THE INFLUENCE OF COMPONENT MATERIALS ON GRASTON TECHNIQUE EFFECTIVENESS DURING THE TREATMENT OF MYOFASCIAL PAIN SYNDROME.

By

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic in the Faculty of Health, at the Durban Institute of Technology.

I, Marcus Georgiou, declare that this dissertation represents my own work in both conception and execution.

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DEDICATION

For friends and family.

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ABSTRACT

Graston Technique Instrument-assisted Soft Tissue Mobilization (GTISTM), is a relatively new form of myofascial pain syndrome (MPS) treatment, that is thought to be an advanced form of soft tissue mobilization. The stainless steel instruments that are used are specifically designed for various parts of the body and are used to detect and release scar tissue, adhesions and fascial restrictions (Carey-Loghmani, 2003:7).

It is speculated that the Graston Technique instruments may be superior to other instruments due to the uniqueness of the instrument design, instrument material (stainless steel), delivery method and technique process. The instruments have been designed to adapt to the various curves of the body allowing the clinician to detect and treat soft tissue dysfunctions in an accurate and specific manner (Carey-Loghmani, 2003;2).

Other soft tissue therapeutic techniques make use of specifically designed aluminium instruments have shown to be successful in the treatment of tendonitis (Davidson et al., 1997).Thus it was the aim of this study to determine if there was a significant clinical difference between the Graston Technique instruments and instruments of the exact design but of a constitutionally different material (i.e. aluminium). This was achieved by varying the instrument material, while maintaining all the other features of the instrument, as well as the treatment protocol in the management of myofascial trigger points (MTrPs) of the trapezius and the levator scapula muscles.

This pilot study was a comparative clinical trial conducted on a quasi-experimental basis, aimed at establishing the influence of component materials of the Graston Technique instruments in the treatment of MPS in terms of clinical outcomes.

The sample size consisted of sixty patients selected from the Durban Metropolitan Area. Patients between the ages of 18 and 55 and diagnosed

with active MTrPs in either the trapezius and/or the levator scapula muscles were accepted into the study.

The subjects who fit the criteria were randomly allocated into 4 groups. Group A received treatment with the original Graston Technique instrument (stainless steel), Group B received the same treatment protocol but with the exception that the instrument was made of aluminum, Group C was made up the placebo group and therefore their intervention consisted of a detuned ultrasound, and the subjects that fell into Group D were used as the control group.

All sixty patients underwent a clinical assessment on the first consultation (objective and subjective findings). The patients who fell into the treatment groups were treated three times within two weeks with a second clinical assessment on the third consultation. The control group was required to attend three clinical assessments at one week intervals for the purpose of gathering data only. The treatment groups were then required to come in for a one week follow up in the third week for the third clinical assessment.

The objective data consisted of algometer and cervical range of motion (CROM) measurements while subjective data was made up of NRS-101 pain rating scale and the CMCC neck disability index. Both objective and subjective readings were taken at the first, third and fourth consultation.

For purposes of analysis the SPSS statistical package version 11.5 (SPSS Inc., Chicago, III, USA) was utilized. The descriptive statistics were analyzed utilizing bar graphs and other appropriate visual summaries. Comparison of treatment effects between treatment groups for quantitative outcomes was achieved using repeated measures ANOVA. Intra-group analysis was done using Friedman's test for both groups. The Dunn Procedure was also used in cases where the null hypothesis was rejected to determine at which consultation an improvement was observed. All data were analyzed at the 5% level of significance and decisions made using appropriate p-values. If $p<0.05$

the null hypothesis was rejected and if $p \geq 0.05$ the null hypothesis was accepted.

With a view to the statistical outcomes it could be stated in conclusion that the GTISTM instruments show better clinical outcomes when applied frequently over the regions of the MTrPs as opposed to the aluminium instruments which show decreased clinical outcomes. It is proposed that the cooling effect of the GTISTM instrument is principally related to this clinical phenomenon, as in principle both instrument groups work at the same mechanical level. This is supported by the results obtained in the placebo group where it is suspected that the cooling effect of the ultrasound gel and/or stainless steel head resulted in similar findings.

In terms of the outcomes between the treatment groups and the placebo and natural history groups, it was found that both instruments where better in attaining improved clinical outcomes over the natural history (control) group.

There were correlations between the improved clinical outcomes between the GTISTM and the placebo, which seems be related to the cooling effect of the two “treatment” modalities utilized. The aluminium group improved but to a lesser extent when compared to the placebo and natural history groups, however because the effect of the intervention is on a mechanical level it too allows for some clinical improvement above natural history but similar to that of the placebo which seems to have affected the clinical syndrome of MTrPs by a physiological mechanism as opposed to a mechanical one.

Therefore the outcomes of this research support the clinical use of the GTISTM above that of aluminium as the GTISTM seems to have had a two fold effect (mechanical and physiological/cooling) as compared to the aluminium which may only have one mechanism of action (mechanical).

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GTISTM – Graston Technique Instrument-assisted Soft Tissue Mobilization

MPS – Myofascial Pain Syndrome

MTrP – Myofascial Trigger Point

DEFINITION OF TERMS

Myofascial Pain Syndrome (MPS)

The sensory, motor, and automatic symptoms cause by myofascial trigger points. The specific muscle or muscle group that causes the symptoms should be identified (Travell and Simons', 1999).

Myofascial Trigger Point (MTrP)

A hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. The spot is painful on compression and can rise to characteristic referred pain, referred tenderness, motor dysfunction, and autonomic phenomena (Travell and Simons', 1999).

Active Myofascial Trigger Point

A myofascial trigger point that causes a clinical pain complaint. It is always tender, prevents full lengthening of the muscle, weakens the muscle, refers a patient-recognised pain on direct compression, mediates a local twitch response of muscle fibers when adequately stimulated, and, when compressed the patient's pain tolerance, produces referred motor phenomena, generally in its pain reference zone, and causes tenderness in the pain reference zone. To be distinguished from a latent myofascial trigger point (Travell and Simons', 1999).

Latent Myofascial Trigger Point

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

Graston Technique Instrument-assisted Soft Tissue Mobilisation (GTISTM)

An advanced form of soft tissue mobilisation that is used to detect and release scar tissue, adhesions and fascial restrictions (Carey-Loghmani, 2003:7).

CHAPTER ONE

INTRODUCTION

1.1 INTRODUCTION

Myofascial Pain Syndrome (MPS) refers to a regional muscle pain disorder accompanied by myofascial trigger points (MTrPs). The term MPS was popularized by Travell and Simons' in the 1980's (Chaitow and DeLany, 2003:67; Han and Harrison, 1997:89; Gatterman and Goe, 1990:285).

A relatively new form of MPS treatment, termed Graston Technique Instrument-assisted Soft Tissue Mobilization (GTISTM), is thought to be an advanced form of soft tissue mobilization. These stainless steel instruments are specifically designed for various parts of the body and are used to detect and release scar tissue, adhesions and fascial restrictions (Carey-Loghmani, 2003:7).

The developers of these instruments speculate that the GTISTM instruments may be superior to other instruments due to the result of a combination of the following aspects (Carey-Loghmani, 2003:12):

- instrument design
- instrument material
- delivery method
- technique process

These claims however have not been validated, but anecdotal evidence has suggested that instruments made of different materials do not yield the same clinical outcomes (Carey-Loghmani, 2003:12).

Thus it was the aim of this study to determine if there is a clinical difference between the GTISTM instruments and instruments of the same design but of a different material (i.e. aluminium).

1.2 AIMS AND OBJECTIVES

This pilot study was a pre-post clinical investigation assessing the influence of component materials on the effectiveness of GTISTM in the treatment of MPS, in terms of clinical outcomes.

1.2.1 The first objective

To determine the relative effectiveness of an aluminium instrument versus the stainless steel GTISTM instrument in terms of objective clinical findings, in the treatment of myofascial trigger points.

1.2.2 The second objective

To determine the relative effectiveness of an aluminium instrument versus the stainless steel GTISTM instruments in terms of subjective clinical findings, in the treatment of myofascial trigger points.

1.2.3 The third objective

To compare the trends that are evident between the subjective and the objective findings in order to ascertain whether there was any relationship between these results.

1.2.4 The fourth objective

To determine the relative effectiveness of each of the instruments versus the control group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

1.2.5 The fifth objective

To determine the relative effectiveness of each of the instruments versus the placebo group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

1.3 HYPOTHESIS

1.3.1 The first hypothesis

The stainless steel GTISTM instrument would be more effective than the aluminium instrument in terms of objective clinical findings, in the treatment of myofascial trigger points.

1.3.2 The second hypothesis

The stainless steel GTISTM instrument would be more effective than the aluminium instrument in terms of subjective clinical findings, in the treatment of myofascial trigger points.

1.3.3 The third hypothesis

Trends would be evident between the objective and subjective clinical findings, demonstrating a relationship between these findings.

1.3.4 The fourth hypothesis

The GTISTM and aluminium instruments would be more effective than the control group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

1.3.5 The fifth hypothesis

The GTISTM and aluminium instruments would be more effective than the placebo group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

1.3 RATIONALE

1. Davidson et al. (1997) found positive results in the treatment of a tendonitis within rats using instrument-assisted soft tissue mobilization with aluminium tools. The instrument used to apply “considerable pressure" to a tendon without breaking the overlying skin. These tools promoted healing and earlier recovery of limb function following injury.

By recovering earlier the tendon allowed increased limb function which also helped in the promotion of fiber realignment.

2. From another perspective, anecdotal and experimental studies utilizing GTISTM showed that aluminium instruments of similar design were not as effective as the instruments made of stainless steel. However the lack of data supporting these claims has necessitated the development of this study in order to validate or negate these assertions and assumptions.

1.4 LIMITATIONS OF THE STUDY

The Graston Technique (GT) = GTISTM + exercise. However, for the purposes of research, participants did not receive the full GT protocol. GTISTM should be used in conjunction with a cardio warm-up, targeted stretching and strengthening exercises and post treatment cryotherapy.

In order to determine the effectiveness of the GTISTM instrument, the above components of the GT protocol were excluded, allowing for a more accurate environment in which to compare the various instruments.

It is however noted that by not following this comprehensive treatment approach, the full benefit/effect of GTISTM may not be realized (Carey-Loghmani, 2003).

1.5 BENEFITS OF THE STUDY

It is hoped that this study will provide important information with regards to the benefit of the stainless steel GTISTM instrument as opposed to an aluminium instrument.

In summary

In order to elaborate on the study, Chapter two will be utilized to give an overview of the syndrome under study as well as the current treatments

available, with Chapter three indicating the materials and methods applicable to this study. Chapter four presents the results obtained from the statistical analysis of the clinical outcome measures, where chapter five discusses the trends observed in the results. Chapter six completes the dissertation with the conclusions of this study and recommendations for future studies in this field.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter will discuss the current theories and facts surrounding MPS and MTrPs, incidence and prevalence, etiology, perpetuating factors, clinical presentation, diagnosis and treatment.

2.2 MYOFASCIAL PAIN SYNDROME

Hong and Simons (1998) and Travell and Simons' (1999), identified MTrPs as the characteristic feature of myofascial pain syndromes. According to Travell and Simons' (1999), MPS is defined as "the sensory, motor and autonomic symptoms caused by MTrPs or hyper-irritable spots within skeletal muscles that are associated with palpable nodules in a taut band".

These hyperirritable spots, or trigger points, are simply a thick knot in the muscle which results in a stiffer, tighter muscle (shortened). Often this muscle is weaker and yet is in a state of involuntary tension at the same time. MTrPs may present in virtually any muscle, however the trapezius is the most commonly involved muscle found in clinical settings (Sciotti et al., 2001). In support of the findings by Sciotti et al. (2001) the most common sites for the development of MTrPs are the postural muscles of the back & neck and the rotator muscles of the shoulders (Gattermann and Goe, 1990:285; Hubbard 1998:18; Travell and Simons', 1999 1:279; and Chaitow and DeLany, 2003:21).

2.3 NATURE OF MYOFASCIAL TRIGGER POINTS

The *Integrated Hypothesis* (Travell and Simons', 1999; Chaitow and Delaney, 2003:65), attempts to explain the pathophysiology of MTrPs through the combination of two independent research investigations,

- the first through electrodiagnostic investigations and
- secondly through histopathological investigations.

The results of these studies have identified the MTrP as a cluster of numerous minute sites ("nidus") of intense abnormality that are found scattered throughout the nodule (Travell and Simons', 1999; Chaitow and Delaney, 2003:65).

The concept of "energy crisis'' has grown over the last 20 years and is an important component of the integrated hypothesis, where injury, strain or overstress of muscle fibers can result in dysfunctional endplate activity, causing the release of excess acetylcholine (ACh) at the synapse; this is often associated with increased calcium levels (Hong and Simons, 1998; Travell and Simons', 1999; Chaitow and Delaney, 2003:65; Mense et al., 2003).

The high calcium levels that result in sustained muscle fiber contracture, lead to increased metabolic demands with resultant oxygen and nutrient deficits. The sustained contraction also impairs circulation to the area, further reducing oxygen and nutrient levels. This completes the vicious cycle, resulting in a local energy crisis and the formation of a taut band. The taut band is the palpable characteristic of the MTrP (Hong and Simons, 1998; Sciotti et al., 1999; 2000; Travell and Simons', 1999; Chaitow and Delaney, 2003:65).

Based on this hypothesis, three main characteristics of MTrPs can be demonstrated (Travell and Simons', 1999:72)

- increased temperature due to increased energy expenditure and impaired circulation to remove heat;
- decreased oxygen levels due to ischemia;
- shortened sarcomeres resulting in a palpable taut band.

2.4 INCIDENCE AND PREVALENCE

The prevalence of myofascial pain has been reported as early as the 1950's (Sola et al., 1981:585). Fricton (1990) identified myofascial pain as one of the most common causes of chronic pain. Furthermore the results of his study are congruent with the study by Gerwin (1995) at a community pain medical centre found that 93% of participants had a portion of their pain caused by MTrPs and in 74% of these cases MTrPs were considered to be the primary cause of their pain.

In support of the above Han and Harrison (1997) found that the incidence of MPS varied between 30% and 85% of patients presenting to pain clinics. Thus Travell and Simons' (1999) concluded that individuals of any age can develop MTrPs, with the study by Hou et al. (2002) indicating that MPS occurs in both sexes; however being more commonly found in females.

2.5 ETIOLOGY

The causative factors in the development of MTrPs are varied, with authors emphasizing one factor over another. Sola et al. (1981) identified emotional stress and physical stress as the main initiating factors. However there is controversy around assessing the relationship between stress and MPS as was indicated by Fricton (1994), citing that stress is difficult to define and measure objectively. He does however quote a study by Evaskus and Laskin (1972) which showed an increased level of the stress hormone catecholamine in patients with MPS compared to the control group. This could be an indirect indicator of stress being an identified etiological factor.

On the other hand the literature is in agreement that the developments of MTrPs are associated with some degree of mechanical abuse of the muscle in the form of acute, sustained and/or repetitive muscle overload (Travell and Simons', 1999). The authors divide the causes according to the nature of the onset, those that result suddenly and those MTrPs that develop gradually. A

similar approach was used by Yunes et al. (1987), dividing the acute causes from the chronic.

In addition to the literature that divides the etiology by onset (gradual or immediate/recent); Fricton et al. (1994) identified two further concepts in the development of MTrPs, which are related to:

1. Directly traumatized muscles due to direct injury or repetitive microtrauma from habits that cause the muscles to be put under continuous tension such as poor posture.
2. Those factors which have an indirect effect on the normal functioning of the muscles, these include factors such as nutritional imbalances, lack of exercise and sleep, structural imbalances and joint disorders.

Nevertheless, the sudden development of MTrPs is thought commonly to result from mechanical stresses such as (Fricton, 1994):

1. Mechanical abuse
    - wrenching movements
    - unaccustomed exercise
2. Trauma
    - motor vehicle accidents
    - falls
    - joint sprains
    - dislocations
    - direct blow on the muscle

However Travell and Simons' (1999) go further and identify the following mechanical stresses in the development of MTrPs over time:

1. Sustained postural overload or mechanical abuse
2. Prolonged immobilization
3. Poor work ergonomics

In addition, conditions such as post-disc syndrome, which occurs when compression of peripheral nerves leads to the activation of MTrPs in the muscles supplied by the compromised nerve, may also play a role (Travell and Simons', 1999).

2.6 PERPETUATING FACTORS

The importance of identifying and treating the perpetuating factors has been thoroughly documented by numerous authors including Fomby and Mellion (1997), Han and Harrison (1997), Travell and Simons' (1999) and Hubbard and Berkoff (1993). In addition Auleciems (1995) points out that the activating and perpetuating factors in the development of MTrPs are quite different, therefore the successful treatment of the perpetuating factor will improve the long term prognosis.

There is a consensus on the extent of the perpetuating factors as indicated by Rubin (1981) and the above mentioned authors. However, the most comprehensive list was developed by research conducted by Graff-Radford et al. (1987). They subdivided these perpetuating factors into three major categories, namely physical, systemic factors and psychological factors.

1. Physical factors:
    - Skeletal asymmetry (short leg or small hemi-pelvis)
    - Poor body mechanics
    - Poor posture
    - Dental malocclusion
    - Poorly designed furniture
    - Vocational stress
    - Sedentary life style

2. Systemic factors:
    - Nutritional, metabolic and endocrine inadequacies
    - Chronic infections and infestations (bacterial or viral)

- Arthritis and other joint disease
- Visceral disease
- Disc disease

3. Psychological factors
   - Mental stresses and anxiety causing increased muscle tension
   - Depression
   - Operant pain

4. Other factors
   - Cold damp weather
   - Poor sleep
   - Fatigue

2.7 CLINICAL CHARACTERISTICS

MTrPs are classified as either active or latent. Latent MTrPs may have all the clinical characteristics of an active MTrPs but is clinically quiescent with respect to spontaneous pain. An active MTrPs causes a clinical pain complaint (Travell and Simons' (1999).

Table A: Comparison of latent and active myofascial trigger points Compiled by Wilks (2003)

Latent MTrPs	Active MTrPs
Commonalities	
Decreased stretch range of motion.	Decreased stretch range of motion.
Muscular stiffness.	Muscular stiffness.
Local twitch response.	Local twitch response
Painful and weak muscle on contraction.	Painful and weak muscle on contraction.
Differences	
Localized pain on manual compression.	Localized and referred pain on manual compression.
No spontaneous pain referral.	Spontaneous pain referral.
Recognition of an unfamiliar or previous pain.	Recognition of current pain.

Common Symptoms

Schneider (1995) found that patients with MPS present with a history of acute or chronic muscle strain which is accompanied with a characteristic pain pattern from the specific muscle. This is in keeping with Travell and Simons' (1999), who state that each muscle has a distinctive pain referral pattern which is specific for the MTrP in that muscle.

Generally acute patients will present with pain in a localized pattern, however patients with chronic MPS generally describe their pain as "widespread", this may be due to the presence of multiple MTrPs that are found in these

patients. Han and Harrison (1997) found that patients' pain may vary from a mild ache to an excruciating pain that may be sharp or dull in nature and is often associated with general fatigue, decreased strength and a decrease in the normal movement of the involved joint.

In light of the above, the clinical symptoms are not restricted to the sensory system, Travell and Simons' (1999) indicate that MTrPs can also adversely affect the autonomic and motor functions. Abnormal sweating, persistent lacrimation, persistent coryza, excessive salivation and pilomotor activity are some of the symptoms that may result from a disturbance in the autonomic system as a result of MPS. Furthermore imbalance, dizziness, tinnitus, and altered weight perception when lifting objects may be evident as a result of disturbances in the proprioceptive mechanism (Travell and Simons', 1999; Chaitow and DeLany 2002:83; Hou et al., 2002:1406)

MTrPs also disturb the motor function of the involved or synergistic and/or antagonistic muscles. The involved muscle may become weaker, uncoordinated and tolerate less work; the synergistic and/or antagonistic muscles may go into spasm (Travell and Simons', 1999; Gerwin et al. 1997:65; Chaitow and DeLany 2003:80)

Common Signs

Gerwin et al. (1997); Chaitow and DeLany (2003); Travell and Simons' (1999); Schneider (1995) and Hong and Simons (1998) identified the following signs upon examination of active MTrPs:

1. Taut Band – this can be felt by the examiner as a nodule at the MTrP and a rope like induration that extends to the attachment of the taut muscle fibers at each end of the affected muscle.

2. Tender Nodule – within a taut band (which may be several centimeters long) a nodule can be palpated (only a few millimeters in diameter). This nodule is normally highly localized and an exquisitely

tender spot which is characteristic of MTrPs. Hubbard and Berkoff (1993) established that these nodules showed spontaneous electromyogram (EMG) activity which were absent in the adjacent muscle fibers.

3. Recognition – one of the most important diagnostic criteria is the recognition by the patient, of a referred pain pattern as a familiar experience when digital pressure is applied over the MTrP.

4. Referred Sensory Signs – besides the referred pain to the various reference zones, MTrP may also refer other sensory changes such as tenderness and dysesthesias.

5. Local Twitch Response – this is usually a response to snapping palpation over the taut band of fibers which contain the MTrPs. Rapid insertion of a needle into the MTrP will also elicit a similar response; and is considered an important phenomenon for assuring effective needling in the treatment of MTrPs.

6. Limited Range of Motion – pain prevents the muscles from achieving their normal range of motion; this is due to the fact that muscles which contain MTrPs are already under increased tension at rest, and therefore attempting to stretch the muscle beyond this limit will increase the pain intensity. Successfully inactivating the MTrPs and releasing the taut band allows range of motion to return to normal. The degree of limitation is relatively muscle-specific because it varies considerably from muscle to muscle; therefore, it is more useful as a diagnostic criterion in some muscles than in others.

7. Jump Sign – this describes a behavioral reaction which includes withdrawal and a verbal response due to applied pressure over the trigger point, this reaction is characteristic of MPS.

8. Painful Contraction – muscles containing MTrPs experience pain when forced to contract against a fixed resistance. The pain is pronounced when the muscle is made to contract in a shortened position.

9. Muscle Weakness – this is a characteristic sign of muscles which contain active MTrPs, however the extent is dependant on the involved muscle and also varies from patient to patient. On examination the patient is unable to develop normal strength on static testing of the involved muscle; as compared to testing of a contralateral uninvolved muscle. Surface electromyographic [EMG] studies indicate that, during dynamic testing of muscles with active MTrPs the muscles are in a state of fatigue to begin with, they fatigue more rapidly and become exhausted sooner than normal muscles.

