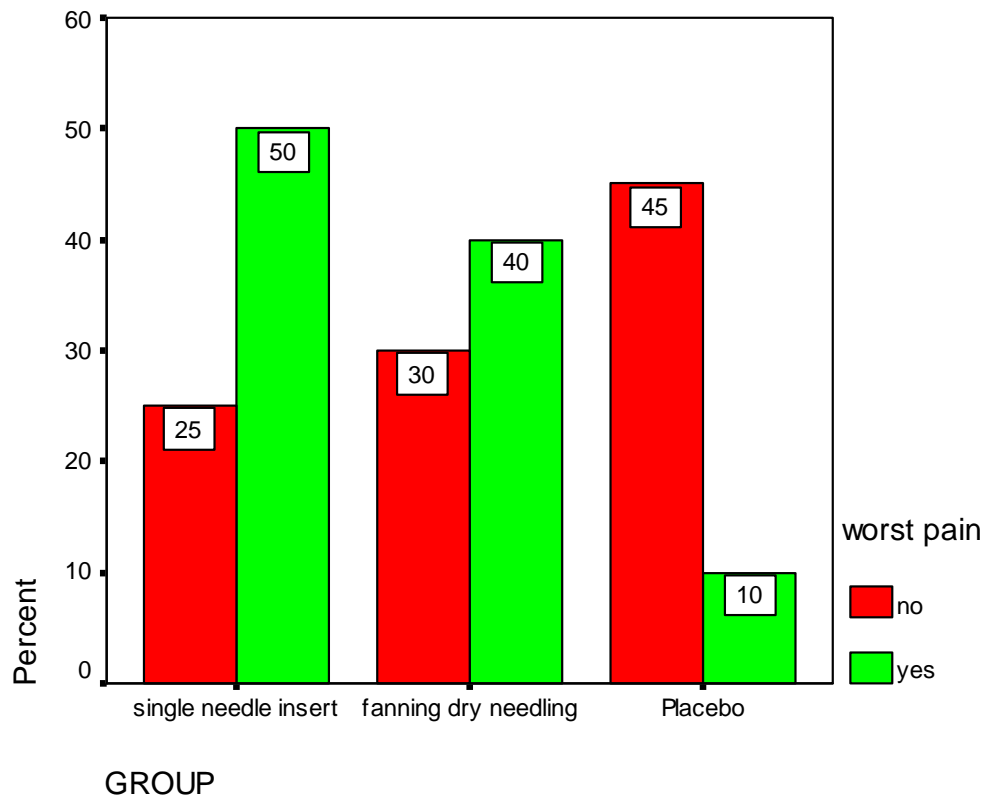


Figure 4: Percentage of participants (by intervention group) reporting a period of worst pain.

Figure 4 indicates that 50% of the subjects in the single needle insertion group reported experiencing a definite period when their pain was at its worst. Forty percent of the fanning dry needling group and 10% of the placebo group reported experiencing their worst pain at some point.

The time at which the subjects' worst pain was felt, following the treatment, was also statistically significantly different between the groups ($p= 0.030$). The single needle insertion group experienced their worst level of post-needling soreness significantly later than the other groups.

Table 11: Descriptive statistics for time elapsed since treatment that the worst pain was felt.

GROUP	Mean (Hours)	Minimum (Hours)	Maximum (Hours)
Single needle insertion	.1250	.00	8.00
Fanning dry needling	.0000	.00	9.00
Placebo	.0000	.00	1.00
Total	.0000	.00	9.00

Table 11 shows the mean time at which the worst pain was experienced per group. For the single needle insertion group the mean time since treatment at which the worst pain was felt was 0.125 hours. For the other two groups it was 0 hours. So few subjects in the fanning dry needling group and the placebo group reported post-needling soreness that no average could be computed for them.

4.5 Summary of results:

In terms of subjective and objective pain measurement there was a very subtle difference between single needle insertion technique and fanning dry needling technique. Mostly the difference was not statistically significant. However, a trend could be observed which showed that post-needling soreness lasted for a longer period in the single needle insertion group. The single needle insertion group also experienced greater post-needling soreness at a later stage following the treatment than the other groups. Thus there is partial evidence to suggest that fanning dry needling is preferential to single needle insertion, but both groups initially experienced more post-needling soreness than the placebo group.

CHAPER FIVE

Discussion of results

5.1 Introduction

This chapter includes the discussion of the results from the statistical analysis of both the subjective (NRS-101 and 24-hour pain diary) and objective (algometer readings) data.

5.2 Subjective data

5.2.1 Numerical Pain Rating Scale 101 (NRS-101):

The results from the NRS-101 yielded some unexpected results. The subjects in the single needle insertion group experienced post-needling soreness of a greater intensity and longer duration than the fanning dry needling group.

Rowley (2000) conducted a study on the relative effectiveness of single dry needle insertion versus fanning dry needling in the treatment of myofascial trigger points. Rowley stated that the subjects who had received the fanning dry needling experienced greater post-needling soreness than the single needle insertion group.

As stated in chapter 2, very little detail is available regarding post-needling soreness and its exact cause. Due to this, some of the findings from this study will be compared to Delayed-Onset Muscle Soreness (DOMS). DOMS is used in research of muscle injuries, as it is controllable and reproducible (Nussbaum and Downes, 1998). It is a condition that develops as a result of untrained muscles performing strenuous eccentric exercise. Blood enzyme analysis and muscle biopsy reveals that biochemical changes occur with the onset of DOMS, including the presence of cellular infiltrates such as neutrophils, macrophages and various other inflammatory mediators. Morphological

changes such as the disruption of myofibrils and supporting connective tissue also occur with DOMS. Accordingly DOMS is a controlled injury that can be imposed on muscle tissue for research purposes (Nussbaum and Downes, 1998). Some of the symptoms of DOMS are pain, tenderness and stiffness, and as such these symptoms increase as the severity of the condition increases. This information, combined with the flow diagram of Gatterman and Goe (1990:P292) (chapter 2) and the statement by Travell, Simons and Simons (1999) that bleeding worsens post-needling soreness, lead the examiner to the assumption that the fanning dry needling technique would result in the development of greater post-needling soreness. Thus the results obtained by the NRS-101 appear to be anomalous.

Although the single needle insertion group and the fanning dry needling group experienced parallel decreases in pain over time, only the fanning dry needling group differed significantly from the placebo group. A possible explanation could stem from the gender distribution between the fanning dry needling group and the placebo group. Although the difference was not statistically significant, there was a slight preponderance of males in the fanning dry needling group and females in the placebo group. Farasyn and Meeusen (2005) commented on the fact that research has consistently indicated that differences in pain perception exist between the genders, with males having more positive expectations regarding the painfulness of potentially painful events.

5.2.2 Pain diary:

The 24-hour pain diaries yielded similar results to the NRS-101, with the single needle insertion group experiencing post-needling soreness for a greater period of time when compared to the fanning dry needling group. On average, the single needle insertion group experienced their worst pain 7.5 minutes after the treatment, with the fanning dry needling group and the placebo group having too few subjects reporting pain that their average time taken to develop post-needling soreness could not be computed (Table 11, pg 48).