In a study conducted by Al-Shenqiti and Oldham (2005) on the reliability of the characteristics of MTrPs, it was established that a high incidence in reliability was found for taut band, spot tenderness, jump sign and pain recognition. The reliability of referred pain and local twitch response was found to be dependent on the muscle involved. Gerwin et al. (1997) state that the taut band and eliciting tenderness are the most reliable features in identifying MTrPs. Referred pain and local twitch response are useful as confirmatory signs of the MTrPs.

2.8 DIAGNOSIS

It is clear that in order to diagnose MPS as accurately as possible, no one clinical characteristic alone is adequate. This has lead to the development of particular diagnostic criteria for MPS. Initially developed by Travell and Simons' (1999), which was then adapted by Schneider (1995), the most characteristic features of MTrPs were classified as major and the less pronounced features as minor criteria.

In order to make the diagnosis of MPS, all 5 major criteria should be present and at least 1 of the minor criteria:

Major criteria:

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

Minor criteria:

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

Another criterion for the diagnosis of MTrPs is the Myofascial Diagnostic Scale (Chettiar, 2001). This uses a scoring system where the four signs of an **active MTrP**, according to Travell and Simons' (1999) are given a value.

The first indicator consists of 5 grades of soft tissue tenderness:

0 = no tenderness (0 points).
1 = tenderness to palpation without grimace of flinch (1 point).
2 = tenderness to palpation with grimace of flinch (2 point).
3 = tenderness with withdrawal (3 points).
4 = withdrawal to non-noxious stimulus (4 points).

The second indicator represents the presence of a local twitch response, the third the presence of a taut band, if present these are given a value of 4.The fourth indicator is the presence of a referred pain pattern due to trigger point compression, this is considered the strongest indicator of active trigger points and is given a value of 5.

A total value of 9 or more is indicative of an **active MTrP** (Chettiar, 2001).

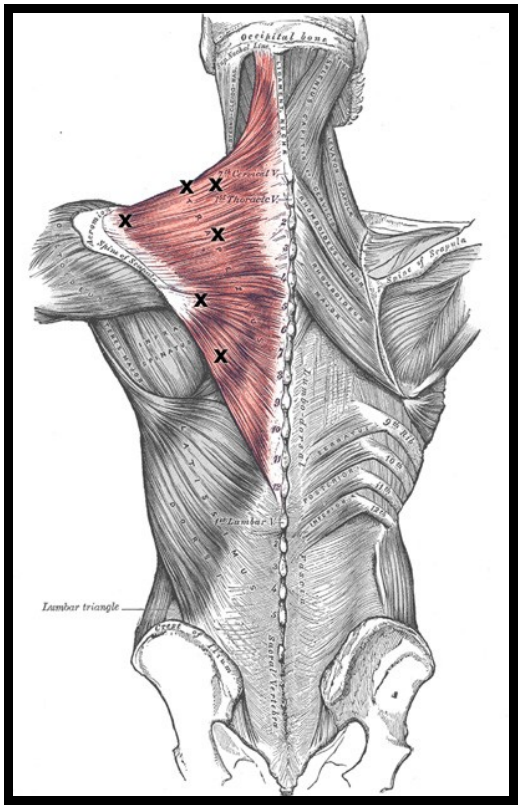
2.9 OVERVIEW OF THE TRAPEZIUS AND LEVATOR SCAPULA MUSCLES

2.9.1 The Trapezius

The trapezius muscle is a large, flat, triangular muscle, which extends in the midline from the occiput above to the twelfth thoracic vertebra below. It reaches laterally to include the acromion, anteriorly to the outer third of the clavicle and posteriorly throughout the length of the spine and the scapular (Moore, 1999; Chaitow and DeLany, 2003:320). The trapezius muscle is made up of fibers, which are divided into three parts.

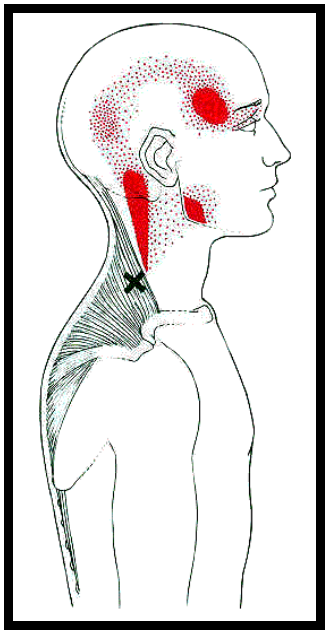
MTrP1 and MTrP2 are found in the upper fibers of the trapezius muscle (Pictures 1, 2 and 3). MTrP1 is located in the upper free border of the muscle. MTrP2 is caudal and slightly laterally to MTrP1. The MTrPs in the upper fibers refer pain and tenderness along the posterolateral aspect of the neck, to the temple and behind the ear (Travell and Simons', 1999:279; Chaitow and DeLany, 2003:320).

On examination, a patient who has trapezius MTrPs will experience pain with active rotation of the neck towards the opposite side; lateral flexion to the opposite side is also moderately restricted (Travell and Simons', 1999:278; Chaitow and DeLany, 2003:320).



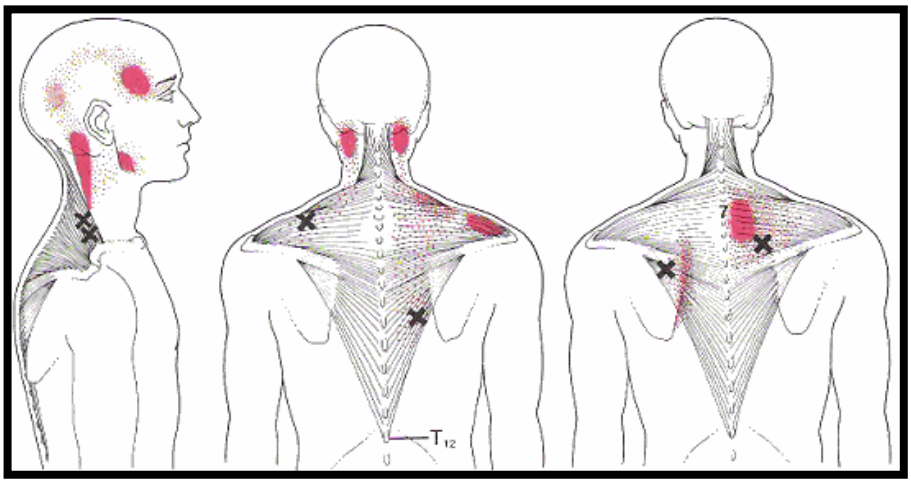
www.triggerpointrelief.com/ trapezius.html

Picture 1: Location of MTrPs in the trapezius muscle



http://www.buckheadbodyworks.com

Picture 2: Location and referred pain pattern of MTrP1 of the trapezius



www.necksolutions.com/ neck-strain.html

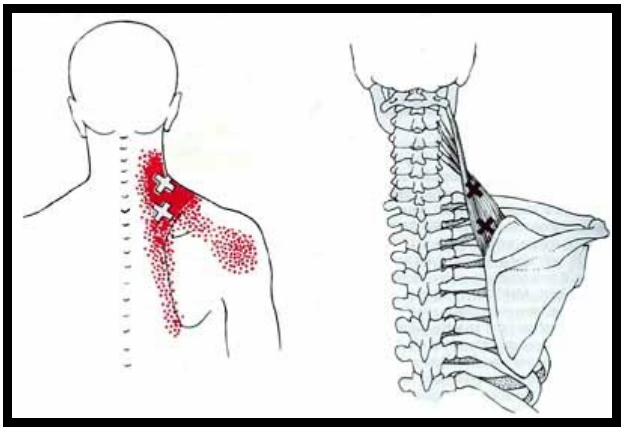
Picture 3: Location and referred pain patterns of trapezius MTrPs

2.9.2 The Levator Scapula

The levator scapula is a strap-like muscle, which originates at the transverse processes of the first three or four cervical vertebra and passes inferiorly to the sternocleidomastoid border of the scapula (Moore, 1999). This muscle is one of the most common muscles involved in MPS (Travell and Simons', 1999:491; Chaitow and DeLany, 2003:329).

MTrPs within this muscle are located in two areas (Picture 4). The primary MTrP is found at the angle of the neck where the muscle emerges beneath the anterior border of the trapezius, and the second slightly above the muscle's attachment to the superior angle of the scapula (Travell and Simons', 1999:491; Chaitow and DeLany, 2003:329). Both refer pain to the angle of the neck with a spill-over along the medial border of the scapula and the posterior aspect of the shoulder.

Patients who suffer from a "stiff neck" often result from MTrPs within the levator scapula muscle, which limits neck rotation due to the pain (Travell and Simons', 1999:491; Chaitow and DeLany, 2003:329).



http://www.buckheadbodyworks.com

Picture 4: Location and referred pain patterns of levator scapula MTrPs

2.10 TREATMENT OF MYOFSCIAL PAIN SYNDROME

The successful resolution of MPS is not solely dependent on the treatment of the MTrPs, but in assessing and treating all of the perpetuating factors (Fomby and Mellion, 1997). In this respect Bruce (1995) focused on diagnosing and treating perpetuating factors such as structural abnormalities, mechanical factors, underlying medical conditions and any psychological factors. In support of this Fricton (1990) believes that failure to address the patient holistically may produce poor results; he recommends a wide variety of therapies including MTrP injections, exercise, vapo-coolant, spray and stretch, postural assessment and correction, biofeedback, transcutaneous electrical nerve stimulation (TENS), medications including anti-depressants and muscle relaxants.

Other authors such as Auleciens (1995), Han and Harrison (1997) and Hubbard (1993) advocate a multidisciplinary approach in the treatment of MPS; they included doctors, psychiatrists, anesthesiologists, physical therapists and social workers.

As a result of the above and considering the prevalence of MTrP in symptomatic and asymptomatic patients, considerable research has been

conducted on the various treatment protocols in the management of MPS. Thus clinical research has shown the effectiveness of the following therapies:

- Neuromuscular techniques (Chaitow and DeLany, 2003)
- Transcutaneous electrical nerve stimulation (Han and Harrison, 1997:97)
- Ultrasound (Gam et al., 1998:73, Esenyel et al., 2000:79)
- Spray and stretch (Han and Harrison, 1997: 97)
- MTrP injection and dry needling (Hong and Simons 1998:256)
- Ischemic compression (Mance et al., 1986)
- Myofascial manipulation (Nook, 2000; Walker, 2002)

Even though a wide variety of effective treatments exist, the choice of treatment varies when it comes to MPS, and is not based on clinical evidence alone, but also on personal preference of both the clinician and patient (Anderson, 1997).

2.10.1 Ischemic Compression

Gatterman and Goe (1990) describe ischemic compression as the application of sustained pressure over the MTrP; this reduces muscle spasm and deactivates the MTrP.

The benefits of ischemic compression were described by Schneider (1995). The application of an intense, specific localized stretch over the taut band is thought to separate the actin-myosin cross fiber links. Reflex vasodilation brings fresh blood carrying oxygen and flushes away metabolites and substances that maintain muscle contraction. The deep pressure blocks the incoming sensory input resulting in the temporary suspension of the reflex motor neuron activity. Lastly, it is also thought that the deep pressure also results in the release of endorphins which mask the perception of pain.

2.10.2 Spray and Stretch

Travell and Simons' (1999) state spray and stretch to be the single most effective non-invasive method of inactivating acute MTrPs. A vapo-coolant spray, such as FlouriMethane or ethyl chloride is used. The muscle is positioned in a stretched position and the spray is applied in parallel sweeps. The sudden drop in skin temperature is thought to inhibit the pain and reflex motor and autonomic responses in the central nervous system. The decrease in pain permits relaxation and lengthening of the muscle which reduces the taut band, inactivating the MTrP. The advantages of this method are that it is non-invasive, does not require precise localization of the MTrP and several MTrPs in one region can be treated simultaneously.

2.10.3 Transcutaneous Electrical Nerve Stimulation (TENS)

The efficacy of TENS as a modality in the treatment of MTrPs is questionable; this is due to the fact that it provides symptomatic relief as opposed to treating the MTrP itself. However its effectiveness in the treatment of MPS has been documented (Han and Harrison 1997; Esenyel et al., 2000; Chettiar, 2001; Graff-Redford et al., 1989).

Since the publication of the "Gate Control Theory" pain by Melzack and Wall (1965), the use of electroanalgesic modalities in the treatment of chronic pain patterns including MPS has gained popularity (Johnson, 2002:259). Melzack and Wall (1965) proposed that pain transmission could be inhibited by activity in the large diameter peripheral afferents or by activity in the pain-inhibitory pathways descending from the brain. The application of TENS focuses on the stimulation of the large diameter "touch fibers" without activating the smaller diameter nociceptive fibers.

In clinical practice, the TENS unit is the most frequently used electrotherapeutic modality for achieving pain relief. Its appeal lies in its non-invasiveness, easy administration and minimal side effects. There is no threat

of overdose or toxicity and the patients can administer and control the treatment themselves (Johnson, 2002:268).

2.10.4 Ultrasound

Ultrasound makes use of a high frequency acoustic energy which upon entering the body influences the cells and tissues by means of two physical mechanisms: thermal and non-thermal (Young, 2002:213). The thermal effect of ultrasound is due to the generation of heat within the tissue. The therapeutic effects of heat include vasodilation, muscle relaxation and sedation of sensory nerve endings. The non-thermal effect refers to the mechanical effect of the ultrasound waves on the tissue. The waves cause vibration of the tissue particles, which may be termed “micro-massage’’ (Liggins, 2002).

Clinically, many therapists have succeeded in inactivating MTrPs using ultrasound; however controlled studies in the effectiveness of ultrasound have revealed inconsistent results.

Gam et al. (1998) conducted a study on patients with neck and shoulder MTrPs, which showed no difference between groups who received ultrasound or sham ultrasound treatment. Hong and Simons (1998) reported the effectiveness of ultrasound in increasing pain threshold in patients with MTrPs. Recently Esenyel et al. (2000) investigated the effectiveness of ultrasound with neck stretches versus trigger point injections combined with neck stretches in the treatment of MTrPs located in the trapezius muscle. There appeared to be no difference between the groups, indicating that the ultrasound was as effective as the MTrP injections.

2.10.5 MTrP Injection and Dry Needling

The application of injections with a local anesthetic, injection with saline or simply dry needling of MTrPs have all shown to be effective (Travell and

Simons', 1999). Usually the decision on whether to inject or make use of manual methods is largely dependent on the skill of the practitioner.

Injection is viewed as one of the most effective therapeutic modalities available to patients with MPS and is most effective in presentations with chronic MTrPs and fibrotic scar formation (Han and Harrison, 1997). Injections are often preferred to dry needling because of the effects of the local anesthetic on the surrounding tissues, however the authors note that contraindications to injections must be taken into consideration: local or systemic infection, allergy to the anesthetic agent, anti-coagulation and other bleeding disorders.

Hong (1994) researched the effectiveness of injections with 0.5% lidocaine versus dry needling of MTrPs of the trapezius muscle. Both groups showed significant improvement with regard to pain intensity and pressure threshold measurements. However the author recommended the use of injections as the subjects who received dry needling experienced post injection soreness of greater intensity and for a longer duration.

The decision on whether to administer injection or dry needling should be based on the above mentioned factors; ultimately the purpose of achieving pain relief remains the same.

The mechanism by which injections and dry needling reduce MTrPs has been proposed by numerous authors (Travell and Simons', 1999; Han and Harrison, 1997):

1. Mechanical disruption of muscle fibers and nerve endings leading to increased intracellular potassium levels and the resultant depolarization of nerve fibers.
2. The positive feedback mechanism that is responsible for perpetuating the pain is interrupted by the mechanical influence of the needle.

3. Infiltration of the local anesthetic or saline solution causes local dilution of the nociceptive substances thereby decreasing the sensation of pain.
4. The vasodilatory effect of the local anesthetic or saline solution causes an increased removal of metabolites.

2.10.6 Other Soft Tissue Therapies

Various treatment techniques have been developed and applied to soft tissue conditions; they include therapies such as ischemic compression which has been discussed separately, massage, post-isometric relaxation, active release and myofascial adhesion manipulation amongst others (Chaitow and DeLany, 2002; Mance et al., 1986:329; Hou et al., 2002:1406).

Transverse friction massage has been used in the treatment of MTrPs to produce localized effects on muscles that have been in a prolonged state of tension and is said to aid in reducing local muscle spasm (Thomson et al., 1991:444; Prentice, 1994:351). The effect of frictions in muscular lesions is to mobilize the muscle, separating adhesions between muscle fibers that restrict movement, Thus restoring mobility between tissue interfaces and increasing extensibility of structures (Cyriax, 1984:9; Hertling and Kessler, 1996:134). Deep friction massage also increases circulation to the area, which is beneficial in the treatment of MTrPs (Cyriax, 1984:9; Hertling and Kessler, 1996:134).

Over the last decade the development of another soft tissue mobilization modality termed Graston Technique, involving the use of stainless steel instruments to detect and treat soft tissue lesions, has provided practitioners with an alternative method of diagnosis and treatment of soft tissue injuries.

The developers of the Graston Technique reported anecdotal evidence to suggest that aluminium instruments of similar design were not as effective as the stainless steel instruments (Carey-Loghmani, 2003:12). However, a study conducted by Davidson et al. (1997) involving the use of soft tissue

mobilization by aluminium instruments on the Achilles tendons of rats, found that these instruments improved limb function as well as facilitated healing of the tendon.

2.10.7 Graston Technique Instrument-assisted Soft Tissue Mobilization (GTISTM)

The Graston Technique (GT) combines the use of GTISTM with a targeted exercise program to address soft tissue injuries (Carey-Loghmani, 2003:2). GTISTM is the use of stainless steel instruments which are specifically designed to fit the shapes and contours of the body. The instruments allow the practitioner to detect and treat soft tissue lesions, adhesions and restrictions (Carey-Loghmani, 2003:7, Hammer, 2003).

GTISTM can be most closely related to transverse friction massage (Carey-Loghmani, 2003:55). The instruments can be used in the break down of cross-fiber links, the splaying of fibers and increasing the mobility of the muscle. GTISTM also stimulates blood flow to the area bringing oxygen and nutrients and removing waste products (Carey-Loghmani, 2003:58).

2.11 CONCLUSION

GTISTM makes use of stainless steel instrument; however the influence of the material on the efficacy of the treatment has not yet been clinically tested. This research aimed to compare aluminium and stainless steel augmented soft tissue instruments in the treatment of MTrPs through objective and subjective measures.

CHAPTER THREE

MATERIALS AND METHODS

3.1 INTRODUCTION

This chapter discusses the details of the research design, subjects, measurement tools and intervention in the treatment of MPS utilizing the various instruments. The methods of statistical analysis used for evaluating the data will also be discussed.

3.2 RESEARCH DESIGN

The study was a prospective quasi-experimental based pilot study (prospective, randomized, comparative clinical trial). The purpose of the study was to determine the efficacy of different component material of the GTISTM instrument in terms of subjective and objective measurements in the treatment of MTrPs in the trapezius and levator scapula musculature.

3.2.1 Data Types

Primary data included key components of:

- Case history (Appendix D)
- Physical Examination (Appendix E)
- Cervical Regional Examination (Appendix F)
- Cervical Range of Motion (CROM) (Appendix H)
- Algometer (Appendix I)
- CMCC Neck Disability Index (Appendix J)
- NRS-101 (Appendix K)

Secondary data included:

- Text books
- Journal articles

- Internet search engines

3.3 ADVERTISING

Advertisements by means of posters, flyers and newspapers were distributed in and around the Durban area. The fundamental prerequisites of the research were described on the advertisement, such as the area of complaint, the required age group, as well as the location and contact details of the Chiropractic Day Clinic (Appendix A).

3.4 SAMPLING

A sample size of 60 subjects was selected by means of convenience sampling (Mouton, 2002) from patients presenting to the Chiropractic Day Clinic at the Durban Institute of Technology.

3.4.1 Sampling Method

The method was that of self-selection (Mouton, 2002) as subjects responded to the advertisement (Appendix A). The sample group was made up of patients from the greater Durban area to avoid non-compliance with attendance of scheduled treatments. A total of 60 subjects who met the study's criteria made up the sample group.

3.4.2 Sample Size and Allocation

This study comprised four groups of fifteen subjects each. Once the subjects were accepted into the study, they were randomly assigned to one of the following groups:

- Group A received treatment with the stainless steel GTISTM instrument,
- Group B received treatment with an aluminum instrument,
- Group C received placebo in the form of detuned ultrasound,
- Group D made up the control group.

Once accepted into the study the subjects were randomly allocated into one of four groups by an independent observer. Sixty slips of paper marked one to sixty were drawn out of a hat by the observer at the start of each patient. Numbers 1-15 were allocated to Group A, 16-30 to Group B, 31-45 to Group C and 46-60 to Group D.

3.4.3 Patient Screening

The evaluation and selection process began with all potential subjects undergoing a cursory telephonic discussion (or in person if they presented to the Chiropractic Day Clinic) with the researcher; this was done to exclude any subjects who did not fit the criteria of the study.

The following questions were asked:

- How old are you?
- Where is the pain located?
- Do you suffer from any systemic disease e.g. bacterial infection, rheumatoid arthritis, infective or gouty arthritis, bursitis and calcification found in soft tissue structures?
- Are you on any medication e.g. anti-coagulant therapy?
- Have you been diagnosed with or suffer from any of the following conditions: vascular compromise, severe diabetes mellitus, sensory deficit and/or infections (local and systemic).
- Do you have a history of recent trauma of the involved area, including whiplash injuries of the cervical spine?

Potential candidates then underwent an initial consultation at the Durban Institute of Technology Chiropractic Day Clinic, where they received a letter of information (Appendix B) and an informed consent form (Appendix C) to sign. The information letter informed the subjects of the details of the study and the consent form was used as an indication that the subjects understood their role and rights within the study. The participants were informed that their involvement was entirely voluntary and they had the option of withdrawing at

any time throughout the study without implications for their further treatment at the Chiropractic Day Clinic.

The initial consultation was then completed with a case history (Appendix D), physical examination (Appendix E) and a cervical spine regional examination (Appendix F). The described examinations (as per the appendices) were necessary to allow the researcher to assess the subjects according to the following inclusion and exclusion criteria.

3.5 INCLUSION AND EXCLUSION CRITERIA

3.5.1 Inclusion Criteria

1) An informed consent form indicating that they understood and agreed to participate in the research was signed by the patient (Appendix C).

2) Subjects had to be between the ages of 18 and 55 years. Individuals of any age can develop MTrPs (Travel and Simons', 1999). This age group is concurrent with that of other studies conducted (Gam et al., 1998: 74; Hanten et al., 2000:999). Esenyel et al. (2000) suggest a relatively young population of patients to minimize pain that may be caused by accompanying degenerative disc or joint disease.

3) Male and female volunteers of all races were able to participate in the study. Individuals of either sex can develop MTrPs (Travel and Simons', 1999). Studies by Hou et al. (2002) as well as Han and Harrison (1997) found that MPS occurred in both sexes; however it was found to be more common in females.

4) Only subjects diagnosed by the researcher as having MPS with active MTrPs of the upper trapezius and/or levator scapula muscles were considered. The Myofascial Diagnostic Scale (Chettiar, 2001) was used as the criterion for inclusion into the study (Appendix G).

5) Subjects who, on examination, presented with a cervical facet dysfunction were accepted into the study but were not treated for this during the duration of the study.

3.5.2 Exclusion Criteria

1) Subjects receiving manual or medicinal therapy such as anti-inflammatory drugs were required to stop all forms of therapy for a period of at least 48 hours before their participation in the study (Poul, 1993). This is to avoid any interference the medication would have on the outcome of the study.

2) Subjects accepted into the study were asked not to change their lifestyle, daily activities, regular medication and exercise programs to avoid being excluded from the study. This is to avoid any impact that these activities may have on the study.

3) Subjects diagnosed with fibromyalgia were excluded from the study. According to Schneider (1995) fibromyalgia is diagnosed by a history of wide spread pain for at least three months (pain on both sides of the body, above and below the waist) and the pain in 11 of 18 tender point sites on digital palpation.

4) Any subjects that exhibited any contra-indications to massage type therapies were excluded from the study. Basmajian (1985:284-285) outlined the following conditions as contra indications: infection due to bacterial actions, rheumatoid arthritis, infective or gouty arthritis, bursitis and calcification found in soft tissue structures.

5) Those subjects who presented with any contra-indications to myofascial adhesion manipulation were also excluded from the study. According to Nook (2000:43) patients with vascular compromise, on anti-coagulant therapy, severe diabetes mellitus, sensory deficit, infections (local and systemic) and a history of recent trauma of the

involved area (including whiplash injuries of the cervical spine) were not treated with myofascial adhesion manipulation therapy.

6) Patients with contra-indications to GTISTM technique as stated by Carey-Loghmani (2003) were also excluded, these include the following:

   Red flags – absolute contraindications including but not limited to such conditions as: open wounds, unhealed suture sites, unhealed fractures, thrombophlebitis, uncontrolled hypertension, patient intolerance/hypersensitivity, haematoma, myositis ossificans and osteomyelitis.

   Yellow flags – relative contraindications including but not limited to such conditions as: anti-coagulant medications, cancer, varicose veins, burn scars, acute inflammatory reactions, kidney dysfunction, inflammatory condition secondary to infection, rheumatoid arthritis and osteoporosis.

3.6 DIAGNOSTIC CRITERIA - MYOFASCIAL DIAGNOSTIC SCALE

Subjects fitting the criteria outlined by the Myofascial Diagnostic Scale (Chettiar, 2001) were accepted into the study. This scale uses a scoring system where the four signs of an **active MTrPs**, according to Travell and Simons' (1999) are given a value (Appendix G).

The first indicator consisted of 5 grades of soft tissue tenderness:

0 = no tenderness (0 points).
1 = tenderness to palpation without grimace of flinch (1 point).
2 = tenderness to palpation with grimace of flinch (2 point).
3 = tenderness with withdrawal (3 points).
4 = withdrawal to non-noxious stimulus (4 points).

The second indicator represented the presence of a local twitch response and the third the presence of a taut band. If present these were given a value of 4 each. The fourth indicator was the presence of a referred pain pattern due to MTrP compression. This was considered the strongest indicator of **active MTrPs** and was given a value of 5. If the indicators were not present no score was given.

Patients were included into the study if their score equaled 9 or more points, as this is indicative of the presence active MTrPs according to Chettiar (2001).

3.7 LOCATION OF THE MTrPs

Locating the MTrPs was done using flat and/or pincer palpation as described by Travell and Simons' (1999).

3.7.1 The Trapezius

MTrP1 and MTrP2 are found in the upper fibers of the trapezius muscle (refer to picture 1, 2, 3, section 2.9.1). MTrP1 is located in the upper free border of the muscle. MTrP2 is caudal and slightly laterally to MTrP1. The MTrPs in the upper fibers refer pain and tenderness along the posterolateral aspect of the neck, to the temple and behind the ear (Travell and Simons', 1999:279; Chaitow and DeLany, 2003).

On examination, a patient who has trapezius MTrPs will experience pain with active rotation of the neck towards the opposite side; lateral flexion to the opposite side is also moderately restricted (Travell and Simons', 1999:278; Chaitow and DeLany, 2003).

3.7.2 The Levator Scapula

MTrPs within this muscle are located in two areas (refer to picture 4, section 2.9.2). The primary MTrP is found at the angle of the neck where the muscle emerges beneath the anterior border of the trapezius, and the second slightly

above the muscles attachment to the superior angle of the scapula (Travell and Simons', 1999:491; Chaitow and DeLany, 2003). Both refer pain to the angle of the neck with a spill-over along the medial border of the scapular and the posterior aspect of the shoulder.

A "stiff neck" in patients often results from MTrPs within the levator scapula muscle, which limits neck rotation due to the pain (Travell and Simons', 1999:491; Chaitow and DeLany, 2003).

3.8 PATIENT PROCEDURE AND INTERVENTION

All potential subjects had to undergo a cursory telephonic discussion (or in person if they presented to the clinic) with the examiner before they were considered for the study. If the subjects fit the criteria an appointment was set for the initial consultation at the Durban Institute of Technology Chiropractic clinic. On the first consultation the patients underwent a clinical assessment (objective and subjective findings), which was followed by a particular treatment intervention. The patients were then treated twice over the next two weeks. Patients in all four groups were required to come in for a clinical assessment in the third week where final readings were taken. All assessments and interventions were performed by the researcher.

3.8.1 Intervention Type and Manner

Group A

The treatment procedure was according to The GTISTM Technique Instruction Manual (Carey-Loghmani, 2003). A starburst pattern around and away from the MTrPs was used, with care being taken not to strum over the MTrPs as this may increase its pain referral and irritability.

The instrument used for the treatment of MTrPs was the GT-4 (Half-moon or Scanner). Treatment was carried out with the patient in the seated position. The GT-4 was used to apply the sweeping and fanning strokes over the trapezius and levator scapula muscles (Carey-Loghmani, 2003:135). An

emollient was used to decrease friction between the surface of the skin and the instrument (Carey-Loghmani, 2003:27).

Group B

An identical treatment protocol as above (Group A) was applied to the patients in Group B; however the instrument used was made of aluminium. (The instrument was made by the Engineering Department at the University of Kwa-Zulu Natal, Durban.)

Group C

The patients who fell into Group C made up the placebo group, receiving treatment in the form of a detuned ultrasound. This was applied to the MTrPs of the trapezius and levator scapula muscles for a period of five minutes.

The purpose of using the detuned ultrasound was firstly to provide some means of tactile stimulation to the affected area, without causing physical changes to the MTrPs or the muscle, which contained the MTrPs. Secondly, because of its similarities in procedure to the active treatment, both treatments involved the use of metal surface and a form of lubrication over the area being treated.

The placebo group would then be used to indicate if there was a measurable clinical outcome as a result of the treatment and whether there was a significant difference to the treatment and control groups. Placebo treatment is a form of treatment often given as an aid to therapeutic suggestion and for eliminating bias. It is important that the patient does not become aware at any stage that a placebo is being used (Beecher, 1955; Kienle and Kiene, 1998:21; Mouton, 2002).

At the completion of the study these patients were informed that they where part of the placebo group and were offered two free treatments at the D.I.T. Chiropractic Day Clinic.

Group D

The participants allocated to Group D made up the control group. This group did not receive any treatment, rather readings were recorded at the allocated times.

The data collected from this group was used to assess the natural progression of patients with myofascial pain. These readings were used as a baseline in comparison to the data from the treatment and the placebo groups' (Mouton, 2002:159; Kienle and Kiene, 1998:21).

Subjects that fell into this group were offered two free treatment consultations at the D.I.T. Chiropractic Day Clinic once the research had been completed.

3.8.2 Intervention Frequency

Table 1: Treatment Protocol

Week	Visit	Group A – GTISTM	Group B – Aluminium	Group C – Placebo	Group D – Control
1	1	Clinical assessment *Treatment*	Clinical assessment *Treatment*	Clinical assessment *Treatment*	Clinical assessment
	2	*Treatment*	*Treatment*	*Treatment*	
2	3	Clinical assessment *Treatment*	Clinical assessment *Treatment*	Clinical assessment *Treatment*	Clinical assessment
3	4	Clinical assessment	Clinical assessment	Clinical assessment	Clinical assessment

Note: Clinical assessment refers to objective and subjective data collection.

3.9 DATA TYPE

3.9.1 Descriptive Data

This includes: age, sex, race, occupation and type of occupation (manual or non-manual).

3.9.2 Inferential Data

a) Objective Data

1) The cervical range of motion goniometer (CROM), (Performance Attainment Associates, St.Paul, MN) was used to measure flexion, extension, lateral flexion and rotation of the cervical spine. The CROM goniometer has been found to be reliable, both intra- and inter-tester, in the measurement of cervical range of motion (Rheault et al. 1992). Youdas et al. (1991) established the CROM goniometer to be highly reliable when compared to other cervical range of motion techniques such as universal or visual estimation.

   To measure flexion and extension, the patient was instructed to flex and extend the neck to the point of pain. Lateral flexion was measured by laterally flexing the neck as far as possible on either side without elevating the shoulders or rotating the head. To measure rotation, the magnetic yoke and rotation arm was used. The sagittal plane and lateral flexion meters were reset to zero, while the rotation meter was reset to zero by manually turning the dial. The patient was then instructed to turn their head as far as possible to the right and then to the left. An observer stabilized the patient's shoulders and the subject moved their eyes along a horizontal line to ensure that no rotation of the shoulders occurred. The measurements were taken and recorded in appendix H.

2) Algometer readings were taken to measure changes in pressure pain threshold over the MTrPs, for each patient for the course of the research (Appendix I). Fischer (1986, 1987:207) refers to pressure threshold as the minimum pressure that induces pain or discomfort. The effectiveness

in diagnosing MTrPs and particularly for the assessment of treatment results has been proven by Fischer (1987:207). The reliability of the pressure algometer has been demonstrated in studies, including Reeves et al. (1986). The algometer used was the FDK20 force dial manufactured by Wagner Instruments: PO Box 1217, Greenwich, CT 06836. The pressure range of the algometer is 11 kilograms.

b) Subjective Data

1) Patients were required to respond to a CMCC Neck Disability Index (Appendix J). This index was used to assess subjective information regarding the degree to which the patients' pain influenced their daily activities. The CMCC Neck Disability Index consists of ten sections dealing with different aspects of the patients' lifestyle. Each section had six options, with the first scoring "0" and the next five increasing progressively by a value of "1" to a maximum of "5". A high level of reliability and internal consistency has been reported by Vernon and Moir (1991). The result also showed that the CMCC Neck Disability index is unaffected by gender and has an acceptable level of validity.

2) Numerical Rating Scale – 101 (NRS-101) (Appendix K) was used to assess the perceived level of pain intensity that the patient experienced (Jenson et al., 1986). The questionnaire consists of a numerical scale from 0 – 100, where 0 = no pain and 100 = pain at its worst. Subjects were asked to give a rating, firstly for when their pain was at its least and secondly for when their pain was at its worst. For statistical analysis the average of the first and the second reading was taken.

Jensen et al. (1986) conducted a comparative study where other pain intensity scales where used on 75 chronic pain patients. The results showed that the NRS-101 was the most practical index to use as it is simple to administer and score, and not restricted to a particular language as it is a numerical scale, it can also be administered in either the written or verbal form.

3.9.3 Data collection Frequency

Data collection took place pre-treatment on the first, third and fourth consultation.

Data set 1: clinical assessment (week 1)
Data set 2: clinical assessment (week 2)
Data set 3: clinical assessment (week 3)

3.10 STATISTICAL METHODS

Data were analyzed in SPSS version 11.5 (SPSS Inc., Chicago, Ill, USA) and tested for departures from normalcy using the skewness statistics. It was accepted that the data were normally distributed and therefore parametric tests were applied. Comparison of treatment effects between treatment groups for quantitative outcomes was achieved using repeated measures ANOVA. Subgroups of the data were selected to examine specific group comparisons. A significant treatment effect was concluded if the p value for the interaction between time and group was <0.05. Profile plots were examined for trends in the data even if the treatment effect was not statistically significant. For algometer measurements at various MTrPs, the sum of the values for each main type of MTrPs on each side was used (trapezius and levator scapula). To analyze correlations between changes in subjective and objective outcome variables, Pearson's correlation coefficients were used.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

This chapter tabulates the results obtained from the statistical analysis of the primary data collected. Demographic data consisting of age, race, gender, occupation and type of occupation (manual or non-manual) were analyzed. Objective and subjective findings were also analyzed, and the correlation between findings tabulated. The measurement criteria were:

- Algometer
- CROM
- NRS-101
- CMCC

4.2 DEMOGRAPHICS

4.2.1 Age

Age of sample (n=60)

The sample consisted of 60 participants ranging in age from 19 to 55 years old. Their mean age was 37.7 years (SD 11.4). The histogram of age in the entire sample is shown in Figure 1.

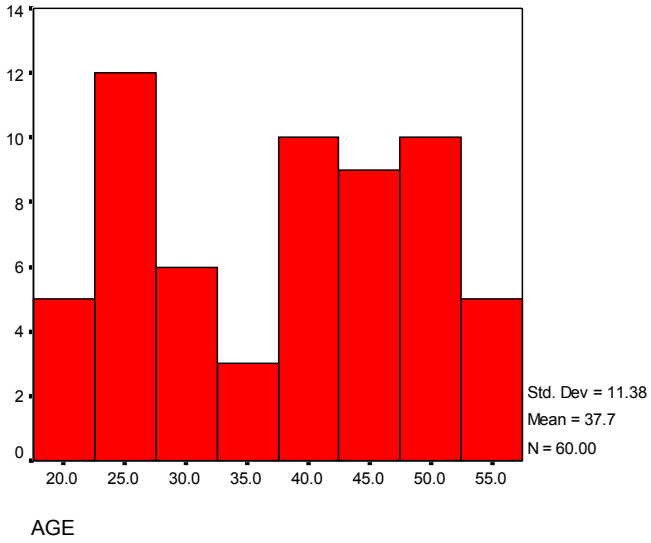


Figure 1: Histogram of age of sample (n=60)

Age of treatment groups (n=15)

There was a borderline significant difference in mean age between the four groups (p=0.056 – Table 1). When post hoc tests were done, there was no actual significant difference in mean age between any two individual treatment groups (Table 2). The control group had a lower mean age than the other groups, but this was not statistically significant.

Table 1: ANOVA table for comparison of mean age between the treatment groups

	Sum of Squares	df	Mean Square	F	P value
Between Groups	957.400	3	319.133	2.672	.056
Within Groups	6687.200	56	119.414		
Total	7644.600	59			

Table 2: Bonferroni post hoc tests for multiple comparisons of mean age between the treatment groups

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	P value	95% Confidence Interval	
					Lower Bound	Upper Bound
GTISTM	Aluminium	-.80	3.990	1.000	-11.71	10.11
	Placebo	-.60	3.990	1.000	-11.51	10.31
	Control	8.73	3.990	.197	-2.18	19.65
Aluminium	GTISTM	.80	3.990	1.000	-10.11	11.71
	Placebo	.20	3.990	1.000	-10.71	11.11
	Control	9.53	3.990	.122	-1.38	20.45
Placebo	GTISTM	.60	3.990	1.000	-10.31	11.51
	Aluminium	-.20	3.990	1.000	-11.11	10.71
	Control	9.33	3.990	.138	-1.58	20.25
Control	GTISTM	-8.73	3.990	.197	-19.65	2.18
	Aluminium	-9.53	3.990	.122	-20.45	1.38
	Placebo	-9.33	3.990	.138	-20.25	1.58

4.2.2 Gender

Gender of sample (n=60)

Table 3 shows the gender distribution of the sample. The majority of participants were female (66.7%).

Table 3: Gender distribution of sample (n=60)

	Frequency	Percent
Male	20	33.3
Female	40	66.7
Total	60	100.0

Gender of treatment groups (n=15)

There was no significant difference between the treatment groups in terms of gender (p=0.494). Table 4 shows that the majority of each group were female. There was a slightly higher percentage of females in the aluminium group compared with the other groups (80%) but this was not statistically significant.

Table 4: Gender by treatment group

		GROUP				Total
		GTISTM	Aluminium	Placebo	Control	
GENDER	Male	5	3	5	7	20
		33.3%	20.0%	33.3%	46.7%	33.3%
	Female	10	12	10	8	40
		66.7%	80.0%	66.7%	53.3%	66.7%
Total		15	15	15	15	60
		100.0%	100.0%	100.0%	100.0%	100.0%

P=0.494

4.2.3 Race

Race of sample (n=60)

The population group, to which the majority of participants belonged, was White (43%), followed by Indian (38%). There were few Africans and Coloureds. This is shown in Figure 2.

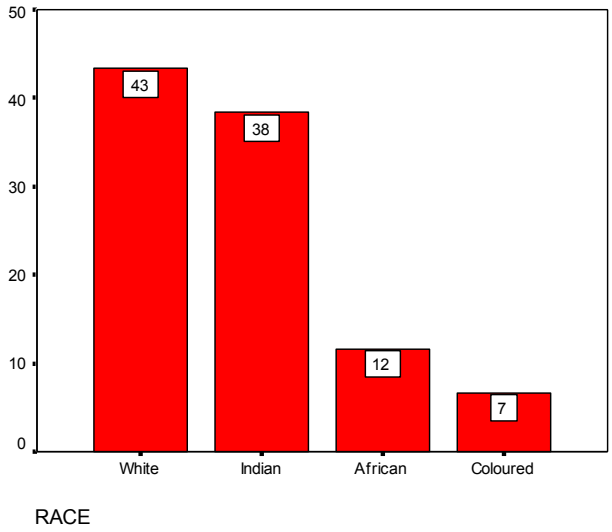


Figure 2: Racial distribution of sample (n=60)

Race of treatment groups (n=15)

There was a statistically significant difference in the distribution of race groups between the treatment groups (p=0.016). The GTISTM group and the control group had a higher proportion of Whites than the other two groups. The aluminium and placebo groups had a higher proportion of Indians than the other two groups. The placebo group had a higher proportion of Africans and Coloureds than the other three groups. This is shown in Table 5.

Table 5: Race by treatment group

		GROUP				Total
		GTISTM	Aluminium	Placebo	Control	
Race	White	9	4	2	11	26
		60.0%	26.7%	13.3%	73.3%	43.3%
	Indian	5	8	8	2	23
		33.3%	53.3%	53.3%	13.3%	38.3%
	African / Coloured	1	3	5	2	11
		6.7%	20.0%	33.3%	13.3%	18.3%
Total		15	15	15	15	60
		100.0%	100.0%	100.0%	100.0%	100.0%

P=0.016

4.2.4 Occupation

Occupation of sample (n=60)

Three participants (5%) had manual occupations, while the remainder had non-manual jobs. The majority of non-manual participants were students (n=12, 20%), followed by educators (n=8, 13.3%) and secretaries (n=7, 11.7%). The three manual workers were a massage therapist, a landscape architect and a construction worker. Frequencies of occupations in the sample are shown in Table 6.

Table 6: Frequencies of occupations in sample (n=60)

Occupation	Frequency	Percent
Student	12	20.0
Educator	8	13.3
Secretary	7	11.7
Unemployed	3	5.0
Housewife	3	5.0
Graphic designer	2	3.3
Retail	2	3.3
Finance	2	3.3
Cargo	2	3.3
Architect technician	1	1.7
Property developer	1	1.7
Sales rep	1	1.7
Hair therapist	1	1.7
Driver	1	1.7
Clothing manufacturer	1	1.7
Musician	1	1.7
Construction	1	1.7
Cashier	1	1.7
Manager	1	1.7
Demand estimator	1	1.7
Psychologist	1	1.7
Personal Consultant	1	1.7
Landscape architect	1	1.7
Relief worker	1	1.7
Massage therapist	1	1.7

Translator	1	1.7
Sales consultant	1	1.7
Systems manager	1	1.7
Total	60	100.0

Occupation of treatment groups (n=15)

There was no significant difference in type of occupation by treatment group (p=0.277). Table 7 shows that the proportion of manual workers was very small in all groups. Although two of the groups did not have any manual workers, this slight difference was not statistically significant.

Table 7: Type of occupation by treatment group

		GROUP				Total
		GTISTM	Aluminium	Placebo	Control	
Type of Occupation	Manual	2	0	1	0	3
		13.3%	.0%	6.7%	.0%	5.0%
	Non-manual	13	15	14	15	57
		86.7%	100.0%	93.3%	100.0%	95.0%
Total		15	15	15	15	60
		100.0%	100.0%	100.0%	100.0%	100.0%

P=0.277

4.3 HYPOTHESIS ONE
GTISTM vs. ALUMINIUM (OBJECTIVE OUTCOMES)

Null hypothesis 1: The effectiveness of the stainless steel GTISTM instrument is the same as that of the aluminium instrument in terms of objective clinical findings (algometer and cervical range of motion) in the treatment of myofascial trigger points.

Alternative hypothesis 1: The effectiveness of the stainless steel GTISTM instrument is different to that of the aluminium instrument in terms of objective clinical findings (algometer and cervical range of motion) in the treatment of myofascial trigger points.

4.3.1 Algometer

4.3.1.1 Right Trapezius

Table 8 shows the effects of treatment by the GTISTM instrument and the aluminium instrument for the outcome of right trapezius algometer measurements. The time by group interaction was not significant (p=0.745), thus the effect over time was the same in both groups. Figure 3 shows that both groups increased between the first and second time points, and then both decreased to time 3. The rate of increase appeared slightly steeper in the GTISTM group. However, the null hypothesis cannot be rejected for this outcome.