As stated earlier in this chapter and in chapter one (the third hypothesis), previously written articles (Travell, Simons and Simons, 1999) and research (Rowley, 2000) lead to the conclusion that the fanning dry needling technique would result in subjects experiencing greater post-needling soreness than groups receiving the single needle insertion technique. The results obtained in this study are as such irregular, and were possibly affected by outliers in the respective groups due to small sample sizes.

5.3 Objective data

5.3.1 Algometer readings:

The results from the algometer readings indicated that the single needle insertion group and the fanning dry needling group were significantly different from the placebo group. This indicates that in both treatment groups the needling process did cause increased tenderness in the area that was needled. However, the algometer readings did not differ from each other between the two treatment groups.

Farasyn and Meeusen (2005) conducted a study on the ppt's (pressure pain thresholds) of individuals suffering from non-specific low back pain and noted that no significant difference, regarding their ppt's, existed between individuals with moderated low back pain and individuals with severe low back pain. They concluded that what was of extreme importance was "the perceived ability to control pain and the role of central nervous system modulation."

In chapter one, it was hypothesized that the group receiving the fanning dry needling technique would experience greater post-needling soreness than the group receiving the single needle insertion technique. The results from the algometer readings do not support this hypothesis.

In chapter one, various hypotheses were made regarding the possible outcome of this study. Once they were compared to the results from the statistical analysis the following conclusions were made: The **first hypothesis** indicated that both groups receiving the

dry needling as well as the placebo group would develop post-needling soreness in terms of subjective clinical findings. This hypothesis was rejected owing to the fact that the results of the NRS-101 and 24-hour pain diary revealed that the placebo group experienced no post-needling soreness, even though both treatment groups experienced post-needling soreness.

The results from the objective measurements, in the form of the algometer readings, indicated that all groups experienced post-needling soreness following the first consultation. As such, the **second hypothesis**, which indicated that all groups would experience post-needling soreness in terms of objective clinical findings, was accepted.

The **third hypothesis** indicated that the group receiving the fanning dry needling technique would develop greater post-needling soreness than the group receiving the single needle insertion technique and that the latter group would develop greater post-needling soreness than the placebo group, all terms of both subjective and objective clinical findings. This hypothesis was also rejected owing to the fact that the group that received the single needle insertion technique developed the greatest amount of post-needling soreness in terms of the subjective and objective clinical findings.

CHAPTER SIX

Conclusions and Recommendations

6.1 Conclusions

The aim of this study was to investigate post-needling soreness following two forms of dry needling therapy on the muscle tissue of asymptomatic subjects, and this was then compared to a placebo group. Research has shown dry needling to be very effective in the treatment of myofascial pain syndrome. Many authors consider it the treatment of choice for myofascial trigger points (Alvarez and Rockwell, 2002). However, a major drawback of this form of therapy is the development of post-needling soreness. Although this phenomenon is mentioned in many articles regarding myofascial trigger points (Awad, 1973, Gatterman and Goe, 1990, Han and Harrison, 1997, Hubbard, 1998), very little detail is available regarding post-needling soreness.

For this reason, this study was performed in order to provide an insight into whether the tissue damage which occurs with needle insertion causes post-needling soreness, or whether the needle serves as an irritant to myofascial trigger points only, which would then cause post-needling soreness.

An intra-group analysis revealed that, objectively, all groups experienced some degree of post-needling soreness. Subjectively however, the placebo group did not experience any post-needling soreness according to the findings from the NRS-101 and 24-hour pain diaries.

An inter-group analysis yielded no statistically significant results regarding the difference in which the two treatment groups (i.e. the single needle insertion group and the fanning dry needling group) experienced post-needling soreness. However, both treatment groups did develop a statistically significantly increased level of post-needling soreness when compared to the placebo group. The study was hampered by the sample size,

allowing outliers to affect the results significantly. Future studies of this nature should include larger sample sizes. The gender distribution, even though it was not statistically significant, also hampered the results somewhat with the males failing to report mild levels of discomfort. Similar studies in the future should include equal representation regarding gender in order to avoid this problem.

6.2 Recommendations

It is recommended that future studies utilise larger sample groups in an attempt to increase the statistical validity in order to prevent outliers from affecting the data to a great extent.

Samples in studies of this nature should either consist of a single sex or equal representation of both sexes in order to avoid differences in gender pain-perception.

Although naivety regarding dry needling was sought in this study, it was felt that subjects who had previously received dry needling of myofascial trigger points responded differently to those who had not received it in the past. Thus, future studies of this nature should attempt to achieve homogeneity in this regard.

It is recommended that future studies of this nature use a double blind procedure where an independent examiner could administer the treatment and the researcher will then take the necessary readings, unaware as to which treatment group the subject belongs to. Readings obtained from a pressure algometer are sensitive to the rate at which the pressure is applied, further increasing the need for the researcher to be blinded as the algometer readings can be manipulated by the examiner (Farasyn and Meeusen, 2005).

The technique currently utilised in obtaining algometer readings, whereby the average of three readings is obtained (Fischer, 1987), should be revised as subjects often complained of the pain and tenderness caused by the pressure from the algometer. It is further recommended that an algometer with a rubber tip be used in a study of this nature, as the steel tip might have added in the discomfort experienced by the subjects.

Future studies on post-needling soreness should be conducted utilising symptomatic subjects in order to gain clinical relevance.

Follow-up interviews could be conducted at a time period greater than the 24 hours allowed in this study as very little is known about the exact duration of post-needling soreness.

Future analysis of post-needling soreness could include measurements regarding muscle stiffness, such as range of motion measurements, following dry needling application.

Studies should be done regarding the limitation of post-needling soreness through the utilisation of ultrasound or other modalities in order to lessen the recovery needed following dry needling.

Various other forms of needle stimulation could be used, possibly also a combination of the fanning dry needling technique and the single needle insertion technique (Rowley, 2000), in studies on dry needling.

REFERENCES

Alvarez, D. J., Rockwell, P. G. 2002. Trigger Points: Diagnosis and Management. American Family Physician. 65(4): 653-660.

Awad, E. A. 1973. Interstitial Myofibrositis: Hypothesis of the Mechanism. Archives of Physical Medical Rehabilitation. 54: 449-453.

Baldry, P. 1998. Acupuncture, Trigger Points and Musculoskeletal Pain. 2nd Edition. Churchill Livingstone, Edinburgh, Scotland. ISBN 0-443-04580-1.

Cumming, L. A. 2002. The Relative Effectiveness of Electroacupuncture as Compared to Single Dry Needle Insertion in the Treatment of Trapezius Myofasciitis. Masters degree in technology: Chiropractic Dissertation, Durban Institute of Technology, Durban, South Africa.

Farasyn, A., Meeusen, R. 2005. The Influence of Non-Specific Low Back Pain on Pressure Pain Thresholds and Disability. European Journal of Pain. 5: 375-381.

Fischer, A. A. 1986. Pressure Threshold Meter: Its Use for Quantification of Tender Spots. Archives of Physical Medical Rehabilitation. 67.

Fischer, A. A. 1987. Pressure Threshold Measurement for the Diagnosis of Myofascial Pain and Evaluation of Treatment Results. The Clinical Journal of Pain. 2: 207-214.

Fischer, A. A., Chang, C. H. 1986. Temperature and Pressure Threshold Measurements in Trigger Points. Thermology. 1: 212-215.

Fricton, J. R. 1990. Myofascial Pain Syndrome. Characteristics and Epidemiology. Advances on Pain Research and Therapy. 17: 43-106.

Gatterman, M.I., Goe, D. R. 1990. Chiropractic Management of Spine-related Disorders. U.S.A. Williams and Wilkins 473p. ISBN 0-6830-3438.

Goddard, G., Shen, Y., Steele, B., Springer, N. 2005. A Controlled Trial of Placebo Versus Real Acupuncture. The Journal of Pain. 6(4): 237-242.

Han, S. C., Harrison, P. 1997. Myofascial Pain Syndrome and Trigger Point Management. Regional Anesthesia. 22(1): 89-101.

Hong, C. Z. 1994. Lidocaine Injection Versus Dry Needling to Myofascial Trigger Points: the Importance of the Local Twitch Response. American Journal of Physical Medicine and Rehabilitation. 73(4): 256-263.

Hubbard, D. R. 1998. Persistent Muscular Pain: Approaches to Relieving Trigger Points. The Journal of Musculoskeletal Medicine. May: 16-27.

Jansen, C. 1998. The Prevalence and Types of Headaches in Afrikaans Speaking High School Children in the Greater Durban Area. Masters degree in technology: Chiropractic Dissertation, Durban Institute of Technology, Durban, South Africa.

Jensen, M. P., Karoly, P., Braver, S. 1986. The Measurement of Clinical Pain Intensity: a Comparison of Six Methods. Pain. 27: 117-126.

Levine, J. D., Gormley, J., Fields, H. L. 1976. Observations of the Analgesic Effects of Needle Puncture. Pain. 2: 149-159.

Lewit, K. 1979. The Needle Effect in the Relief of Myofascial Pain. Pain. 6: 83-90.

Mouton, J. 1996. Understanding Social Research. 1st Edition. Van Schaik Publishers, Pretoria, South Africa. Pp53, 93, 133 ISBN 0-627-02163-8.

Nussbaum, E. L., Downes, L. 1998. Reliability of Clinical Pressure-Pain Algometric Measurements Obtained on Consecutive Days. Physical Therapy. 78(2): 160-169.

Rowley, N.C. 2000. The Relative Effectiveness of a Single Dry Needle Insertion Compared to Multiple Fanning Dry Needling Insertions in the Treatment of Myofasciitis in the Cervical and Upper Thoracic Spine. Masters degree in technology: Chiropractic Dissertation, Durban Institute of Technology, Durban, South Africa.

Ruane, J. J. 2001. Identifying and Injecting Myofascial Trigger Points. The Physician and Sportsmedicine. 29(12).

Simons, D. G. 1981. Myofascial Trigger Points: a Possible Explanation. Pain. 10: 106-109.

Sola, A.E., Rodenburger, M.L. and Getty, B.B. 1955. Incidence of Hypersensitive areas in Posterior Shoulder Muscles. American Journal of Physical Medicine. 34: 585-590.

Streitberger, K., Kleinhenz, J. 1998. Introducing a Placebo Needle into Acupuncture Research. The Lancet. 352(9125): 364-365.

Travell, J., Simons, D.G. and Simons, L.S. 1999. Myofascial Pain and Dysfunction: Trigger Point Manual. 2nd Edition. U.S.A. 351 West Camden Street, Baltimore: Williams & Wilkins. Vol 1: ISBN 0-683-08363-5.

Wilks, C. L. 2003. The Therapeutic Efficacy of Dry Needling Latent Myofascial Trigger Points. Masters degree in technology: Chiropractic Dissertation, Durban Institute of Technology, Durban, South Africa.

www.bmj.com. 2005 [online]. Available from: <http://bmj.com>. [Accessed 24 October 2005].

www.isixsigma.com. 2005 [online]. Available from: <http://isixsigma.com>. [Accessed 24 October 2005].

APPENDIX A

INFORMED CONSENT FORM

(To be completed by patient / subject)

Date _____ :

Title of research project : A clinically controlled study investigating the effect of dry needling muscle tissue in asymptomatic subjects with respect to post-needling soreness.

Name of supervisor : Dr. A. Docrat
Tel : (031) 2042589

Name of research student : Emile Ferreira
Tel : (031) 2042205

<u>Please circle the appropriate answer</u>		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.	Do you understand the implications of your involvement in this study?	Yes	No
7.	Do you understand that you are free to withdraw from this study? at any time without having to give any a reason for withdrawing, and without affecting your future health care.	Yes	No
8.	Do you agree to voluntarily participate in this study	Yes	No
9.	Who have you spoken to?		

Please ensure that the researcher completes each section with you

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

Please Print in block letters:

Patient /Subject Name: _____ Signature: _____

Parent/ Guardian: _____ Signature: _____

Witness Name: _____ Signature: _____

Research Student Name: _____ Signature: _____

APPENDIX B

Letter of Information

Dear patient.

Welcome to my research study. In this study I will be determining whether needling asymptomatic muscle tissue results in post-needling soreness.

Title of the Study:

A clinically controlled study investigating the effect of dry needling muscle tissue in asymptomatic subjects with respect to post-needling soreness.

Supervisor: Dr. A. Docrat. (031) 204 2589

Research Student: Emile Ferreira (031) 204 2205/ 083 375 0115

Institution: Durban Institute of Technology.

Purpose of the Study:

The purpose of this study is to establish whether applying dry needling to asymptomatic muscle tissue does cause post-needling soreness.

Procedure:

At the initial consultation you will undergo a History, Physical, and a regional examination, after which you will be selected providing you fit the necessary criteria for the research. Once accepted into the study you will receive one treatment, after which you will be required to complete the 24-hour diary, which will be provided. A follow-up assessment will take place 24 hours after the initial treatment. You will remain in the study as long as you commit to the appointment schedule.

Risks or Discomforts:

You may experience soreness in the area that the needle was inserted.

Reasons why you may be withdrawn from this study without your consent :

You may be removed from this study without your consent for the following reasons:

- If you are unable to attend your follow-up appointment.
- If you have changed any lifestyle habits during your participation in this study that may effect the outcome of this research (e.g. Medication, supplements or treatment).

Benefits:

Your contribution to this study, by volunteering to partake, will help us as chiropractors to build on our knowledge. This will benefit you as a patient in the long run, as we will be able to provide you with more effective health care in the future.