Table 8: Within and between –treatment effects for right trapezius algometer measurements: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.934	0.396
Time*group	Wilk's Lambda=0.978	0.745
Group	F=0.098	0.756

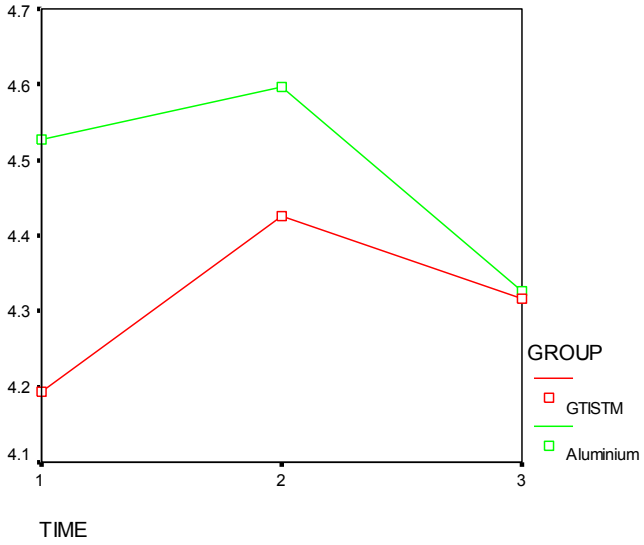


Figure 3: Profile plot of mean right trapezius algometer measurement over time by group (GTISTM vs. Aluminium)

4.3.1.2 Left Trapezius

In Table 9 the time by group interaction was not significant (p=0.155) for left trapezius. Figure 4 shows that the aluminium group showed a very slight increase in mean values over the three time points, but the GTISTM group showed a very dramatic increase followed by a steep decrease in mean algometer readings. Therefore the null hypothesis cannot be rejected for this outcome.

Table 9: Within and between –treatment effects for left trapezius algometer measurements : GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.906	0.262
Time*group	Wilk's Lambda=0.871	0.155
Group	F=0.025	0.875

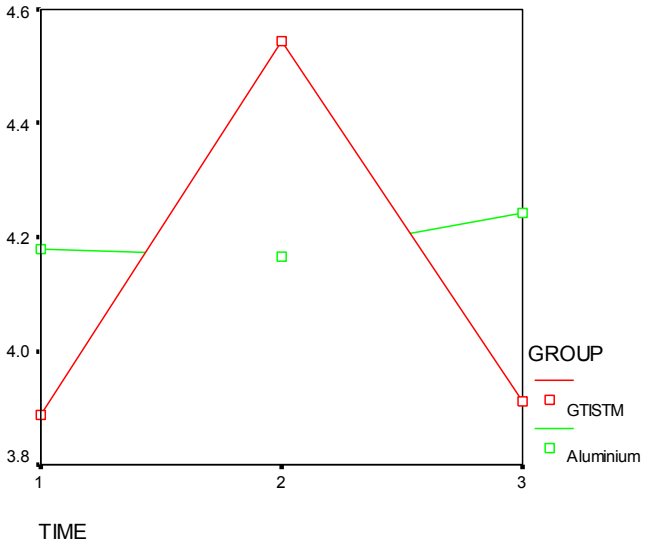


Figure 4: Profile plot of mean left trapezius algometer measurements over time by group (GTISTM vs. Aluminium)

4.3.1.3 Right Levator Scapula

Table 10 shows that there was a statistically significant interaction between time and group for this outcome (p=0.047). Figure 5 shows that the mean values of the aluminium group increased over time while the mean of the GTISTM group decreased over time. Thus the null hypothesis can be rejected in favour of the alternative hypothesis for this outcome. The direction of the significance indicates that the aluminium instrument is more effective than the steel one for this outcome. Note that not all participants were included in this analysis as not all participants had levator scapula MTrPs.

Table 10: Within and between –treatment effects for right levator scapula algometer measurements: GTISTM vs. Aluminium (n=27)

Effect	Statistic	p value
Time	Wilk's Lambda=0.913	0.335
Time*group	Wilk's Lambda=0.775	0.047
Group	F=0.160	0.218

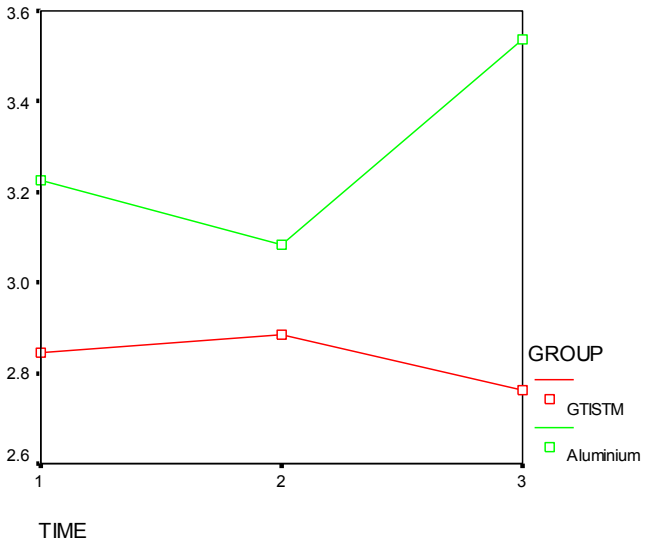


Figure 5: Profile plot of mean right levator scapula algometer measurements over time by group (GTISTM vs. Aluminium)

4.3.1.4 Left Levator Scapula

Similarly the null hypothesis is rejected for this outcome, as there was a statistically significant interaction between time and group (p=0.032 – Table 11). Figure 6 shows that the means for the aluminium group increased over time while the opposite happened in the GTISTM group. Therefore the aluminium instrument was more effective than the GTISTM instrument.

Table 11: Within and between –treatment effects for left levator scapular algometer measurements: GTISTM vs. Aluminium v (n=28)

Effect	Statistic	p value
Time	Wilk's Lambda=0.951	0.533
Time*group	Wilk's Lambda=0.760	0.032
Group	F=1.807	0.190

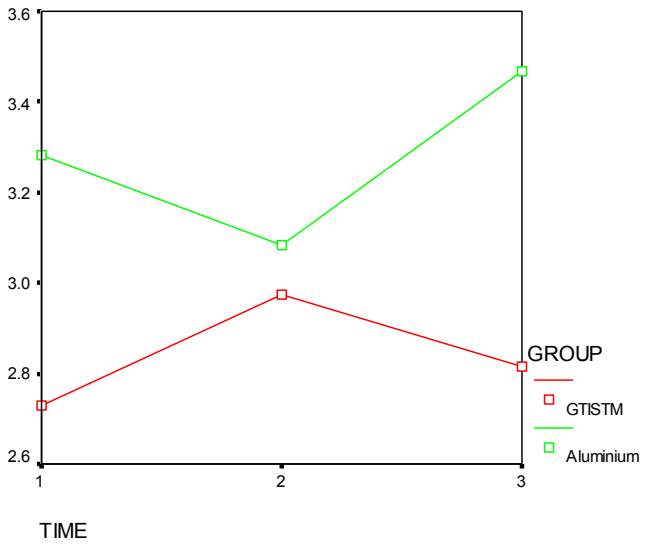


Figure 6: Profile plot of mean left levator scapular algometer measurements over time by group (GTISTM vs. Aluminium)

4.3.2 CROM

4.3.2.1 Flexion

For flexion there was a statistically significant interaction between time and group (p=0.020 – Table 12). Therefore the null hypothesis can be rejected for this outcome. The effects of the two treatments are not the same. Figure 7 shows that the overall rate of increase in the GTISTM group was steeper than that of the aluminium group, which hardly increased at all. Therefore in this instance the GTISTM group showed a more effective result than the aluminium group.

Table 12: Within and between –treatment effects for Flexion: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.836	0.089
Time*group	Wilk's Lambda=0.748	0.020
Group	F=2.639	0.115

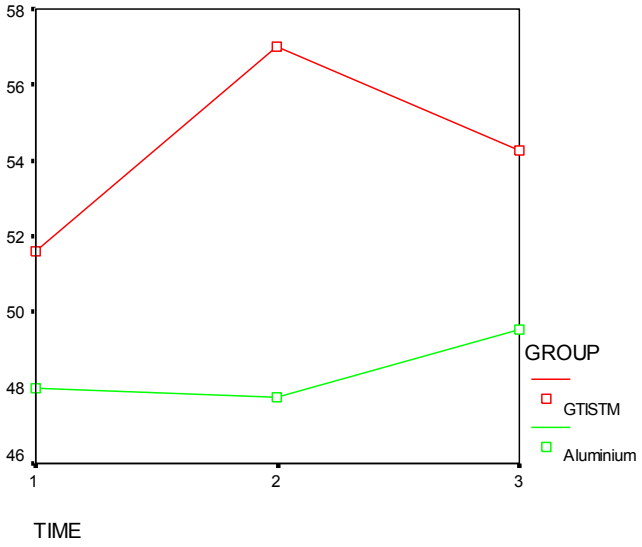


Figure 7: Profile plot of mean flexion over time by group (GTISTM vs. Aluminium)

4.3.2.2 Extension

There was no significant interaction for extension (p=0.944 – Table 13). Therefore the null hypothesis cannot be rejected. Figure 8 shows that both groups increased at the same rate over time.

Table 13: Within and between –treatment effects for Extension: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.977	0.726
Time*group	Wilk's Lambda=0.996	0.944
Group	F=0.808	0.376

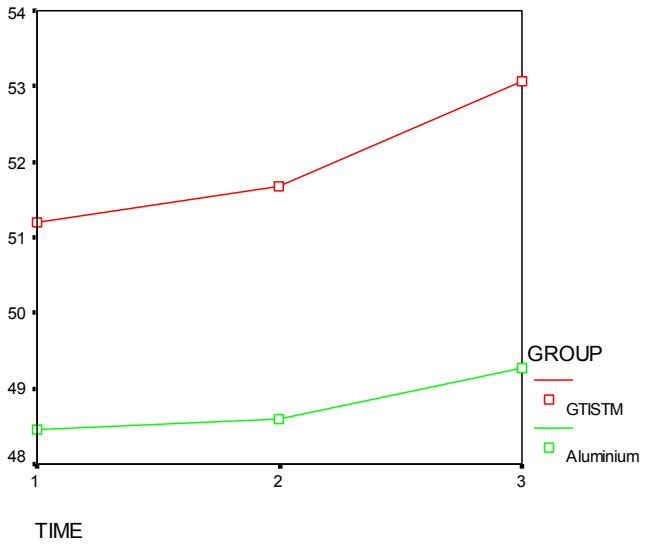


Figure 8: Profile plot of mean extension over time by group (GTISTM vs. Aluminium)

4.3.2.3 Left Lateral Flexion

For this outcome there was no significant time by group interaction (p=0.259) (Table 14), therefore the null hypothesis cannot be rejected. Figure 9 however, shows a trend. The aluminium group increased over time while the GTISTM group decreased over time. However this trend was not statistically significant.

Table 14: Within and between –treatment effects for left lateral flexion: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.985	0.818
Time*group	Wilk's Lambda=0.905	0.259
Group	F=0.904	0.350

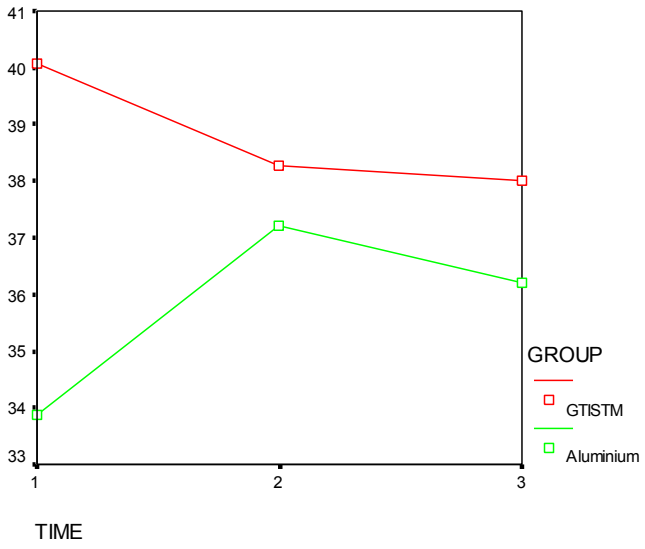


Figure 9: Profile plot of mean left lateral flexion over time by group (GTISTM vs. Aluminium)

4.3.2.4 Right Lateral Flexion

For right lateral flexion the null hypothesis cannot be rejected, as there was no evidence of an interaction or treatment effect (p=0.440)(Table 15). Figure 10 shows parallel profiles of the two groups.

Table 15: Within and between –treatment effects for right lateral flexion: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.828	0.078
Time*group	Wilk's Lambda=0.941	0.440
Group	F=0.016	0.900

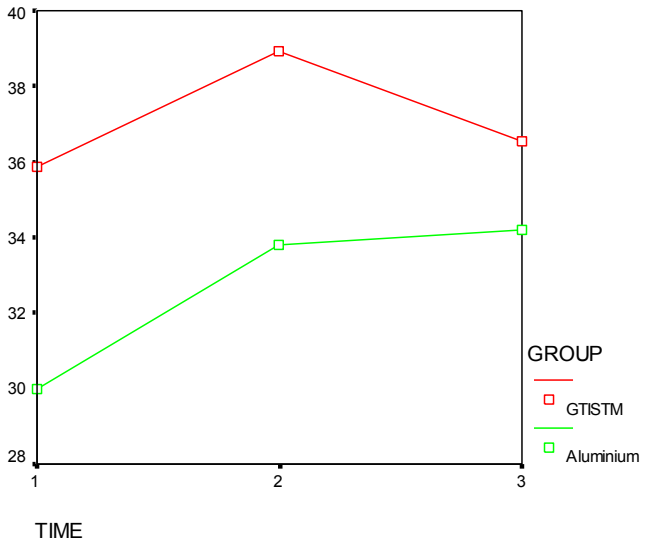


Figure 10: Profile plot of mean right lateral flexion over time by group (GTISTM vs. Aluminium)

4.3.2.5 Left Rotation

There was no significant treatment effect for left rotation (p=0.285 – Table 16). Figure 11 shows that the GTISTM group increased slightly over time, but the aluminium group increased sharply and then decreased. Therefore the null hypothesis cannot be rejected for this outcome.

Table 16: Within and between –treatment effects for left rotation: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.760	0.024
Time*group	Wilk's Lambda=0.911	0.285
Group	F=0.313	0.580

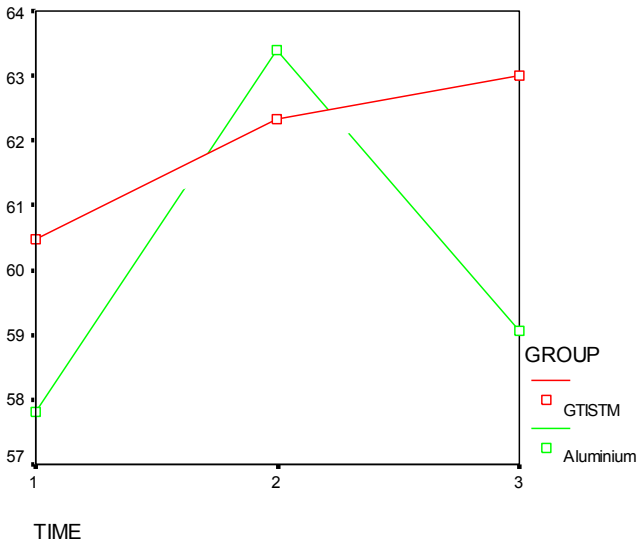


Figure 11: Profile plot of mean left rotation over time by group (GTISTM vs. Aluminium)

4.3.2.6 Right Rotation

The null hypothesis could not be rejected for this outcome either (p=0.411)(Table 17). Figure 12 shows a non significant trend. Both groups reacted in the same way between time 1 and 2, but between time 2 and 3 the GTISTM group continued to increase, while the aluminium group decreased.

Table 17: Within and between – treatment effects for right rotation: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.821	0.070
Time*group	Wilk's Lambda=0.936	0.411
Group	F=0.084	0.744

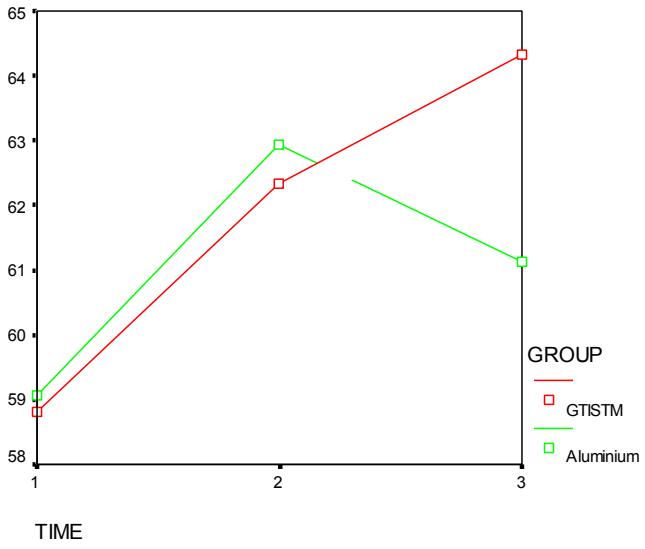


Figure 12: Profile plot of mean right rotation over time by group (GTISTM vs. Aluminium)

4.4 HYPOTHESIS TWO
GTISTM vs. ALUMINIUM (SUBJECTIVE OUTCOMES)

Null hypothesis 2: The effectiveness of the stainless steel GTISTM instrument is the same as that of the aluminium instrument in terms of subjective clinical findings (CMCC and NRS-101) in the treatment of myofascial trigger points.

Alternative hypothesis 2: The effectiveness of the stainless steel GTISTM instrument is different to that of the aluminium instrument in terms of subjective clinical findings (CCMC and NRS-101) in the treatment of myofascial trigger points.

4.4.1 NRS-101

Table 18 shows that the null hypothesis cannot be rejected for this outcome (p=0.339). Both groups showed a significant decrease in score over time (p<0.001). Figure 13 shows that the overall rate of decrease in NRS-101 score was similar in both groups.

Table 18: Within and between –treatment effects for NRS-101: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.349	<0.001
Time*group	Wilk's Lambda=0.923	0.339
Group	F=0.210	0.650

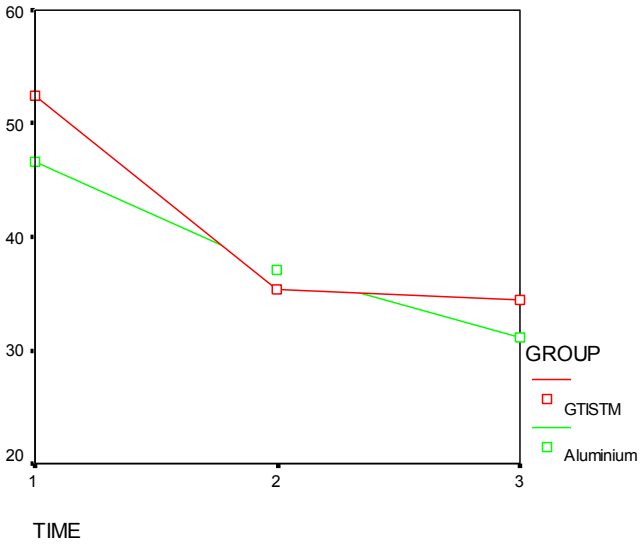


Figure 13: Profile plot of mean NRS-101 over time by group (GTISTM vs. Aluminium)

4.4.2 CMCC

4.4.2.1 CMCC Total Score

The CMCC items were summed to produce the total score. There was no evidence of treatment effect between the two groups in terms of this score (p=0.748 – Table 19). Figure 14 shows a non significant trend which suggests that the score decreased at a faster rate overall in the aluminium group than the GTISTM group. However, the null hypothesis could not be rejected for this outcome.

Table 19: Within and between –treatment effects for CMCC total score: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.616	0.001
Time*group	Wilk's Lambda=0.979	0.748
Group	F=0.026	0.874

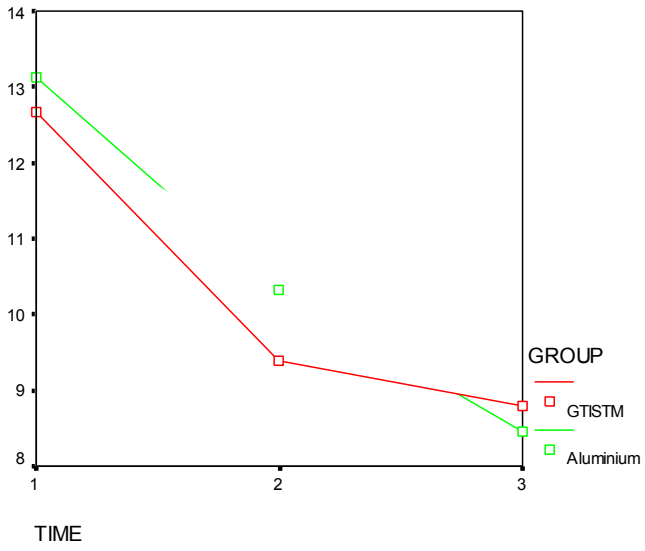


Figure 14: Profile plot of mean CMCC score over time by group (GTISTM vs. Aluminium)

4.4.2.2 Pain Intensity

The null hypothesis could not be rejected for this outcome (p=0.699)(Table 20). Figure 15 shows a non significant trend suggesting that the rate of decrease was faster in the aluminium group.

Table 20: Within and between –treatment effects for pain intensity: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.646	0.003
Time*group	Wilk's Lambda=0.974	0.699
Group	F=0.549	0.465

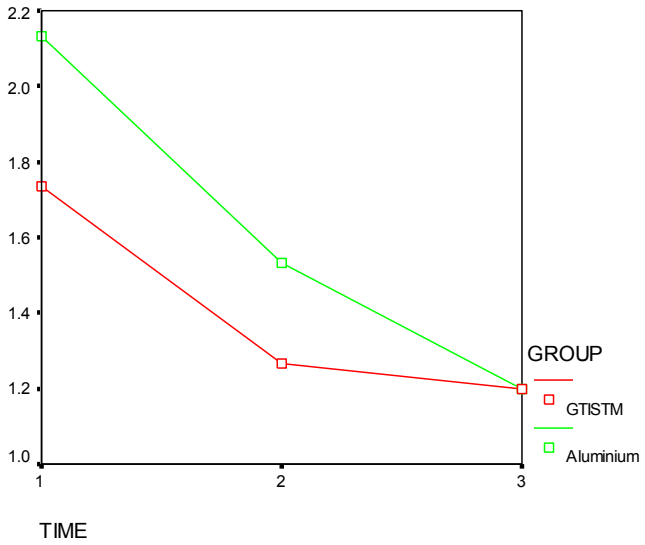


Figure 15: Profile plot of mean pain intensity score over time by group (GTISTM vs. Aluminium)

4.4.2.3 Personal Care

There was no difference between the two groups for this outcome and no evidence of a treatment effect (p=0.252, Figure 16 – Table 21). The null hypothesis was not rejected.

Table 21: Within and between –treatment effects for personal care: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.910	0.279
Time*group	Wilk's Lambda=0.988	0.252
Group	F=0.711	0.235

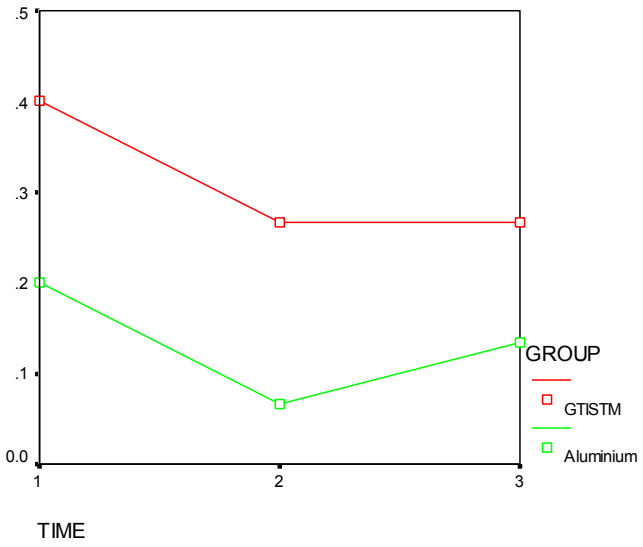


Figure 16: Profile plot of mean personal care score over time by group (GTISTM vs. Aluminium)

4.4.2.4 Lifting

The null hypothesis was not rejected for this outcome. There was no time by group interaction (p=0.717 – Table 22). However, Figure 17 shows a trend which suggests that the GTSITM group decreased to a greater extent than the aluminium group.

Table 22: Within and between –treatment effects for lifting: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.980	0.790
Time*group	Wilk's Lambda=0.976	0.717
Group	F=0.827	0.371

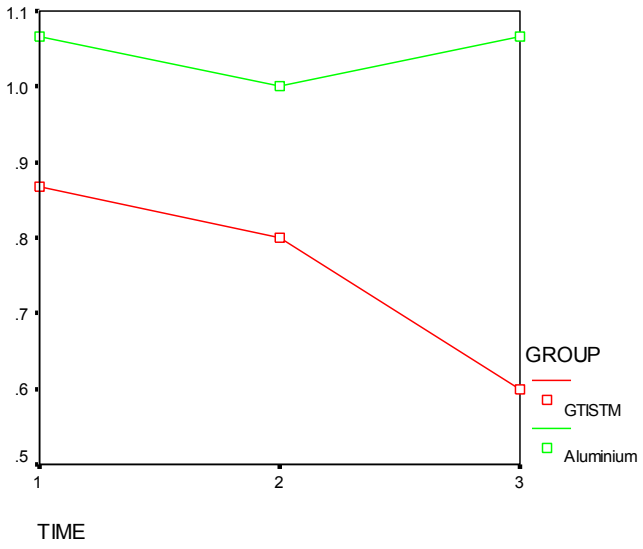


Figure 17: Profile plot of mean lifting score over time by group (GTISTM vs. Aluminium)

4.4.2.5 Reading

Table 23 shows that there was no evidence of a treatment effect for this outcome (p=0.952). Figure 18 shows the profiles of the two groups were parallel over time. Therefore the null hypothesis was not rejected.

Table 23: Within and between –treatment effects for reading: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.488	<0.001
Time*group	Wilk's Lambda=0.996	0.952
Group	F=1.089	0.306

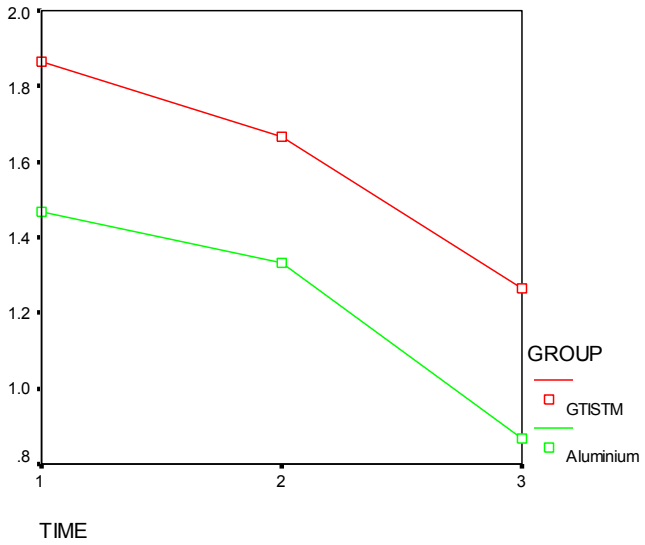


Figure 18: Profile plot of mean reading score over time by group (GTISTM vs. Aluminium)

4.4.2.6 Headaches

The null hypothesis was not rejected for this outcome (p=0.373 - Table 24). However, Figure 19 shows that the GTISTM group actually showed a mean increase in values between time 2 and 3 while the aluminium group continued to decrease.

Table 24: Within and between –treatment effects for reading: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.745	0.019
Time*group	Wilk's Lambda=0.930	0.373
Group	F=0.252	0.619

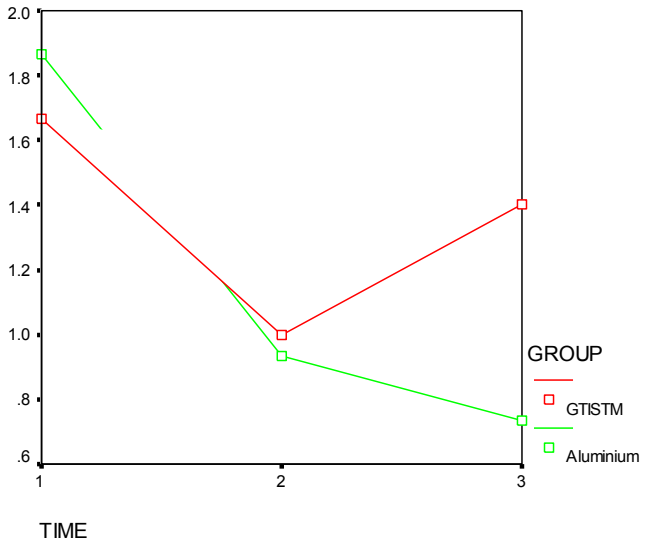


Figure 19: Profile plot of mean headaches score over time by group (GTISTM vs. Aluminium)

4.4.2.7 Concentration

There was no treatment effect for this outcome (p=0.916)(Table 25). Figure 20 shows almost parallel profiles over time of the two groups. The null hypothesis was not rejected for this outcome.

Table 25: Within and between –treatment effects for concentration: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.812	0.060
Time*group	Wilk's Lambda=0.994	0.916
Group	F=0.579	0.453

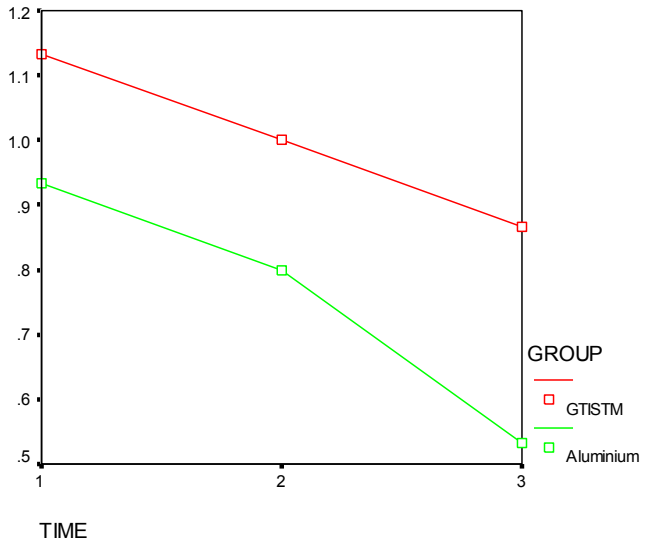


Figure 20: Profile plot of mean concentration score over time by group (GTISTM vs. Aluminium)

4.4.2.8 Work

The null hypothesis was not rejected for this outcome. However, Figure 21 shows that the rate of mean decrease was faster in the GTISTM group.

Table 26: Within and between –treatment effects for work: GTISTM vs. Aluminium vs. (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.888	0.202
Time*group	Wilk's Lambda=0.958	0.559
Group	F=0.071	0.792

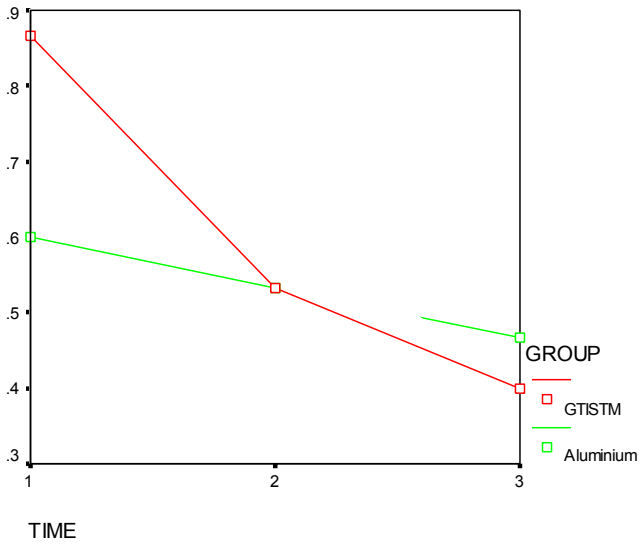


Figure 21: Profile plot of mean work score over time by group (GTISTM vs. Aluminium)

4.4.2.9 Driving

The null hypothesis was not rejected for this outcome (p=0.588). Figure 22 shows parallel profiles over time.

Table 27: Within and between –treatment effects for driving: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.672	0.005
Time*group	Wilk's Lambda=0.961	0.588
Group	F=3.235	0.083

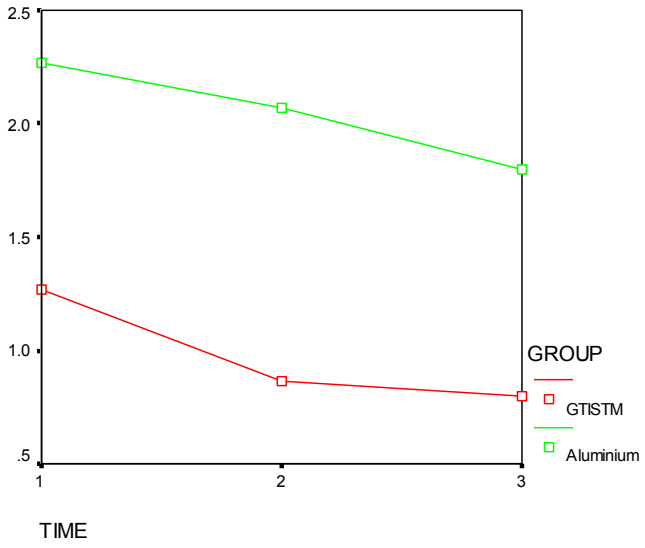


Figure 22: Profile plot of mean driving score over time by group (GTISTM vs. Aluminium)

4.4.2.10 Sleeping

The null hypothesis was not rejected (p=0.406 – Table 28). Figure 23 shows overall similar rates of decrease in both groups.

Table 28: Within and between –treatment effects for sleeping: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.852	0.115
Time*group	Wilk's Lambda=0.935	0.406
Group	F=0.010	0.920

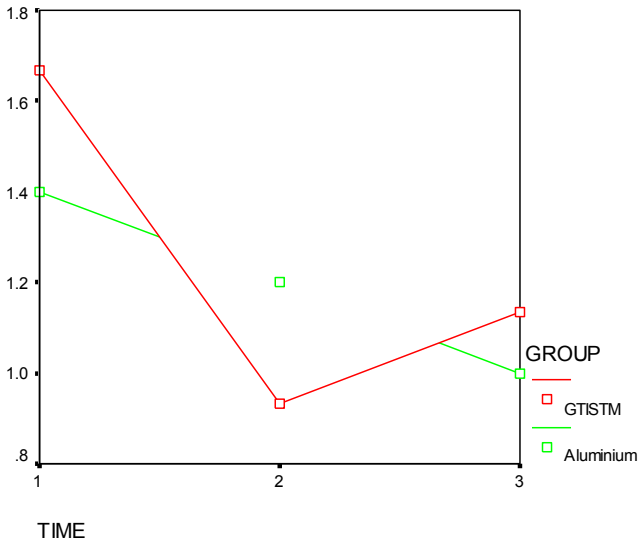


Figure 23: Profile plot of mean sleeping score over time by group (GTISTM vs. Aluminium)

4.4.2.11 Recreation

The null hypothesis was not rejected (p=0.759)(Table 29). The rates of decrease were similar in both groups (Figure 24).

Table 29: Within and between –treatment effects for recreation: GTISTM vs. Aluminium (n=30)

Effect	Statistic	p value
Time	Wilk's Lambda=0.787	0.040
Time*group	Wilk's Lambda=0.980	0.759
Group	F=0.196	0.661

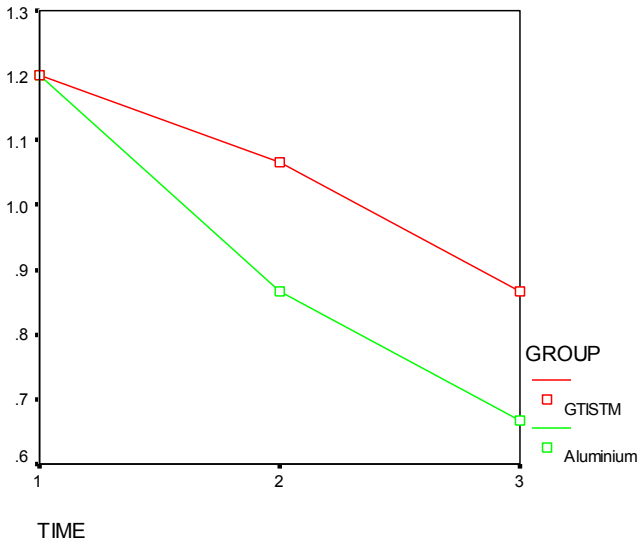


Figure 24: Profile plot of mean recreation score over time by group (GTISTM vs. Aluminium)

4.5 HYPOTHESIS THREE
INTRAGROUP CORRELATIONS

Null hypothesis 3: There is no correlation between the objective and subjective clinical changes within the treatment groups.

Alternative hypothesis 3: There is correlation between the objective and subjective clinical changes within the treatment groups.

Tables 30 to 33 show the intra-group correlations within each of the treatment groups. Many of the subjective and objective measurements were significantly correlated with each other. Therefore the null hypothesis is rejected.

Table 30: Pearson's correlation matrix between subjective and objective changes in the GTISTM group (n=15)

		Change in NRS	Change in CMCC	Change in Flexion	Change in Extension	Change in Left lateral flexion	Change in right lateral flexion	Change in left rotation	Change in right rotation	Change in Trapezius right	Change in Trapezius left	Change in Levator Scapular right	Change in Levator Scapular left
Change in NRS	Pearson Correlation	1	.227	.346	-.420	-.619(*)	-.514(*)	-.792(**)	-.045	-.200	-.154	-.439	-.182
	Sig. (2-tailed)	.	.417	.206	.119	.014	.050	.000	.874	.476	.583	.116	.533
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in CMCC	Pearson Correlation	.227	1	-.033	-.301	.017	-.559(*)	-.064	.199	-.366	-.519(*)	-.664(**)	-.598(*)
	Sig. (2-tailed)	.417	.	.907	.276	.951	.030	.821	.477	.180	.048	.010	.024
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Flexion	Pearson Correlation	.346	-.033	1	-.179	-.102	-.327	-.494	.019	-.298	.382	.143	-.027
	Sig. (2-tailed)	.206	.907	.	.524	.716	.235	.061	.946	.281	.160	.625	.926
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Extension	Pearson Correlation	-.420	-.301	-.179	1	.264	.143	.056	.153	-.089	-.021	.366	.196
	Sig. (2-tailed)	.119	.276	.524	.	.343	.611	.842	.586	.751	.941	.198	.502
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Left lateral flexion	Pearson Correlation	-.619(*)	.017	-.102	.264	1	.504	.589(*)	.491	.331	.047	.487	.159
	Sig. (2-tailed)	.014	.951	.716	.343	.	.056	.021	.063	.228	.868	.077	.587
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in right lateral flexion	Pearson Correlation	-.514(*)	-.559(*)	-.327	.143	.504	1	.527(*)	.241	.588(*)	.124	.464	.496
	Sig. (2-tailed)	.050	.030	.235	.611	.056	.	.044	.386	.021	.660	.095	.071
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in left rotation	Pearson Correlation	-.792(**)	-.064	-.494	.056	.589(*)	.527(*)	1	.185	.356	-.124	.307	.133
	Sig. (2-tailed)	.000	.821	.061	.842	.021	.044	.	.510	.193	.659	.286	.651
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in right rotation	Pearson Correlation	-.045	.199	.019	.153	.491	.241	.185	1	.253	-.082	.236	.082
	Sig. (2-tailed)	.874	.477	.946	.586	.063	.386	.510	.	.362	.773	.418	.781
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Trapezius right	Pearson Correlation	-.200	-.366	-.298	-.089	.331	.588(*)	.356	.253	1	.463	.628(*)	.820(**)
	Sig. (2-tailed)	.476	.180	.281	.751	.228	.021	.193	.362	.	.082	.016	.000
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Trapezius left	Pearson Correlation	-.154	-.519(*)	.382	-.021	.047	.124	-.124	-.082	.463	1	.519	.589(*)
	Sig. (2-tailed)	.583	.048	.160	.941	.868	.660	.659	.773	.082	.	.057	.027
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Levator Scapular right	Pearson Correlation	-.439	-.664(**)	.143	.366	.487	.464	.307	.236	.628(*)	.519	1	.879(**)
	Sig. (2-tailed)	.116	.010	.625	.198	.077	.095	.286	.418	.016	.057	.	.000
	N	14	14	14	14	14	14	14	14	14	14	14	13
Change in Levator Scapular left	Pearson Correlation	-.182	-.598(*)	-.027	.196	.159	.496	.133	.082	.820(**)	.589(*)	.879(**)	1
	Sig. (2-tailed)	.533	.024	.926	.502	.587	.071	.651	.781	.000	.027	.000	.
	N	14	14	14	14	14	14	14	14	14	14	13	14

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

Table 31: Pearson's correlation matrix between subjective and objective changes in the aluminium group (n=15)

		Change in NRS	Change in CMCC	Change in Flexion	Change in Extension	Change in Left lateral flexion	Change in right lateral flexion	Change in left rotation	Change in right rotation	Change in Trapezius right	Change in Trapezius left	Change in Levator Scapular right	Change in Levator Scapular left
Change in NRS	Pearson Correlation	1	.548(*)	-.169	-.567(*)	-.346	-.659(**)	-.136	-.902(**)	-.384	-.494	-.512	-.623(*)
	Sig. (2-tailed)	.	.035	.547	.027	.207	.008	.629	.000	.157	.061	.061	.017
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in CMCC	Pearson Correlation	.548(*)	1	-.064	-.484	-.440	-.495	-.526(*)	-.460	-.449	-.428	-.332	-.404
	Sig. (2-tailed)	.035	.	.820	.068	.101	.061	.044	.085	.093	.112	.247	.152
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Flexion	Pearson Correlation	-.169	-.064	1	-.020	.213	.147	-.094	.097	-.267	-.010	-.187	.108
	Sig. (2-tailed)	.547	.820	.	.944	.446	.601	.739	.730	.335	.971	.522	.714
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Extension	Pearson Correlation	-.567(*)	-.484	-.020	1	.554(*)	.422	.271	.409	.127	.104	.140	.375
	Sig. (2-tailed)	.027	.068	.944	.	.032	.118	.328	.130	.652	.711	.633	.186
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Left lateral flexion	Pearson Correlation	-.346	-.440	.213	.554(*)	1	.696(**)	.510	.239	.159	.269	.099	.249
	Sig. (2-tailed)	.207	.101	.446	.032	.	.004	.052	.390	.570	.332	.736	.391
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in right lateral flexion	Pearson Correlation	-.659(**)	-.495	.147	.422	.696(**)	1	.532(*)	.660(**)	.460	.574(*)	.462	.459
	Sig. (2-tailed)	.008	.061	.601	.118	.004	.	.041	.007	.084	.025	.096	.099
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in left rotation	Pearson Correlation	-.136	-.526(*)	-.094	.271	.510	.532(*)	1	.205	.290	.147	-.008	.120
	Sig. (2-tailed)	.629	.044	.739	.328	.052	.041	.	.464	.295	.602	.978	.683
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in right rotation	Pearson Correlation	-.902(**)	-.460	.097	.409	.239	.660(**)	.205	1	.541(*)	.611(*)	.591(*)	.743(**)
	Sig. (2-tailed)	.000	.085	.730	.130	.390	.007	.464	.	.037	.016	.026	.002
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Trapezius right	Pearson Correlation	-.384	-.449	-.267	.127	.159	.460	.290	.541(*)	1	.709(**)	.773(**)	.527
	Sig. (2-tailed)	.157	.093	.335	.652	.570	.084	.295	.037	.	.003	.001	.053
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Trapezius left	Pearson Correlation	-.494	-.428	-.010	.104	.269	.574(*)	.147	.611(*)	.709(**)	1	.858(**)	.752(**)
	Sig. (2-tailed)	.061	.112	.971	.711	.332	.025	.602	.016	.003	.	.000	.002
	N	15	15	15	15	15	15	15	15	15	15	14	14
Change in Levator Scapular right	Pearson Correlation	-.512	-.332	-.187	.140	.099	.462	-.008	.591(*)	.773(**)	.858(**)	1	.723(**)
	Sig. (2-tailed)	.061	.247	.522	.633	.736	.096	.978	.026	.001	.000	.	.004
	N	14	14	14	14	14	14	14	14	14	14	14	14
Change in Levator Scapular left	Pearson Correlation	-.623(*)	-.404	.108	.375	.249	.459	.120	.743(**)	.527	.752(**)	.723(**)	1
	Sig. (2-tailed)	.017	.152	.714	.186	.391	.099	.683	.002	.053	.002	.004	.
	N	14	14	14	14	14	14	14	14	14	14	14	14