AS A VOLUNTARY PARTICIPANT IN THIS RESEARCH STUDY, YOU ARE FREE TO WITHDRAW FROM THE STUDY AT ANY TIME, WITHOUT GIVING A REASON.

Remuneration:

None

Costs of study:

None

Confidentiality:

All patient information is confidential. The results from this study will be used for research purposes only. Only individuals that are directly involved in this study (Dr. A. Docrat and myself) will be allowed access to these records.

Persons to contact should you have any problems or questions:

Should you have any problems or questions that you would prefer being answered by an independent individual, feel free to contact my supervisor on the above number. If you are not satisfied with a particular area of this study, please feel free to forward any concerns to the Durban Institute of Technology Research and Ethics Committee.

Thank you for participating in my research study.

**Emile Ferreira
(Researcher)**

**Dr. A. Docrat
(Supervisor)**

APPENDIX C

Dear patient.

Thank you for participating in my study on post-needling soreness.

Kindly complete this pain diary documenting any soreness you may experience, in the area that was needled, during the 24 hours following your treatment.

Did you experienced pain in the area that was needled at:	YES	NO
3 hours		_____
6 hours		_____
9 hours		_____
12 hours		_____
24hours		_____

My pain was worst at_____hours after receiving dry needling therapy.

If you have any questions regarding the research, kindly contact Emile Ferreira on (031) 204 2205 or 083 375 0115 or you can contact my research supervisor Dr. Docrat on (031) 204 2589.

Patient Name:_____

Patient Signature:_____

Research Student Name:_____

Research Student's Signature:_____

APPENDIX D

Numerical Pain Rating Scale – 101

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

Patient name: _____

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

Please write only one number.

0 _____ 100

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

Please write only one number.

0 _____ 100

APPENDIX E

Algometer readings:

PATIENT NAME: _____		GROUP: _____	
ALGOMETER READING	PRIOR TO NEEDLING	IMMEDIATELY AFTER NEEDLING	24 HOURS AFTER NEEDLING

Research Article

A clinically controlled study investigating the effect of dry needling muscle tissue in asymptomatic subjects with respect to post-needling soreness.

Ferreira, Emile P; Docrat, Aadil.

Department of Chiropractic; Faculty of Health; Durban Institute of Technology

Objectives: To determine whether applying dry needling to muscle tissue in asymptomatic subjects results in the development of post-needling soreness in terms of subjective and objective findings. Two different dry needling techniques were also compared with a placebo group in order to determine which technique resulted in the least post-needling soreness.

Design: A prospective, randomized, placebo controlled experimental investigation.

Setting: Chiropractic Day Clinic; Durban Institute of Technology.

Participants: Sixty volunteers were randomly allocated into three groups of twenty subjects each. All subjects were required to be asymptomatic regarding the low back region.

Intervention: Group one received the single needle insertion technique and the second group received the fanning dry needling technique. The last group formed the control group and the subjects were treated using the Park Sham Device (placebo needles). Algometer reading were taken immediately before and after the dry needling procedure and again at the follow-up visit 24 hours later. Subjects were asked to rate, using the Numerical Pain Rating Scale 101, any post-needling soreness they might experience. This was also done immediately after the dry needling was completed and at the follow-up visit. A 24-hour pain diary was also provided to all the subjects, which they were required to complete at three-hour intervals following the dry needling.

Main Outcome Measures: Pressure Threshold Algometry; Numerical Pain Rating Scale 101; 24-Hour Pain Diary.

Results: In terms of subjective and objective pain measurement there was a very subtle difference between single needle insertion technique and fanning dry needling technique. Mostly the difference was not statistically significant. However, a trend could be observed which showed that post-needling soreness lasted for a longer period in the single needle insertion group. The single needle insertion group also experienced greater post-needling soreness at a later stage following the treatment than the other groups.

Conclusion: Objectively, all groups experienced some degree of post-needling soreness. Subjectively, the placebo group did not experience any post-needling soreness. An inter-group analysis yielded no statistically significant results regarding the difference in which the two treatment groups (i.e. the single needle insertion group and the fanning dry needling group) experienced post-needling soreness. However, both treatment groups did develop a statistically significantly increased level of post-needling soreness when compared to the placebo group. A trend could be observed which showed that post-needling soreness lasted for the longest period in the single needle insertion group

Key Words: Myofascial Pain Syndrome; Myofascial trigger point; Dry needling; Post-needling soreness; Placebo needling.

Introduction

Myofascial Pain Syndrome, which results from myofascial trigger points, is a common source of frustration for both practitioners and patients suffering from it. It is the second most common reason for patients visiting their health care practitioner and constitutes up to 85% of the causes for visits to pain clinics (Han and Harrison, 1997). As muscle pain is the most common work-related injury (Hubbard, 1998), it costs billions of dollars in lost revenue every year due to lost productivity (Fricton, 1990).

Despite the high prevalence of myofascial trigger points, the pathophysiology of it is not appropriately emphasised in the training of healthcare practitioners (Gatterman and Goe, 1990). The treatment of Myofascial Pain Syndrome has been researched and discussed more extensively. This may be due to the fact that a wide range of treatment modalities exist, including massage, ischaemic compression, exercise, the application of heat or cold, ultrasonography, transcutaneous electrical nerve stimulation, Spray-and-Stretch technique, trigger points injection and dry needling (Wilks, 2003)(Cumming, 2002).

Trigger point injection, using saline, steroids or local anaesthetics is probably the most effective way of inactivating and relieving the painful symptoms of trigger points (Alvarez and Rockwell, 2002). However, studies have shown dry needling to be as effective as the injection of medication (Han and Harrison, 1997). Thus it has been assumed that the therapeutic value of both dry needling and medicinal injections may actually be the mechanical disruption of the needle (Alvarez and Rockwell, 2002). Therefore it is possible to avoid the development of unwanted side effects of medicinal injections such as allergic reactions, muscle necrosis (Travell, Simons and Simons, 1999), skin depigmentation and tendon atrophy, as well as syncope, apnoea and palpitations (Ruane, 2001).

Dry needling involves the insertion of a thin gauge needle, usually an acupuncture needle, into the most painful spot in the tender nodule. Immediate analgesia can be

expected, termed the 'needle effect', if local twitch responses are elicited (Lewit, 1979, Travell, Simons and Simons, 1999: p 151). The proposed mechanisms through which dry needling inactivates trigger points are as follows:

- The needle causes disruption of the contraction knot in the muscle. This in turn terminates the basis for the sensitisation of local nerve endings and the local energy crisis, which is responsible for the perpetuation of trigger points (Travell, Simons and Simons, 1999).
- Mechanical disruption of muscle fibres also causes increased levels of extracellular potassium, which leads to the depolarisation of nerve fibres (Han and Harrison, 1997: p95).
- The needle causes mechanical disruption of local nerve endings (Han and Harrison, 1997:p95).
- Dry needling utilises hyperstimulation analgesia to interrupt the positive feedback mechanism that perpetuates pain (the pain-spasm-pain cycle). The three major properties of hyperstimulation analgesia are a) a moderate to severe sensory input in order to alleviate pain, b) a sensory input sometimes applied to a site distant from the site of pain and c) the sensory input, applied briefly up to 30 minutes, may relieve chronic pain for a short period of time or even permanently (Gatterman and Goe, 1990: p296). Levine (1976) also stated that counter-irritation is the possible explanation for the efficacy of dry needling.