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

Table 32: Pearson's correlation matrix between subjective and objective changes in the control group (n=15)

		Change in NRS	Change in CMCC	Change in Flexion	Change in Extension	Change in Left lateral flexion	Change in right lateral flexion	Change in left rotation	Change in right rotation	Change in Trapezius right	Change in Trapezius left	Change in Levator Scapular right	Change in Levator Scapular left
Change in NRS	Pearson Correlation	1	.800(**)	-.210	-.317	.097	.170	-.388	-.185	-.167	-.246	-.114	-.112
	Sig. (2-tailed)	.	.000	.453	.249	.731	.546	.153	.509	.552	.376	.698	.729
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in CMCC	Pearson Correlation	.800(**)	1	-.292	-.046	.136	.205	-.372	-.265	.084	-.067	.065	.089
	Sig. (2-tailed)	.000	.	.291	.872	.628	.463	.172	.340	.766	.812	.825	.783
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in Flexion	Pearson Correlation	-.210	-.292	1	-.068	.487	.187	.294	.488	-.117	-.079	-.246	-.145
	Sig. (2-tailed)	.453	.291	.	.809	.065	.505	.288	.065	.679	.778	.396	.653
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in Extension	Pearson Correlation	-.317	-.046	-.068	1	.159	.092	.556(*)	.199	.507	.318	.514	.434
	Sig. (2-tailed)	.249	.872	.809	.	.571	.745	.031	.477	.054	.248	.060	.158
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in Left lateral flexion	Pearson Correlation	.097	.136	.487	.159	1	.437	.308	.293	.467	.283	.237	.384
	Sig. (2-tailed)	.731	.628	.065	.571	.	.103	.264	.289	.079	.307	.415	.218
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in right lateral flexion	Pearson Correlation	.170	.205	.187	.092	.437	1	.050	-.004	.209	-.062	.076	.044
	Sig. (2-tailed)	.546	.463	.505	.745	.103	.	.860	.989	.455	.826	.797	.892
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in left rotation	Pearson Correlation	-.388	-.372	.294	.556(*)	.308	.050	1	.673(**)	.307	.413	.413	.116
	Sig. (2-tailed)	.153	.172	.288	.031	.264	.860	.	.006	.266	.126	.142	.720
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in right rotation	Pearson Correlation	-.185	-.265	.488	.199	.293	-.004	.673(**)	1	.257	.363	.016	.129
	Sig. (2-tailed)	.509	.340	.065	.477	.289	.989	.006	.	.356	.184	.956	.689
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in Trapezius right	Pearson Correlation	-.167	.084	-.117	.507	.467	.209	.307	.257	1	.787(**)	.256	.830(**)
	Sig. (2-tailed)	.552	.766	.679	.054	.079	.455	.266	.356	.	.000	.377	.001
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in Trapezius left	Pearson Correlation	-.246	-.067	-.079	.318	.283	-.062	.413	.363	.787(**)	1	.070	.742(**)
	Sig. (2-tailed)	.376	.812	.778	.248	.307	.826	.126	.184	.000	.	.812	.006
	N	15	15	15	15	15	15	15	15	15	15	14	12
Change in Levator Scapular right	Pearson Correlation	-.114	.065	-.246	.514	.237	.076	.413	.016	.256	.070	1	.292
	Sig. (2-tailed)	.698	.825	.396	.060	.415	.797	.142	.956	.377	.812	.	.356
	N	14	14	14	14	14	14	14	14	14	14	14	12
Change in Levator Scapular left	Pearson Correlation	-.112	.089	-.145	.434	.384	.044	.116	.129	.830(**)	.742(**)	.292	1
	Sig. (2-tailed)	.729	.783	.653	.158	.218	.892	.720	.689	.001	.006	.356	.
	N	12	12	12	12	12	12	12	12	12	12	12	12

** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).

Table 33: Pearson's correlation matrix between subjective and objective changes in the placebo group (n=15)

		Change in NRS	Change in CMCC	Change in Flexion	Change in Extension	Change in Left lateral flexion	Change in right lateral flexion	Change in left rotation	Change in right rotation	Change in Trapezius right	Change in Trapezius left	Change in Levator Scapular right	Change in Levator Scapular left
Change in NRS	Pearson Correlation	1	.618(*)	-.517(*)	-.514	-.129	-.260	-.041	-.267	-.486	-.460	-.297	-.509
	Sig. (2-tailed)	.	.014	.049	.050	.647	.350	.884	.336	.066	.098	.324	.063
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in CMCC	Pearson Correlation	.618(*)	1	-.462	-.416	-.286	-.522(*)	-.354	-.258	-.341	-.357	-.207	-.346
	Sig. (2-tailed)	.014	.	.083	.123	.302	.046	.195	.352	.213	.211	.498	.225
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in Flexion	Pearson Correlation	-.517(*)	-.462	1	.414	.408	.542(*)	.000	.353	.674(**)	.372	.367	.199
	Sig. (2-tailed)	.049	.083	.	.125	.131	.037	.999	.197	.006	.190	.218	.494
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in Extension	Pearson Correlation	-.514	-.416	.414	1	.643(**)	.655(**)	.164	.420	.387	.435	.169	.120
	Sig. (2-tailed)	.050	.123	.125	.	.010	.008	.560	.119	.154	.120	.582	.682
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in Left lateral flexion	Pearson Correlation	-.129	-.286	.408	.643(**)	1	.720(**)	.004	.512	.320	.430	.216	.052
	Sig. (2-tailed)	.647	.302	.131	.010	.	.002	.988	.051	.245	.125	.479	.859
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in right lateral flexion	Pearson Correlation	-.260	-.522(*)	.542(*)	.655(**)	.720(**)	1	.043	.398	.358	.203	-.050	-.250
	Sig. (2-tailed)	.350	.046	.037	.008	.002	.	.878	.142	.190	.487	.870	.389
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in left rotation	Pearson Correlation	-.041	-.354	.000	.164	.004	.043	1	.334	.227	.183	.393	.127
	Sig. (2-tailed)	.884	.195	.999	.560	.988	.878	.	.224	.416	.530	.184	.665
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in right rotation	Pearson Correlation	-.267	-.258	.353	.420	.512	.398	.334	1	.712(**)	.692(**)	.576(*)	.416
	Sig. (2-tailed)	.336	.352	.197	.119	.051	.142	.224	.	.003	.006	.039	.139
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in Trapezius right	Pearson Correlation	-.486	-.341	.674(**)	.387	.320	.358	.227	.712(**)	1	.816(**)	.871(**)	.526
	Sig. (2-tailed)	.066	.213	.006	.154	.245	.190	.416	.003	.	.000	.000	.053
	N	15	15	15	15	15	15	15	15	15	14	13	14
Change in Trapezius left	Pearson Correlation	-.460	-.357	.372	.435	.430	.203	.183	.692(**)	.816(**)	1	.802(**)	.749(**)
	Sig. (2-tailed)	.098	.211	.190	.120	.125	.487	.530	.006	.000	.	.002	.003
	N	14	14	14	14	14	14	14	14	14	14	12	13
Change in Levator Scapular right	Pearson Correlation	-.297	-.207	.367	.169	.216	-.050	.393	.576(*)	.871(**)	.802(**)	1	.745(**)
	Sig. (2-tailed)	.324	.498	.218	.582	.479	.870	.184	.039	.000	.002	.	.004
	N	13	13	13	13	13	13	13	13	13	12	13	13
Change in Levator Scapular left	Pearson Correlation	-.509	-.346	.199	.120	.052	-.250	.127	.416	.526	.749(**)	.745(**)	1
	Sig. (2-tailed)	.063	.225	.494	.682	.859	.389	.665	.139	.053	.003	.004	.
	N	14	14	14	14	14	14	14	14	14	13	13	14

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

4.6 HYPOTHESIS FOUR AND FIVE
GTISTM AND ALUMINIUM vs. CONTROL AND PLACEBO

Null Hypothesis 4: The stainless steel GTISTM instrument and the aluminium instrument will differ in effectiveness from the control group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

Alternative hypothesis 4: The stainless steel GTISTM instrument and the aluminium instrument will not differ in effectiveness from the control group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

Null Hypothesis 5: The stainless steel GTISTM instrument and the aluminium instrument will differ in effectiveness from the placebo group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

Alternative hypothesis 5: The stainless steel GTISTM instrument and the aluminium instrument will not differ in effectiveness from the placebo group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

4.6.1 Objective outcomes

4.6.1.1 Algometer

4.6.1.1.1 Right Trapezius

Table 30 shows that neither the GTISTM group nor the aluminium group was significantly different from the control group with regard to this outcome. Figure 25 shows a trend towards a beneficial treatment effect in the GTISTM group compared with the control group. The null hypothesis is not rejected.

Both the aluminium group and the GTISTM group showed a mean increase in algometer measurement over time, while the placebo group did not change much (Figures 26 and 28). However, the treatment effect was not significant for either group comparisons. The null hypothesis was not rejected.

Table 34 and 35: Table of time by group interactions for right trapezius algometer measurements (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value		Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.914	0.296		GTISTM vs. placebo	Wilk's lambda=0.944	0.459
Aluminium vs. control	Wilk's lambda=0.964	0.611		Aluminium vs. placebo	Wilk's lambda=0.875	0.164

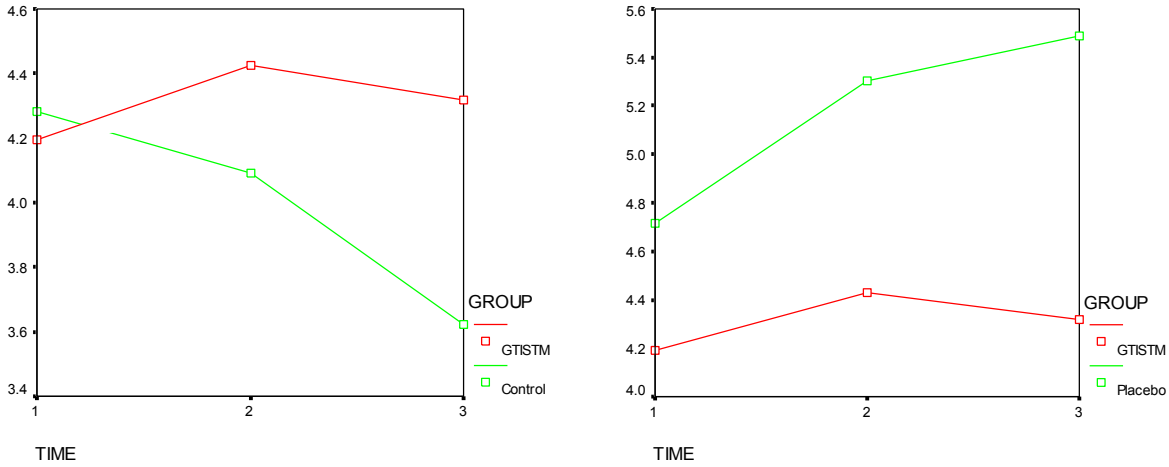


Figure 25 and 26: Profile plot of mean right trapezius algometer measurement over time by group GTISTM vs. Control and GTISTM vs. Placebo

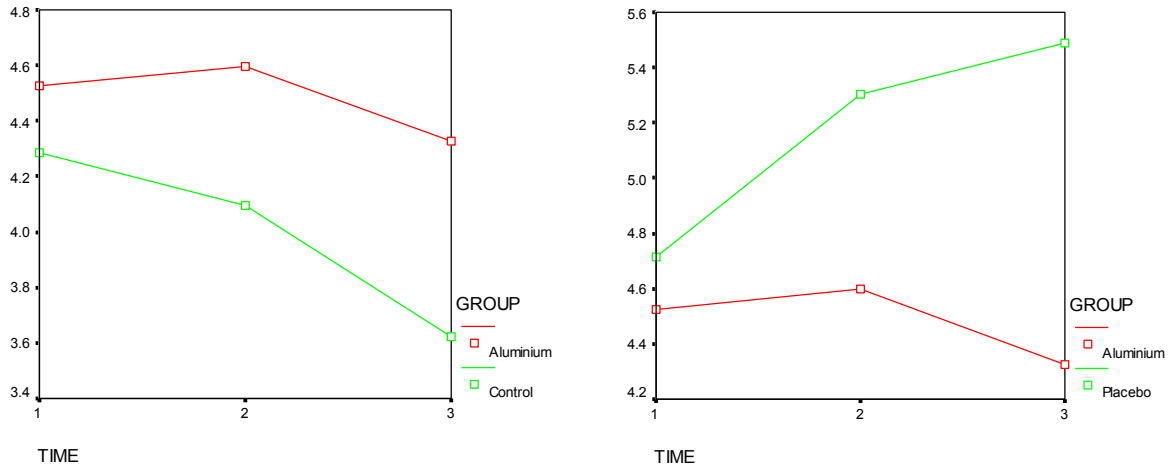


Figure 27 and 28: Profile plot of mean right trapezius algometer measurement over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.1.1.2 Left Trapezius

Table 36 shows that there was a non significant effect for GTISTM versus the control group (p=0.088). Figure 29 shows that the GTISTM group increased between time 1 and time 2 while the control group decreased. This was followed by a dramatic decrease in the GTISTM group. Figure 31 show that the aluminium group showed a gradual increase over time while the control group decreased. However the scale of

the changes was small and not statistically significant and the null hypothesis is not rejected.

The null hypothesis was not rejected for this outcome. There was no time by group interaction for either GTISTM or aluminium group versus the placebo group. Figures 30 and 32 show that both treatment effect of the GTISTM and aluminium groups were less effective than the placebo group.

Table 36 and 37: Table of time by group interactions for left trapezius algometer measurements (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value	Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.835	0.088	GTISTM vs. placebo	Wilk's lambda=0.868	0.160
Aluminium vs. control	Wilk's lambda=0.991	0.885	Aluminium vs. placebo	Wilk's lambda=0.968	0.657

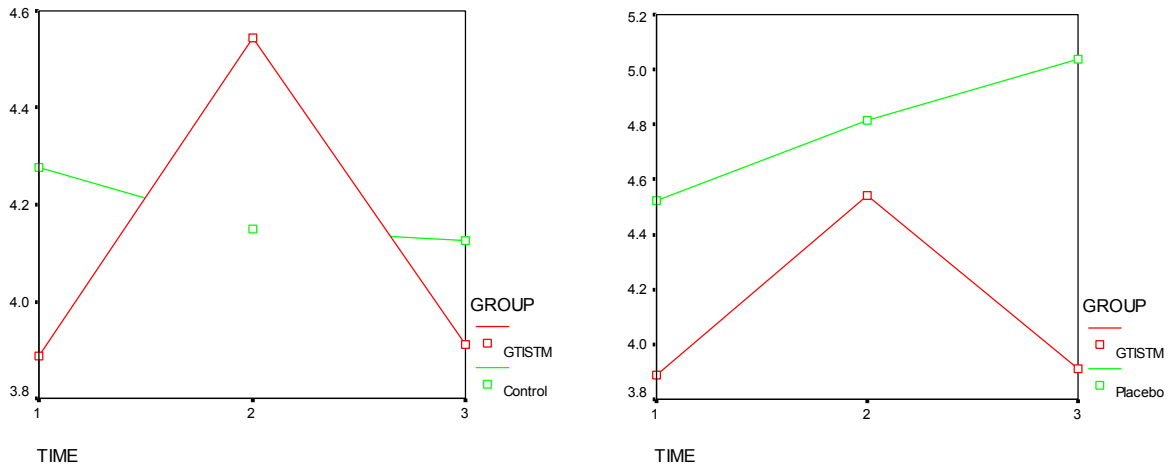
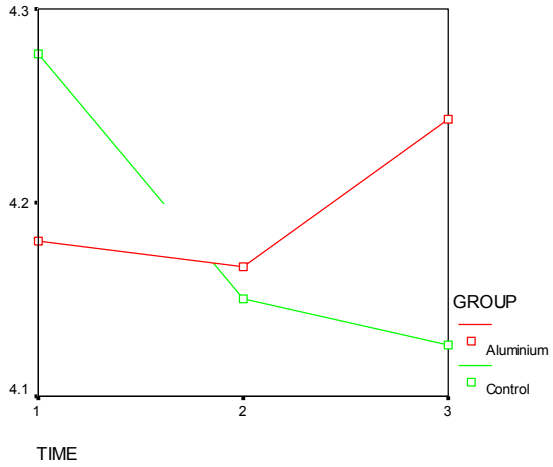


Figure 29 and 30: Profile plot of mean left trapezius algometer measurements over time by group: GTISTM vs. Control and GTISTM vs. Placebo



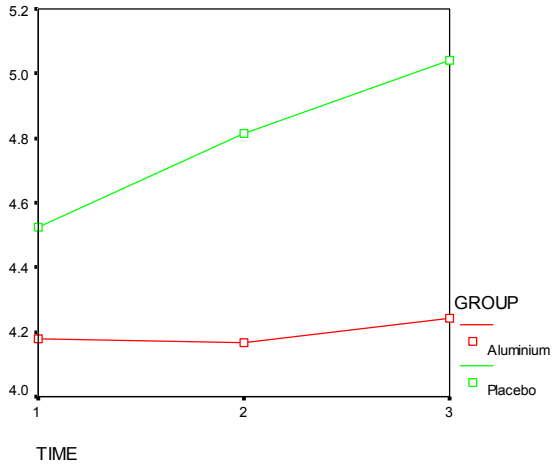


Figure 31 and 32: Profile plot of mean left trapezius algometer measurements over time by group: Aluminium vs. Control and Aluminium vs. Placebo

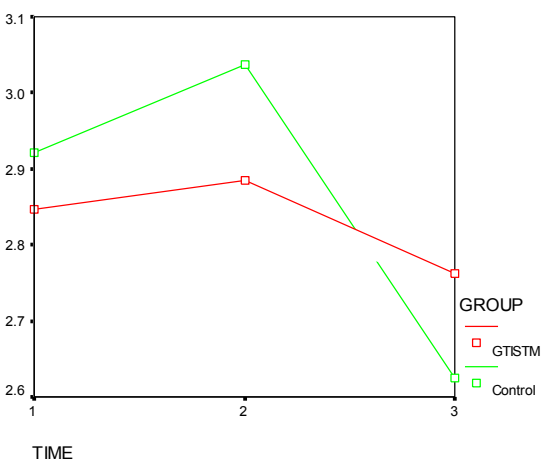
4.6.1.1.3 Right Levator Scapula

There was a significantly beneficial treatment effect in the Aluminium group relative to the control group for this outcome (p=0.021)(Table 38). Figure 35 shows that between time 2 and time 3 the aluminium group showed an increase in mean values while the control group showed a decrease. This was not shown in the GTISTM group. The null hypothesis is rejected for this outcome.

There was no evidence of treatment effect over the placebo treatment for either group. Figure 34 shows almost parallel lines for both groups over time. Figure 36 does suggest an interaction, but it was not statistically significant.

Table 38 and 39: Table of time by group interactions for right levator scapula algometer measurements (n=27): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value		Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.959	0.559		GTISTM vs. placebo	Wilk's lambda=0.979	0.784
Aluminium vs. control	Wilk's lambda=0.716	0.021		Aluminium vs. placebo	Wilk's lambda=0.955	0.574



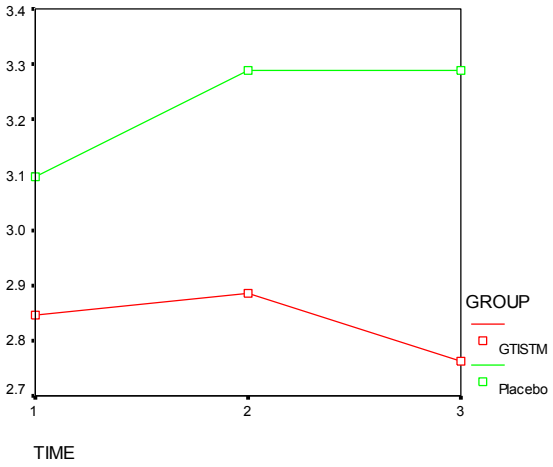
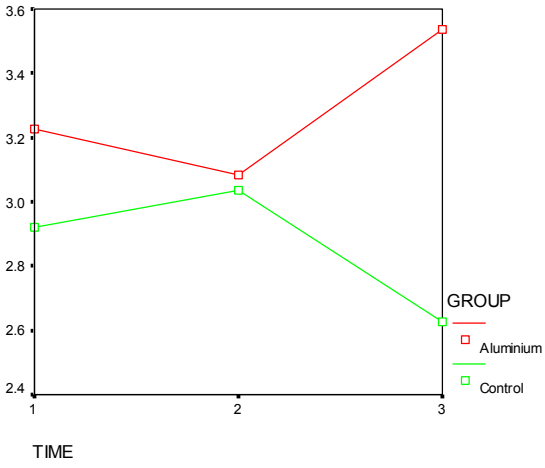


Figure 33 and 34: Profile plot of mean right levator scapula algometer measurements over time by group: GTISTM vs. Control and GTISTM vs. Placebo



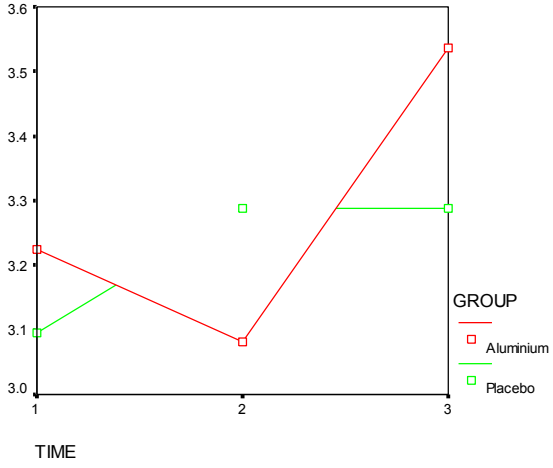


Figure 35 and 36: Profile plot of mean right levator scapula algometer measurements over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.1.1.4 Left Levator Scapula

There was no significant treatment effect for this outcome in either of the intervention groups over the control group. The null hypothesis is not rejected for this outcome.

For the GTISTM treatment relative to the placebo group there was no difference in effect. However, the aluminium group showed a significantly better treatment effect than the placebo (p=0.033 – Table 41). This is shown in Figure 40. The aluminium group showed a general increase in treatment effect over time which was mainly between time 2 and 3, while the placebo group showed a decrease over time.

Table 40 and 41: Table of time by group interactions for left levator scapular algometer measurements (n=28): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value	Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.901	0.303	GTISTM vs. placebo	Wilk's lambda=0.993	0.912
Aluminium vs. control	Wilk's lambda=0.943	0.510	Aluminium vs. placebo	Wilk's lambda=0.716	0.033

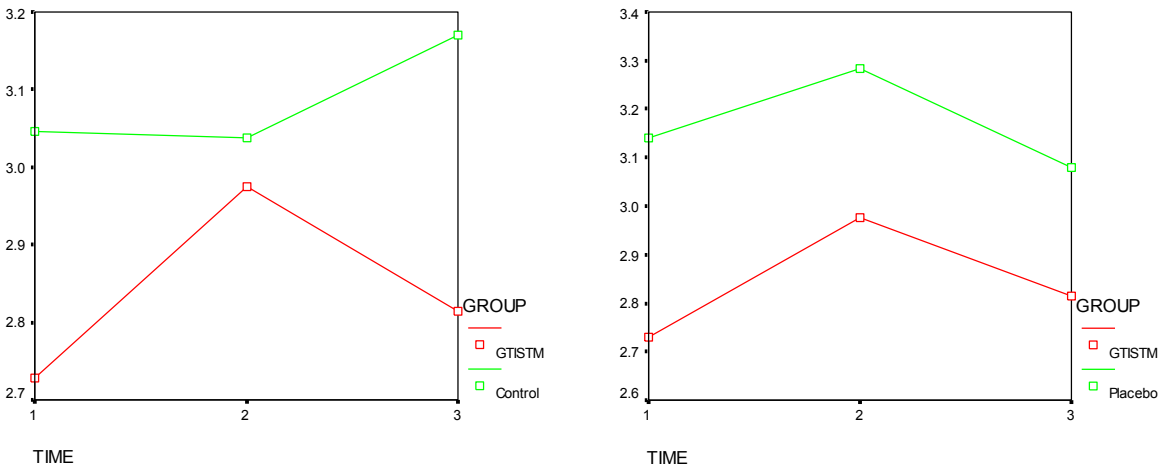


Figure 37 and 38: Profile plot of mean left levator scapula algometer measurements over time by group: GTISTM vs. Control and GTISTM vs. Placebo

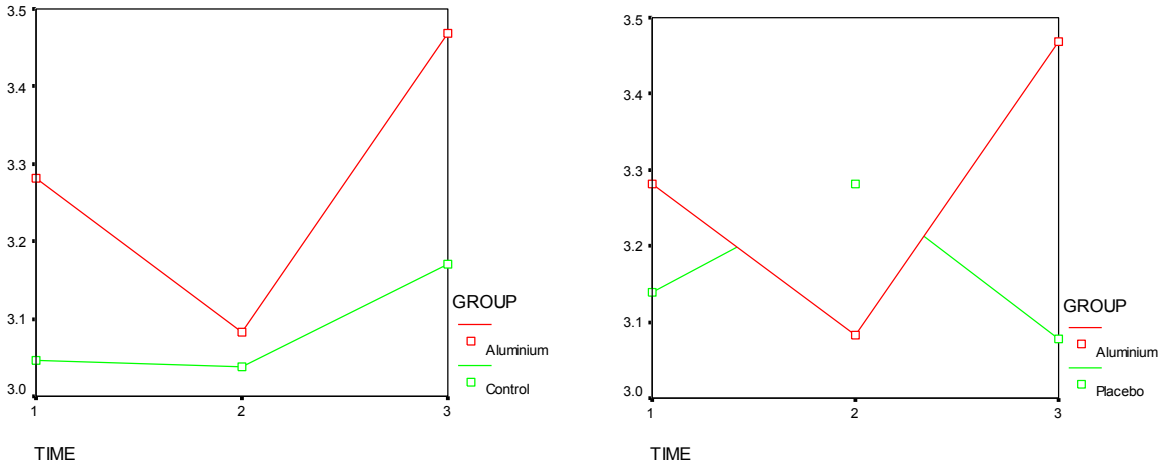


Figure 39 and 40: Profile plot of mean left levator scapula algometer measurements over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.1.2 CROM

4.6.1.2.1 Flexion

Neither of the intervention groups were significantly different from the control group for flexion. The null hypothesis is not rejected for this outcome. Figure 41 shows a trend towards a steeper rate of increase between time 1 and 2 in the GTISTM group than the control group.

There was a non significant treatment effect for the GTISTM group versus the placebo (p=0.057 – Table 43). Figure 42 shows that that the GTISTM group showed an increase over time while the placebo group showed a decrease. The aluminium group was no different from the placebo group with regard to flexion, although the Figure 44 shows that the aluminium group started to show a slow increase in treatment effect slowly between time 2 and 3.

Table 42 and 43: Table of time by group interactions for flexion (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value	Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.947	0.477	GTISTM vs. placebo	Wilk's lambda=0.809	0.057
Aluminium vs. control	Wilk's lambda=0.9902	0.247	Aluminium vs. placebo	Wilk's lambda=0.972	0.683

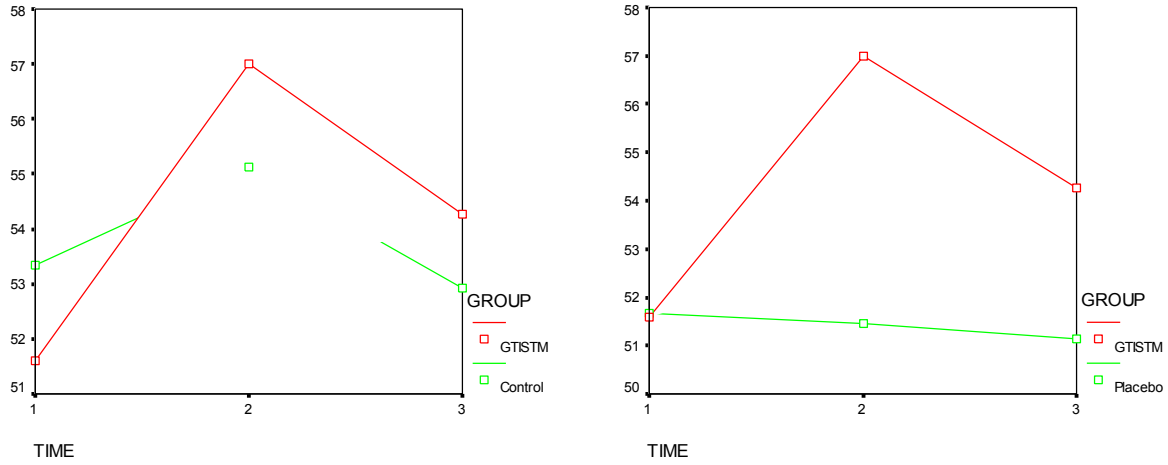


Figure 41 and 42: Profile plot of mean flexion over time by group: GTISTM vs. Control and GTISTM vs. Placebo

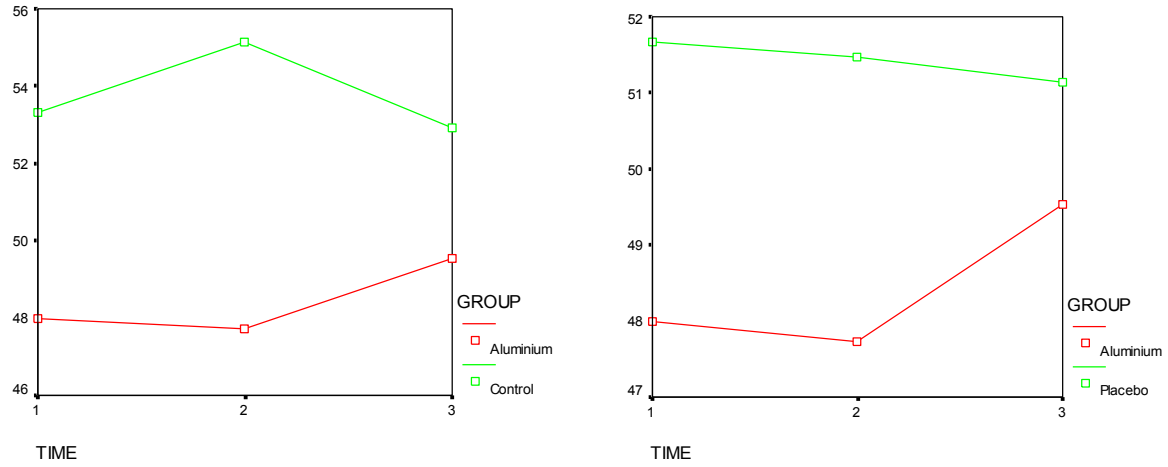


Figure 43 and 44: Profile plot of mean flexion over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.1.2.2 Extension

There was no significant treatment effect in either group over the control group for extension. However, both Figures 45 and 47 shows that there was a general decrease in the control group over time while both intervention groups increased gradually. This trend was not statistically significant. Thus the null hypothesis is not rejected.

Although the null hypothesis could not be rejected for this outcome, both Figures 46 and 48 show an interaction between time and group, ie. the groups react differently over time. In both figures the treatment groups show an increase over time while the placebo group decreased over time.

Table 44 and 45: Table of time by group interactions for extension (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value	Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.850	0.112	GTISTM vs. placebo	Wilk's lambda=0.878	0.172
Aluminium vs. control	Wilk's lambda=0.876	0.165	Aluminium vs. placebo	Wilk's lambda=0.879	0.176

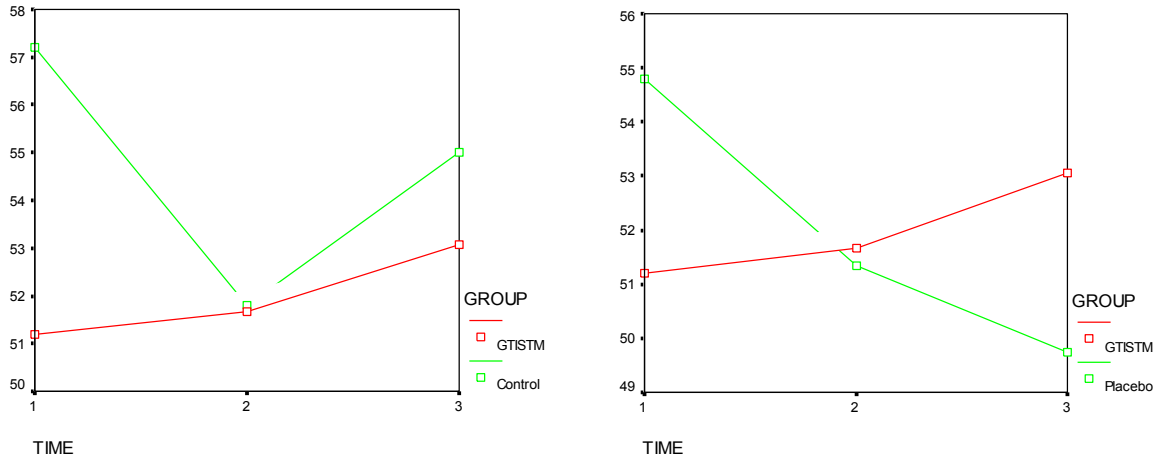


Figure 45 and 46: Profile plot of mean extension over time by group: GTISTM vs. Control and GTISTM vs. Placebo

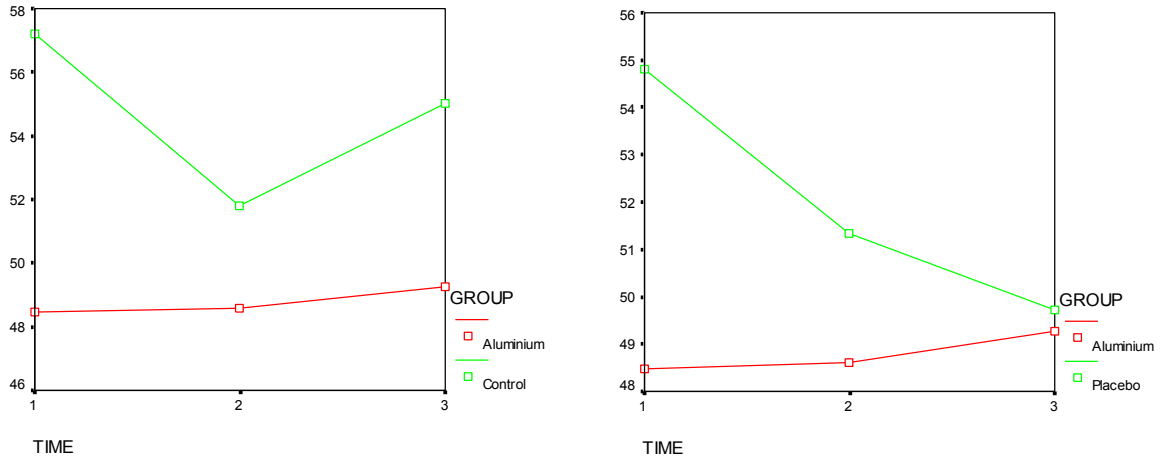


Figure 47 and 48: Profile plot of mean extension over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.1.2.3 Left Rotation

There was no evidence of a beneficial effect for left rotation compared to the control group in any of the intervention groups. This is shown in Figures 49 and 51. The null hypothesis is not rejected.

The null hypothesis could not be rejected for left rotation. However, Figure 50 shows a non significant interaction between the GTISTM group and the placebo group over time. The GTISTM group appeared to increase at a faster rate over time than the placebo group.

Table 46 and 47: Table of time by group interactions for left rotation (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value		Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.977	0.734		GTISTM vs. placebo	Wilk's lambda=0.987	0.833
Aluminium vs. control	Wilk's lambda=0.962	0.596		Aluminium vs. placebo	Wilk's lambda=0.856	0.122

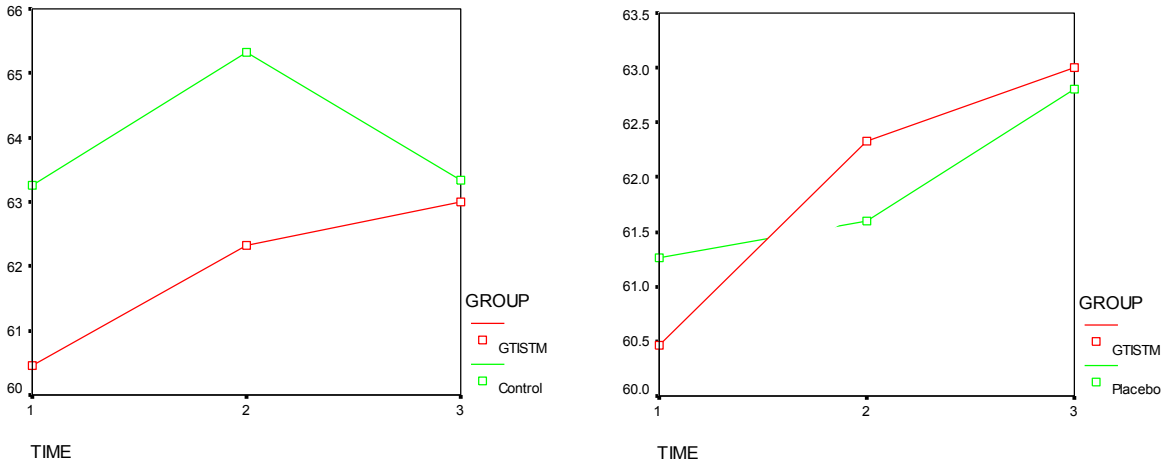


Figure 49 and 50: Profile plot of mean left rotation over time by group; GTISTM vs. Control and GTISTM vs. Placebo

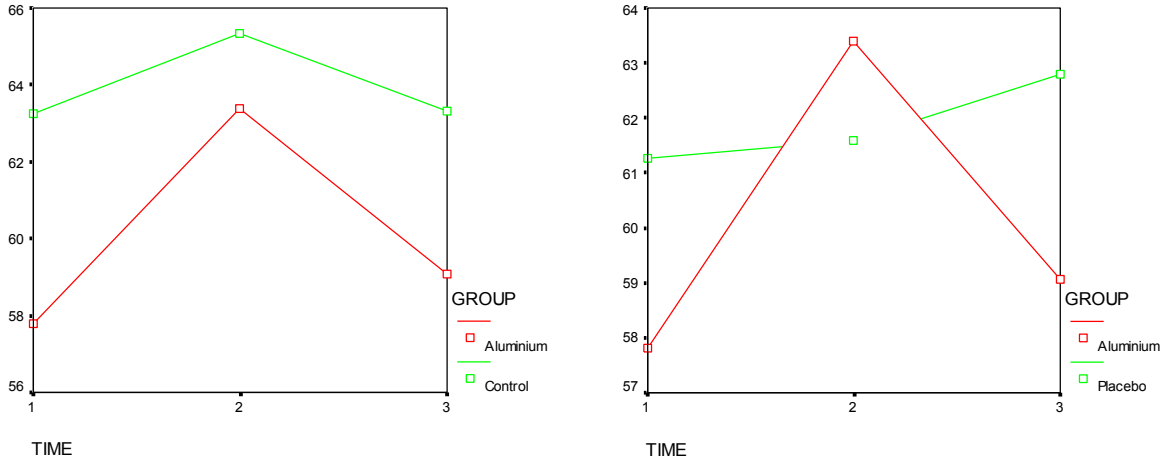


Figure 51 and 52: Profile plot of mean left rotation over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.1.2.4 Right Rotation

There was no treatment effect for the stainless steel or aluminium instrument compared with the control group for the outcome of right rotation. However, both figure 53 and 55 show a trend towards a greater improvement in the GTISTM group and the aluminium group relative to the control group. The null hypothesis cannot be rejected, however.

The null hypothesis could not be rejected for right rotation. There was no significant interaction between time and group for either comparison. However, there was a trend displayed in Figure 54 showing that the rate of increase in the GTISTM group was steeper than in the placebo group.

Table 48 and 49: Table of time by group interactions for right rotation (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value		Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.921	0.330		GTISTM vs. placebo	Wilk's lambda= 0.970	0.664
Aluminium vs. control	Wilk's lambda=0.925	0.347		Aluminium vs. placebo	Wilk's lambda=0.961	0.580

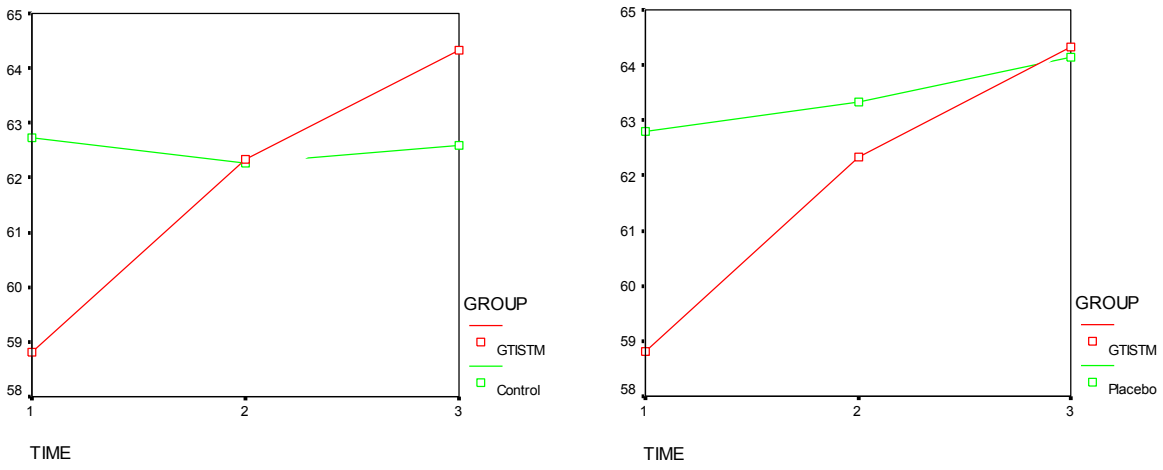


Figure 53 and 54: Profile plot of mean right rotation over time by group: GTISTM vs. Control and GTISTM vs. Placebo

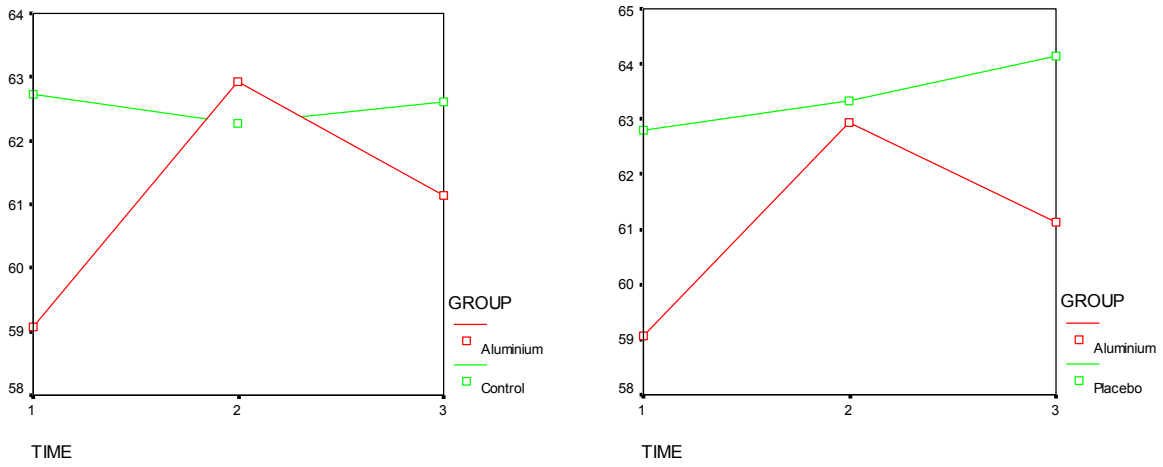


Figure 55 and 56: Profile plot of mean right rotation over time by group: Aluminium vs. Control and Aluminium vs. Placebo

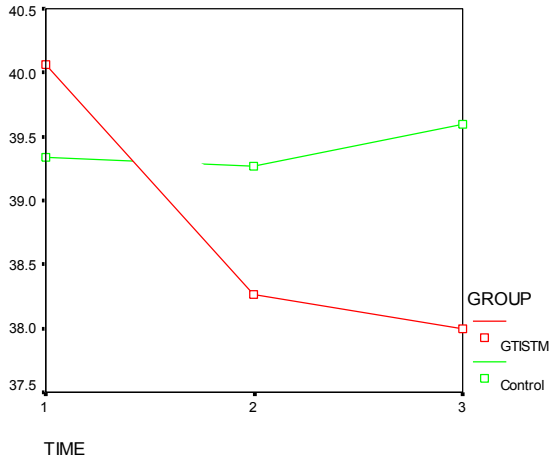
4.6.1.2.5 Left Lateral Flexion

There was no difference between the treatment effects in either intervention group relative to the control group. Therefore the null hypothesis was not rejected. Figures 57 and 59 show that the treatment effects of the GTISTM group decreased over time while there was a small increase in the control group and aluminium group means over the three time points. However this was not statistically significant.