A side effect common to both dry needling and the injection of medication is the development of post-needling soreness. Post-needling soreness appears to be worse after dry needling, with respect to both intensity and duration, when comparing dry needling to trigger point injection (Alvarez and Rockwell, 2002). Although post-needling soreness is commented on by many authors (Han and Harrison, 1997, Lewit, 1979, Hubbard, 1998), its exact cause has not been documented. Travell, Simons and Simons (1999) noted that post-needling soreness experienced by patients was aggravated if bleeding occurred with trigger point injection or dry needling. Lewit (1979) noted that post-needling soreness resulted even when a trigger point was not precisely needled.

Therefore, it is unclear whether the pain arises from the trigger point itself or whether the tissue damage caused by the needle insertion is responsible.

Therefore the aim of this study was to investigate whether dry needling muscle tissue in asymptomatic subjects (i.e. subjects not suffering from myofascial pain syndrome) resulted in post-needling soreness. Two different techniques of dry needling were compared to each other in order to determine which technique caused the least amount of post-needling soreness. Both techniques were also compared to a placebo group.

Thus far two forms of placebo treatment are available for needling/acupuncture research. Sham needling/acupuncture is invasive and involves inserting a needle into a non-acupoint or merely varying the depth of needle penetration. Placebo needling/acupuncture is considered non-invasive and can be performed by using a retractable needle or a needle with a blunted tip. It has however been suggested that the insertion of a needle into the skin can still activate noxious inhibitory control and as such, placebo needling/acupuncture appears to be the modality of choice (Goddard et al., 2005).

Materials and Methods

Sample Population

The study incorporated 60 volunteers randomly assigned to three groups of 20 each.

Inclusion Criteria

4. Subjects between the ages of 18 and 50 were selected for this study.
5. All subjects were required to be asymptomatic in the low back pain region.

Exclusion Criteria

7. Subjects with contra-indications to dry needling were excluded. These were:
 - Subjects under the influence of alcohol or those suffering from systemic illness, fever, bleeding disorders, anxiety or syncopial reactions (Travell

and Simons, 1999). Subjects who report initially being adverse to the thought of dry needling were excluded. All smokers were also excluded as tobacco causes low vitamin C levels which can lead to increased fragility of capillaries, possibly resulting in unsightly ecchymoses and altered development of post-needling soreness.

8. Subjects taking or those who have taken analgesic or anti-coagulant medication during the three days prior to the initial consultation were excluded from the study.
9. Subjects receiving or those who had received dry needling in the three months prior to the initial consultation were excluded, as maximal naivety regarding the onset of post-needling soreness was desired (Mouton, 1996).
10. Subjects with a confirmable diagnosis of a lumbar radiculopathy or myelopathy based on the neurological examination were not considered.
11. Subjects suffering from Primary Fibromyalgia Syndrome were not allowed to participate in the study (Han and Harrison, 1997).
12. Subjects found to have either active or latent myofascial trigger points in the Quadratus Lumborum, Gluteus Medius or Iliopsoas muscles were excluded from the study due to their referral pattern to the low back (Travell, Simons and Simons, 1999).

Measurement Tools

1. Numerical Pain Rating Scale 101 (NRS-101) The NRS-101 was used in order to monitor the development, if any, of post-needling soreness as perceived by the patient. The NRS-101 involves asking the subject to rate his or her pain intensity on a

numerical scale from a score of 0 to 100, with 0 representing the subject experiencing no pain and 100 representing the subject experiencing the pain at its worst.

2. Pain Diary. Owing to the uncertainty regarding the time period pertaining to the onset of post-needling soreness, all subjects were required to complete a 24-hour pain diary in order to monitor the onset, if any, of post-needling soreness following the treatment. The pain diary is divided into three-hour periods, commencing immediately after the treatment, and subjects were required to either tick 'yes' or 'no' to whether or not they were experiencing pain at that point. The pain diary also required subjects to record at which time, in hours, they experienced the most pain.

Did you experience pain in the area that was needed at:	YES	NO
3 hours	<input type="checkbox"/>	<input type="checkbox"/>
6 hours	<input type="checkbox"/>	<input type="checkbox"/>
9 hours	<input type="checkbox"/>	<input type="checkbox"/>
12 hours	<input type="checkbox"/>	<input type="checkbox"/>
24hours	<input type="checkbox"/>	<input type="checkbox"/>

My pain was worst at _____ hours after receiving dry needling therapy.

3. Pressure Threshold Algometry. The algometer was used in this study in order to measure the subjects' pressure pain threshold (ppt), defined as "the minimum pressure (force) that induces pain or discomfort" (Fischer, 1987). In a study performed by Nussbaum et al. (1998) it was concluded that the non-electronic algometer is a reliable way of measuring pressure pain threshold over three consecutive days, especially if the same examiner obtains the measurements.

Data Collection

Once the subject had undergone a full case history, revised physical examination, low back regional examination, including screening the Quadratus Lumborum muscles for active and latent trigger points, and had read and signed the Informed Consent form (Appendix B), patients were positioned prone for the duration of the procedure. An algometer reading was obtained from the exact area that was to be needled prior to the commencement of dry needling.

Group 1 received the single needle insertion technique. The needle was inserted into the muscle until roughly only one quarter of the needle shaft was still showing. The needle was left in place for five minutes, after which it was rolled clockwise and anti-clockwise, using the thumb and forefinger, for up to one minute. The needle was again left in place for a further five minutes and again stimulated as before. The same procedure was repeated three times and lasted approximately 20 minutes. After the third manipulation of the needle, it was left in place for five minutes and withdrawn (Rowley, 2000).

Group 2 received the fanning dry needling technique. The needle was inserted into the muscle as above and repeatedly withdrawn and redirected to another position ten times, without withdrawing the needle from the skin completely. For the sake of homogeneity the needle was stimulated at the same time intervals as Group 1.

In both Group 1 and 2, 0,25 x 25mm acupuncture needles were used. The Quadratus Lumborum muscles were needled in all instances and all sites that were needled were marked with henna in order to ensure that all measurements were obtained from the exact area that was needled.

Group 3 received the placebo needle and stimulation of the needle was repeated as for Group 1.

For the purposes of this study the Park Sham Device was selected in order to administer the application of placebo needling: Acuprime, 33 Southerhay East, Exeter, EX1, 1NX,U

Results

Table 1: Descriptive statistics for age by group.

GROUP	Mean (Years)	N	Std. Deviation
Single needle insertion	19.15	20	5.344
Fanning dry needling	24.00	20	7.056
Placebo	25.70	20	9.476
Total	22.95	60	7.873

Table 1 depicts that sixty participants were randomised into 3 equal groups (n=20). The mean age of the sample was 22.95 years (SD 7.9 years). It also reflects the mean age of each group. It is clear that the subjects in the single needle insertion group were on average younger than the other two groups. This was a random event as subjects were allocated to their groups according to the randomisation process.

Table 2: Comparison of gender by group.

		GROUP			Total
		Single needle insertion	Fanning dry needling	Placebo	
GENDER	Male	8(29.6%)	12(44.4%)	7(25.9%)	27(100.0%)
	Female	12(36.4%)	8(24.2%)	13(39.4%)	33(100.0%)
Total		20(33.3%)	20(33.3%)	20(33.3%)	60(100.0%)

P=0.243

Table 2 reflects that there was no significant difference in gender distribution between the groups ($p=0.243$). There was a slight preponderance of males in the fanning dry needling group and of females in the placebo group, but the difference in proportions was not significant.

Baseline outcomes:

Only the algometer measurements were obtained at baseline (before any treatment). There was a significant difference in mean baseline algometer measurements between the groups ($p=0.024$). Many studies have noted that ppt's (pressure pain threshold) vary significantly between individuals and therefore, to prevent this factor from determining the outcome, it was controlled for in subsequent analysis (Farasyn and Meeusen, 2005).

Table 3: Descriptive statistics for mean algometer baseline measurement by group.

GROUP	Mean Kg/cm ²	N	Std. Deviation
Single needle insertion	14.28	20	3.806
Fanning dry needling	16.97	20	3.733
Placebo	17.65	20	4.455
Total	16.30	60	4.208

Effect of the treatment according to the Algometer:

When looking at Figure 1 it is clear that the profiles of the single needle insertion group (red line) and the fanning dry needling group (green line) are parallel over time. Thus both treatment groups reacted significantly differently over time when compared to the placebo group, however they were not different from each other.

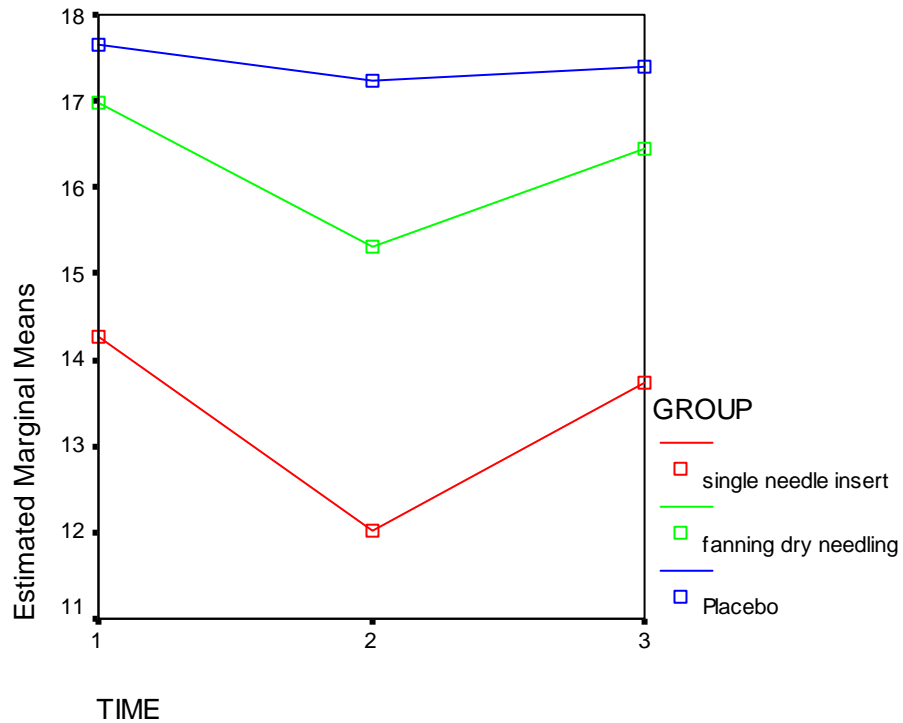


Figure 1: Profile plot (by intervention group) of mean algometer over time.

Effect of the treatment according to the NRS-101:

Figure 2 reveals that the fanning dry needling group (green line) reached the mean pain level of the placebo group at time 2, but the single needle insertion group (red line) experienced a higher mean pain level than both groups both immediately following the needling and at the follow-up visit 24 hours later. The fanning dry needling group and the single needle insertion group showed no difference over time when compared to each other ($p=0.708$). Therefore the fanning dry needling technique and single needle technique both showed a similar decrease in pain over time, however, compared to the placebo (blue line), the fanning dry needling showed a significantly steeper rate of decrease in pain.

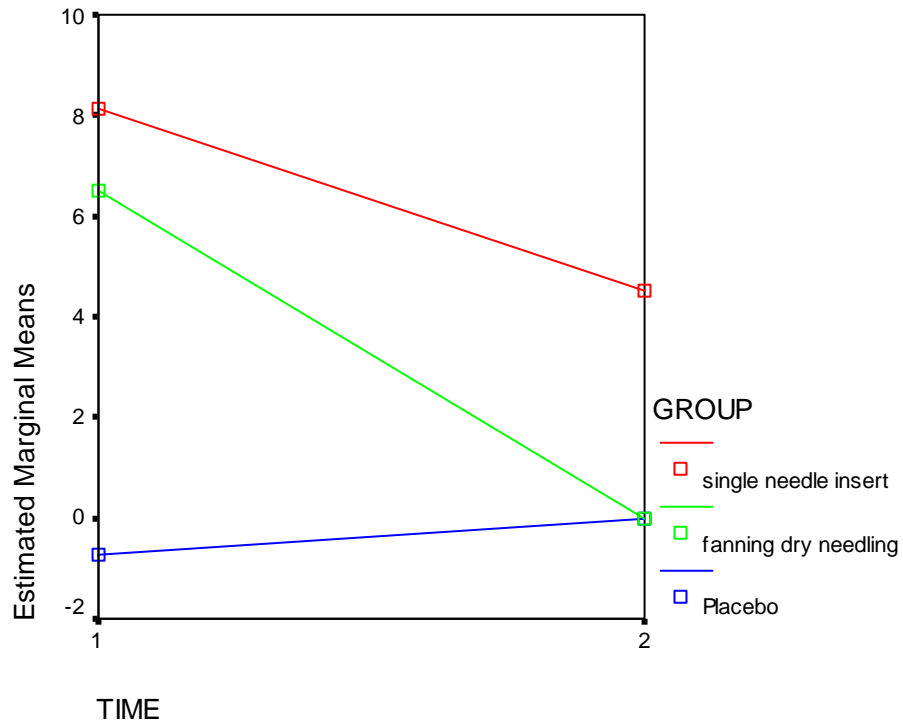


Figure 2: Profile plot (by intervention group) of mean NRS-101 over time.

Post-needling soreness as reported in the 24-hour pain diaries:

Post-needling soreness was reported very infrequently by diary assessment. Cross-sectional analysis of pain at each time point (every three hours following the treatment) revealed no significant differences between the groups. At 3 hours 15% of the single needle insertion group had pain and 5% of the fanning dry needling group had pain. At no time did any participant from the placebo group report pain. At 6 hours only one subject had pain (single needle group). At 9 hours post-treatment only 2 subjects had pain, one in each of the single needle and fanning dry needle groups. No participants experienced pain at 12 and 24 hours following the treatment.

Table 3: Proportions of participants per group who reported experiencing post-needling soreness at 3, 6 and 9 hours post treatment.

GROUP	Diary 3		Diary 6		Diary 9	
	Yes	No	Yes	No	Yes	No
Single needle insertion	3 (15%)	17(85%)	1(5%)	19(95%)	1(5%)	19(95%)
Fanning dry needling	1(5%)	19(95%)	0(0%)	20(100%)	1(5%)	19(95%)
Placebo	0(0%)	20(100%)	0(0%)	20(100%)	0(0%)	20(100%)
Total	4(6.7%)	56(93.3%)	1(1.7%)	59(98.3%)	2(3.3%)	58(96.7%)

P=0.153

Table 3 reveals that 3 participants (15%) in the single needle insertion group experienced post-needling soreness 3 hours after the receiving dry needling. It also shows that only 1 participant (5%) in the group that received fanning dry needling, and none of the participants in the placebo group, experienced post-needling soreness.

Table 3 indicates that only one of the participants from the single needle insertion group experienced post-needling soreness 6 hours after the treatment and that none of the participants from neither the fanning dry needling group nor the placebo group experienced any post-needling soreness at the same time interval.

Table 3 also shows that only one participant from each of the treatment groups experienced post-needling soreness 9 hours after receiving dry needling therapy, and that none of the participants from the placebo group experienced any post-needling soreness.

Figure 3 indicates that the single needle insertion group was the group that experienced the most post-needling soreness at 3 hours and 6 hours following the treatment, although this slight difference was not statistically significant.

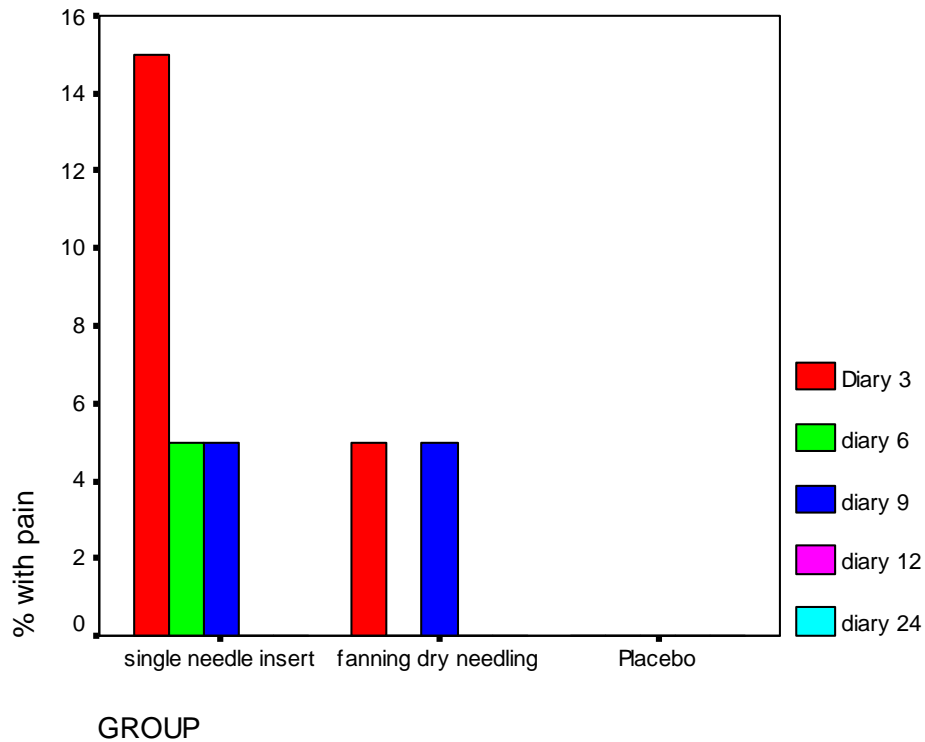


Figure 3: Percentage of participants (by intervention group) with pain at each time point.

Time taken for worst pain to develop:

The time at which the subjects' worst pain was felt, following the treatment, was also statistically significantly different between the groups ($p= 0.030$). The single needle insertion group experienced their worst level of post-needling soreness significantly later than the other groups.

Table 11: Descriptive statistics for time elapsed since treatment that the worst pain was felt.

GROUP	Mean (Hours)	Minimum (Hours)	Maximum (Hours)
Single needle insertion	.1250	.00	8.00
Fanning dry needling	.0000	.00	9.00
Placebo	.0000	.00	1.00
Total	.0000	.00	9.00

Table 11 shows the mean time at which the worst pain was experienced per group. For the single needle insertion group the mean time since treatment at which the worst pain was felt was 0.125 hours. For the other two groups it was 0 hours. So few subjects in the fanning dry needling group and the placebo group reported post-needling soreness that no average could be computed for them.

Summary of results:

In terms of subjective and objective pain measurement there was a very subtle difference between single needle insertion technique and fanning dry needling technique. Mostly the difference was not statistically significant. However, a trend could be observed which showed that post-needling soreness lasted for a longer period in the single needle insertion group. The single needle insertion group also experienced greater post-needling soreness at a later stage following the treatment than the other groups. Thus there is partial evidence to suggest that fanning dry needling is preferential to single needle insertion, but both groups initially experienced more post-needling soreness than the placebo group.

Discussion

Numerical Pain Rating Scale 101 (NRS-101):

The results from the NRS-101 yielded some unexpected results. The subjects in the single needle insertion group experienced post-needling soreness of greater intensity and longer duration than the fanning dry needling group.

Rowley (2000) conducted a study on the relative effectiveness of single dry needle insertion versus fanning dry needling in the treatment of myofascial trigger points. Rowley stated that the subjects who had received the fanning dry needling experienced greater post-needling soreness than the single needle insertion group.

As stated earlier, very little detail is available regarding post-needling soreness and its exact cause. Due to this, some of the findings from this study will be compared to Delayed-Onset Muscle Soreness (DOMS). DOMS is used in research of muscle injuries, as it is controllable and reproducible (Downes and Nussbaum, 1998). It is a condition that develops as a result of untrained muscles performing strenuous eccentric exercise. Blood enzyme analysis and muscle biopsy reveals that biochemical changes occur with the onset of DOMS, including the presence of cellular infiltrates such as neutrophils, macrophages and various other inflammatory mediators. Morphological changes such as the disruption of myofibrils and supporting connective tissue also occur with DOMS. Accordingly DOMS is a controlled injury that can be imposed on muscle tissue for research purposes (Downes and Nussbaum, 1998). Some of the symptoms of DOMS are pain, tenderness and stiffness, and as such these symptoms increase as the severity of the condition increases. This information, combined with the statement by Travell, Simons and Simons (1999) that bleeding worsens post-needling soreness, lead the examiner to the assumption that the fanning dry needling technique would result in the development of greater post-needling soreness. Thus the results obtained by the NRS-101 appear to be anomalous.

Although the single needle insertion group and the fanning dry needling group experienced parallel decreases in pain over time, only the fanning dry needling group differed significantly from the placebo group. A possible explanation could stem from the gender distribution between the fanning dry needling group and the placebo group. Although the difference was not statistically significant, there was a slight preponderance of males in the fanning dry needling group and females in the placebo group. Farasyn and Meeusen (2005) commented on the fact that research has consistently indicated that differences in pain perception exist between the genders, with males having more positive expectations regarding the painfulness of potentially painful events.

Pain diary:

The 24-hour pain diaries yielded similar results to the NRS-101, with the single needle insertion group experiencing post-needling soreness for a greater period of time when compared to the fanning dry needling group. On average, the single needle insertion group experienced their worst pain 7.5 minutes after the treatment, with the fanning dry needling group and the placebo group having too few subjects reporting pain that their average was 0.

Previously written articles (Travell, Simons and Simons, 1999) and research (Rowley, 2000) lead to the conclusion that the fanning dry needling technique would result in subjects experiencing greater post-needling soreness than groups receiving the single needle insertion technique. The results obtained in this study are as such anomalous, and were possibly affected by outliers in the respective groups due to small sample sizes.

Algometer readings:

The results from the algometer readings indicated that the single needle insertion group and the fanning dry needling group were significantly different from the placebo group. This indicates that in both treatment groups the needling process did cause increased

tenderness in the area that was needles. However, the algometer readings did not differ from each other between the two treatment groups.

Farasyn and Meeusen (2005) conducted a study on the ppt's (pressure pain thresholds) of individuals suffering from non-specific low back pain and noted that no significant difference, regarding their ppt's, existed between individuals with moderated low back pain and individuals with severe low back pain. They concluded that what was of extreme importance was "the perceived ability to control pain and the role of central nervous system modulation."

It was hypothesized that the group receiving the fanning dry needling technique would experience greater post-needling soreness than the group receiving the single needle insertion technique. The results from the algometer readings do not support this hypothesis.

Conclusion

The aim of this study was to investigate post-needling soreness following two forms of dry needling therapy on the muscle tissue of asymptomatic subjects, and this was then compared to a placebo group. It was hoped that this study would provide an insight into whether or not the tissue damage which occurs with needle insertion causes post-needling soreness, or whether post-needling soreness is a phenomenon peculiar to the dry needling of actual myofascial trigger points.

An intra-group analysis revealed that, objectively, all groups experienced some degree of post-needling soreness. Subjectively however, the placebo group did not experience any post-needling soreness according to the findings from the NRS-101 and 24-hour pain diaries.

An inter-group analysis yielded no statistically significant results regarding the difference in which the two treatment groups (i.e. the single needle insertion group and the fanning

dry needling group) experienced post-needling soreness. However, both treatment groups did develop a statistically significantly increased level of post-needling soreness when compared to the placebo group. The study was hampered by the sample size, allowing outliers to affect the results significantly. Future studies of this nature should include larger sample sizes. The gender distribution, even though it was not statistically significant, also hampered the results somewhat with the males failing to report mild levels of discomfort. Similar studies in the future should include equal representation regarding gender in order to avoid this problem.

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References

Alvarez, D. J., Rockwell, P. G. 2002. Trigger Points: Diagnosis and Management. American Family Physician. **65**(4): 653-660.

Cumming, L. A. 2002. The Relative Effectiveness of Electroacupuncture as Compared to Single Dry Needle Insertion in the Treatment of Trapezius Myofasciitis. Masters degree in technology: Chiropractic Dissertation, Durban Institute of Technology, Durban, South Africa.

Farasyn, A., Meeusen, R. 2005. The Influence of Non-Specific Low Back Pain on Pressure Pain Thresholds and Disability. European Journal of Pain. **5**: 375-381.

Fischer, A. A. 1987. Pressure Threshold Measurement for the Diagnosis of Myofascial Pain and Evaluation of Treatment Results. The Clinical Journal of Pain. **2**: 207-214.

Fricton, J. R. 1990. Myofascial Pain Syndrome. Characteristics and Epidemiology. Advances on Pain Research and Therapy. **17**: 43-106.

Gatterman, M.I., Goe, D. R. 1990. Chiropractic Management of Spine-related Disorders. U.S.A. Williams and Wilkins 473p. ISBN 0-6830-3438.

Goddard, G., Shen, Y., Steele, B., Springer, N. 2005. A Controlled Trial of Placebo Versus Real Acupuncture. The Journal of Pain. **6**(4): 237-242.

Han, S. C., Harrison, P. 1997. Myofascial Pain Syndrome and Trigger Point Management. Regional Anesthesia. **22**(1): 89-101.

Hubbard, D. R. 1998. Persistent Muscular Pain: Approaches to Relieving Trigger Points. The Journal of Musculoskeletal Medicine. May: 16-27.

Levine, J. D., Gormley, J., Fields, H. L. 1976. Observations of the Analgesic Effects of Needle Puncture. Pain. **2**: 149-159.

Lewit, K. 1979. The Needle Effect in the Relief of Myofascial Pain. Pain. **6**: 83-90.

Mouton, J. 1996. Understanding Social Research. 1st Edition. Van Schaik Publishers, Pretoria, South Africa. Pp53, 93, 133 ISBN 0-627-02163-8.

Nussbaum, E. L., Downes, L. 1998. Reliability of Clinical Pressure-Pain Algometric Measurements Obtained on Consecutive Days. Physical Therapy. **78**(2): 160-169.

Rowley, N.C. 2000. The Relative Effectiveness of a Single Dry Needle Insertion Compared to Multiple Fanning Dry Needling Insertions in the Treatment of Myofasciitis in the Cervical and Upper Thoracic Spine. Masters degree in technology: Chiropractic Dissertation, Durban Institute of Technology, Durban, South Africa.

Ruane, J. J. 2001. Identifying and Injecting Myofascial Trigger Points. The Physician and Sportsmedicine. **29**(12).

Travell, J., Simons, D.G. and Simons, L.S. 1999. Myofascial Pain and Dysfunction: Trigger Point Manual. 2nd Edition. U.S.A. 351 West Camden Street, Baltimore: Williams & Wilkins. Vol 1: ISBN 0-683-08363-5.

Wilks, C. L. 2003. The Therapeutic Efficacy of Dry Needling Latent Myofascial Trigger Points. Masters degree in technology: Chiropractic Dissertation, Durban Institute of Technology, Durban, South Africa.