There was no treatment effect for this outcome. The null hypothesis could not be rejected. Figure 58 shows that the GTISTM group decreased over time while the placebo group showed an increase.

Table 50 and 51: Table of time by group interactions for left lateral flexion (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value		Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.976	0.718		GTISTM vs. placebo	Wilk's lambda=0.928	0.336
Aluminium vs. control	Wilk's lambda=0.930	0.376		Aluminium vs. placebo	Wilk's lambda=0.962	0.593



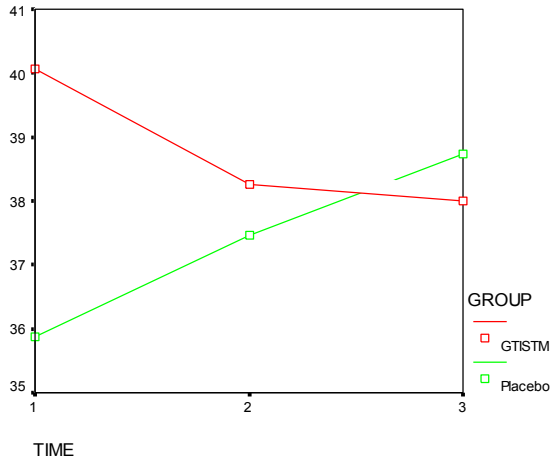
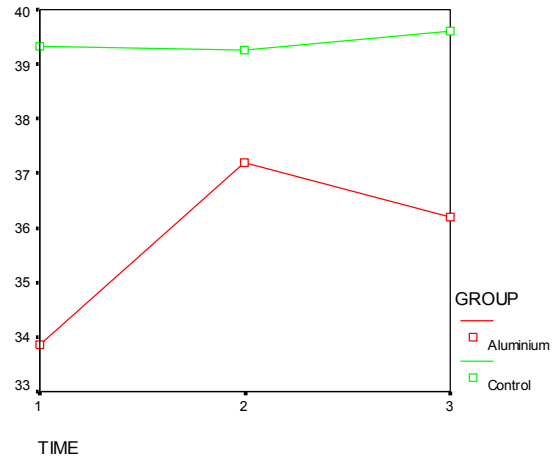


Figure 57 and 58: Profile plot of mean left lateral flexion over time by group: GTISTM vs. Control and GTISTM vs. Placebo



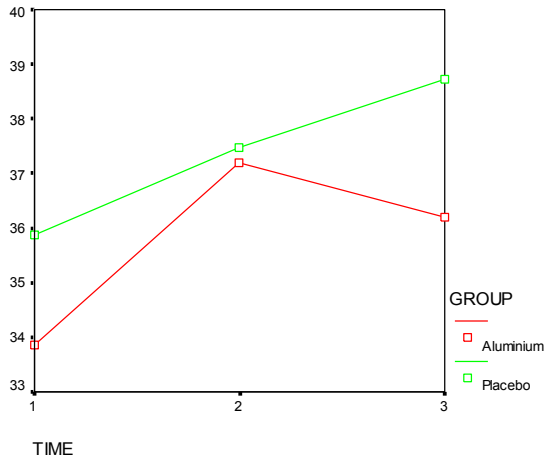


Figure 59 and 60: Profile plot of mean left lateral flexion over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.1.2.6 Right Lateral Flexion

There was no significant treatment effect for right lateral flexion between either the GTSITM group or the aluminium group and control. However, Figure 61 shows that the GTISTM group showed an increase in mean values between time 1 and 2, and an overall increase from baseline, and the aluminium group showed a slight increase in readings overall, while the control group decreased over time.

The null hypothesis could not be rejected for this outcome. For aluminium group versus placebo group the profiles are approximately parallel (Figure 64). However, in Figure 62 the GTISTM group versus the placebo group a non significant interaction occurred. The placebo group showed a general increase over time.

Table 52 and 53: Table of time by group interactions for right lateral flexion (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value	Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.945	0.468	GTISTM vs. placebo	Wilk's lambda=0.839	0.094
Aluminium vs. control	Wilk's lambda=0.835	0.117	Aluminium vs. placebo	Wilk's lambda=0.923	0.338

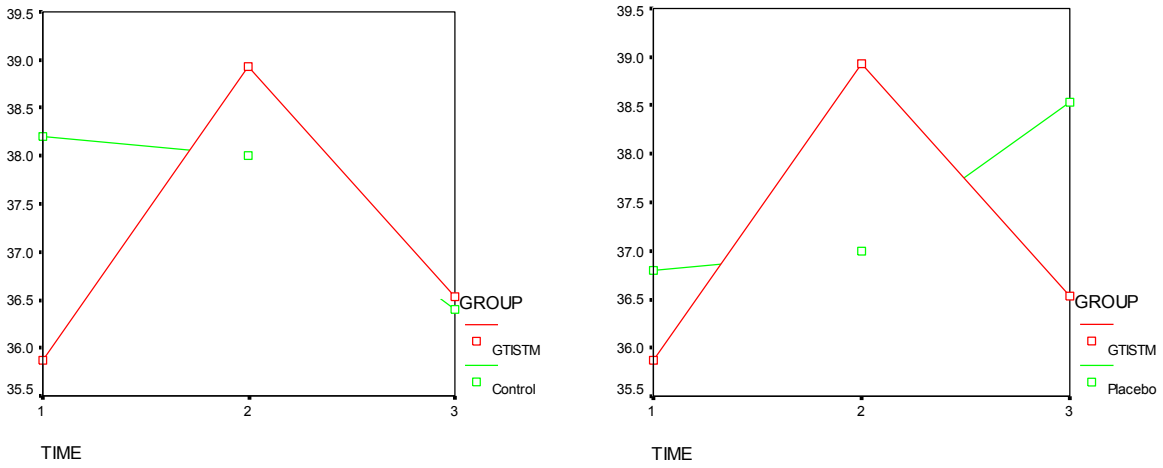


Figure 61 and 62: Profile plot of mean right lateral flexion over time by group: GTISTM vs. Control and GTISTM vs. Placebo

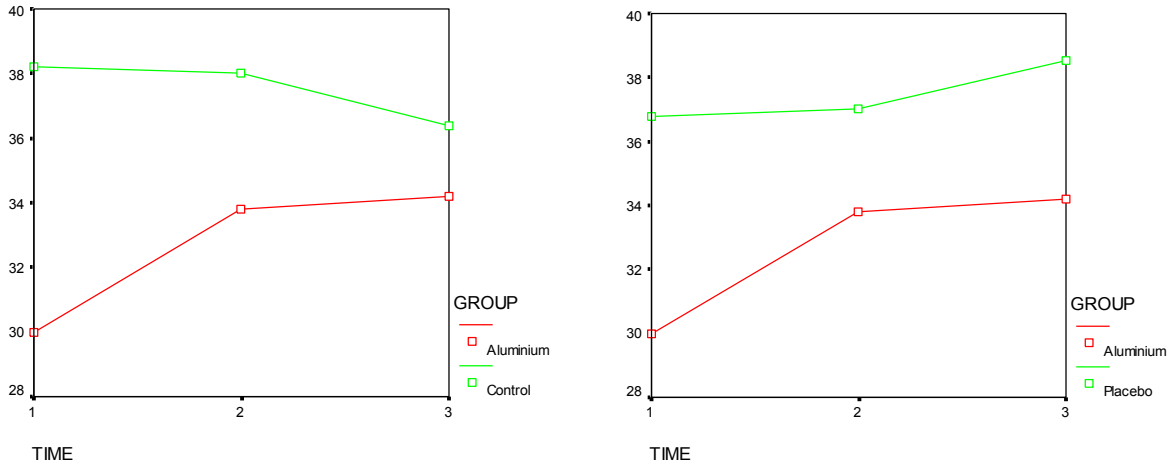


Figure 63 and 64: Profile plot of mean right lateral flexion over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.2 Subjective outcomes

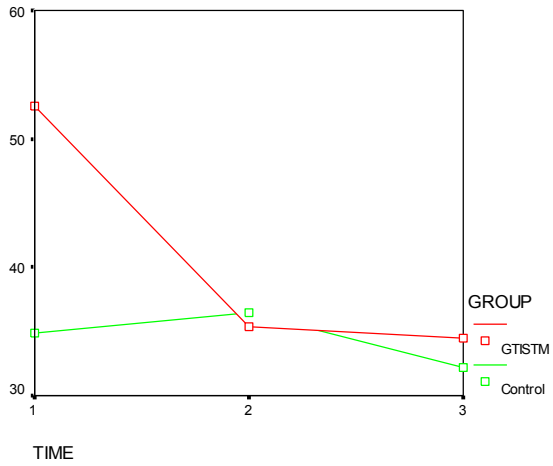
4.6.2.1 NRS-101

Both the GTISTM instrument ($p<0.001$) and the aluminium instrument ($p=0.003$) were significantly more effective than the control in terms of NRS score (Table 54). Figures 65 and 67 show that the control group mean score did not change over time, while the GTISTM and aluminium groups showed a decrease over time.

The effect of the placebo was similar to that of the GTISTM instrument and the aluminium instrument, therefore the null hypothesis could not be rejected. This is shown in Figures 66 and 68.

Table 54 and 55: Table of time by group interactions for NRS-101 (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value	Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.515	<0.001	GTISTM vs. placebo	Wilk's lambda=0.960	0.574
Aluminium vs. control	Wilk's lambda=0.649	0.003	Aluminium vs. placebo	Wilk's lambda=0.970	0.662



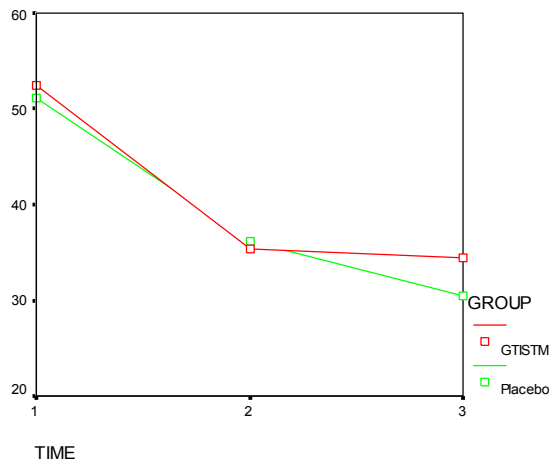
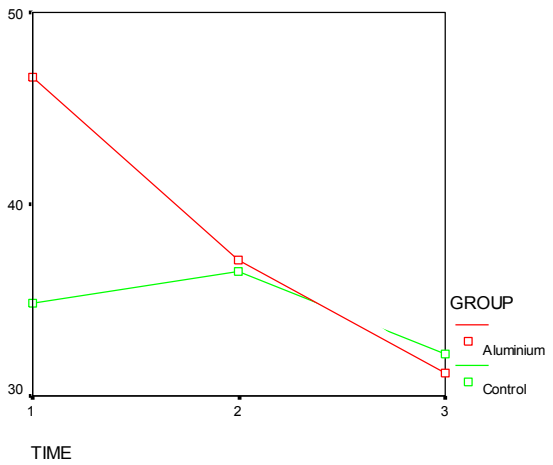


Figure 65 and 66: Profile plot of mean NRS-101 over time by group: GTISTM vs. Control and GTISTM vs. Placebo



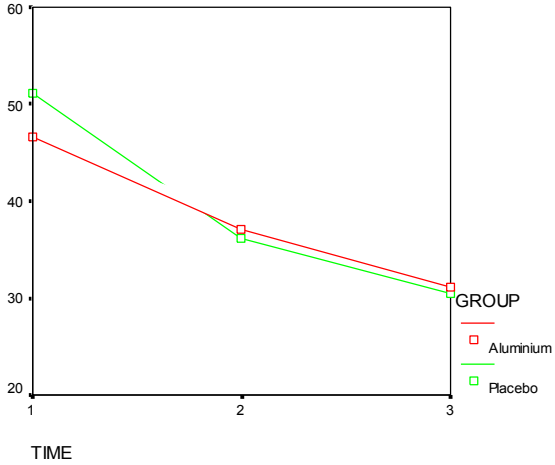


Figure 67 and 68: Profile plot of mean NRS-101 over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.6.2.2 CMCC score

The treatment effects for the GTISTM group was significantly more effective than the control for total CMCC score (p=0.036 – Table 56). Scores decreased at a faster rate in the GTISTM group than in the control group (Figure 69). This was also apparent in the aluminium group, but it was not statistically significant (p=0.105 – Table 56).

The null hypothesis could not be rejected for this outcome. The changes in scores over time for the treatment groups were very similar to the placebo group. This is shown in Figures 70 and 72.

Table 56 and 57: Table of time by group interactions for total CMCC score (n=30): GTISTM and Aluminium vs. Control and Placebo

Comparison	Statistic	p value	Comparison	Statistic	p value
GTISTM vs. control	Wilk's lambda=0.782	0.036	GTISTM vs. placebo	Wilk's lambda=0.989	0.860
Aluminium vs. control	Wilk's lambda=0.846	0.105	Aluminium vs. placebo	Wilk's lambda=0.982	0.787

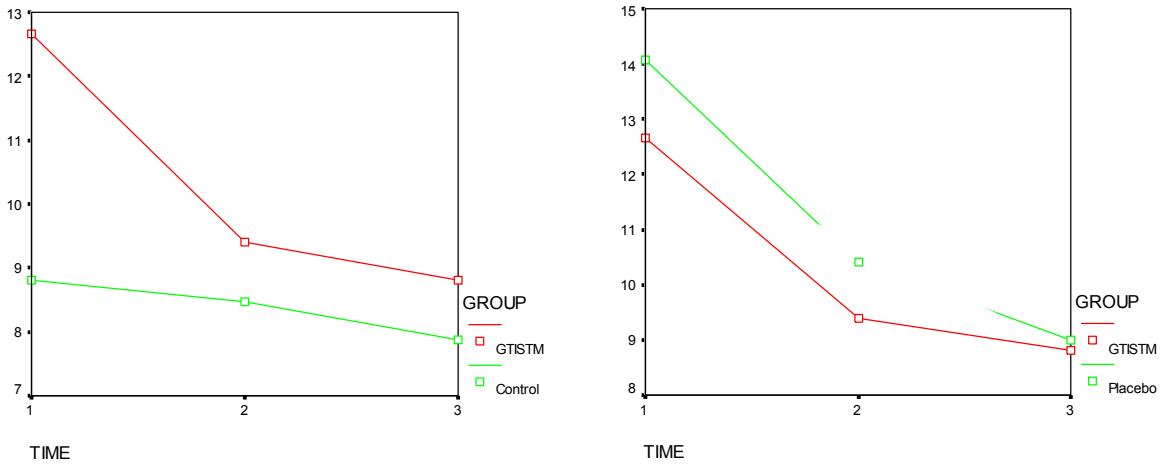


Figure 69 and 70: Profile plot of mean CMCC score over time by group: GTISTM vs. Control and GTISTM vs. Placebo

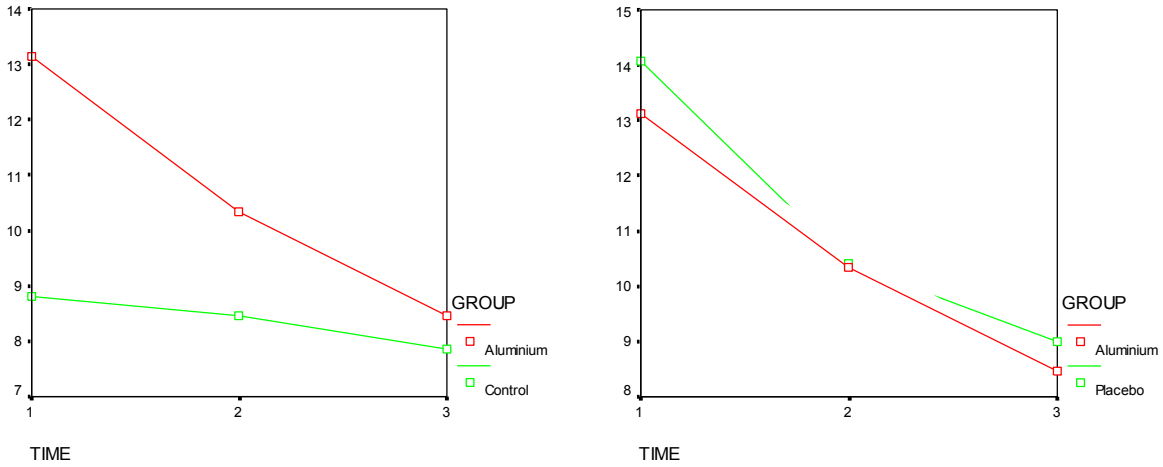


Figure 71 and 72: Profile plot of mean CMCC score over time by group: Aluminium vs. Control and Aluminium vs. Placebo

4.7 SUMMARY AND CONCLUSIONS

In the comparison of the treatment effects of the GTISTM instrument with the aluminium instrument, three outcomes showed significant differences in treatment effect. These were algometer measurements for left levator scapula, right levator scapular, and flexion. In the first two of these outcomes the aluminium instrument was superior to the stainless steel instrument and in the last outcome the stainless steel instrument was better.

Both the Stainless steel and the aluminium instrument were superior to the control treatment for two outcomes each. For the stainless steel instrument these outcomes were NRS-101 and CMCC (both subjective) and for the aluminium group these outcomes were the right levator scapular algometer and NRS-101.

The treatment effect of the aluminium instrument was superior to the treatment effect of the placebo group for one outcome (left levator scapula). The stainless steel group was not significantly better than the placebo group for any outcome. There was evidence of a placebo effect as for many of the outcomes the placebo group showed an improvement over time.

In many tests there was a trend which showed or suggested a beneficial treatment effect in either of the treatment groups, but due to lack of statistical power this interaction did not reach statistical significance. Further larger studies are recommended, where participants are randomized into two groups to receive treatment with either the stainless steel instrument or the aluminium instrument in order to conclusively answer this research question.

CHAPTER FIVE

DISCUSSION OF RESULTS

5.1 INTRODUCTION

The results obtained from demographic data and the statistical analysis of the subjective and objective data will be discussed in this chapter. This data will be discussed in terms of the objectives described in chapter one.

5.2 DISCUSSION OF DEMOGRAPHIC DATA

Sixty participants who met eligibility criteria were randomised into four groups: GTISTM (stainless steel), aluminum instrument, placebo and control. Demographic characteristics were compared among the four groups to ensure that the randomization process was complete in eliminating confounding variables between the groups.

5.2.1 Age

The sample consisted of 60 participants ranging in age from 19 to 55 years, with a mean age of 37.7 years (Figure 1). Travel and Simons' (1999) state that individuals of any age can develop MTrPs, the age group demonstrated in this study is congruent with that of other studies conducted. Hanten et al. (2000) described an age group of and 23 to 58 years, and Gam et al. (1998) an age group of 18 to 60 years.

There was no actual significant difference in the mean age between the treatment groups (Table 1); however the mean age of the control group was lower than that of the treatment groups. It is therefore acknowledged that their response to observation would be greater (Hawthorne effect–Mouton, 2002) than patients of an older age. This assertion is however negated in that the condition understudy (MTrPs) has similar activating and perpetuating

factors (Travel and Simons', 1999) which are more closely related to occupation as apposed to age (Travel and Simons', 1999), therefore the effect of age is not considered as a confounding variable in this study.

5.2.2 Gender

The majority of the participants in the study were female (66.7% - Table 3). There was no significant difference in the distribution of men and women among the treatment groups (Table 4). Individuals of either sex can develop MTrPs (Travel and Simons, 1999). Studies by Hou et al. (2002) as well as Han and Harrison (1997) found that MPS occurred in both sexes; however it was found to be more common in females.

5.2.3 Race

Figure 2 shows that the majority of the participants were White (43%), followed by Indians (38%), the remaining 19% consisted of Africans and Coloureds. However, this racial distribution does not reflect the population of the province. The largest racial group in the province of Kwa-Zulu Natal is African, followed by Indian and thirdly the White (Lehohla, 2004).

Although the largest racial group is African, the majority of this population lives in rural areas (Lehohla, 2004); this may account for the lower number of African participants. In addition the African population may not be familiar with Chiropractic, which is derived from Western culture.

These results are however congruent with those of other studies conducted on MPS at the DIT Chiropractic Clinic which also found a majority of White participants followed by Indians (Walker, 2002; Bedell-Sivright, 2005).

The GTISTM and control group had the highest proportion of White participants, 60% and 26.7% respectively, with the aluminium and placebo groups having a majority of Indian participants (53.3% each) as shown in Table 5.

Prout (1996) concludes that the notion of cultural bias is a more flexible, realistic and useful way of conceptualizing variations in household health practices and beliefs. Therefore there seems to be a need to educate parts of our society so that all may benefit from that part of health care that chiropractic provides.

5.2.4 Occupation

The majority of participants (95%) had non-manual occupations (Table 7); this is consistent with Sola et al. (1981) who found that sedentary workers were more susceptible to MPS than manual workers. Walker (2002) and Pillay (2003) also found larger percentages of non-manual occupations (secretaries and students), this is supported by Han and Harrison (1997) who stated that poor posture associated with prolonged sitting at a desk may be related to an increased prevalence of MPS.

Table 7 shows that there was no significant difference in type of occupation between treatment groups and that the proportion of manual workers was very small in all groups. The highest percentage of manual workers was found in the GTISTM group (13.3%) but this constituted only two subjects as compared to one subject in the placebo and no subjects in the aluminium and control groups, therefore no significant treatment effect is expected as a result of this difference in the group's constitution.

5.3 DISCUSSION OF OBJECTIVE DATA (GTISTM vs. ALUMINIUM)

5.3.1 Algometer

The algometer is an instrument that is used to quantitatively measure the amount of pressure needed to produce local pain or tenderness. Measurements were taken at the minimum point of discomfort; this is known as the minimum pressure threshold (Fischer, 1987:207). The higher the pressure tolerated by the participant, the lower the level of local tenderness.

The decease in pain levels can be attributed to the beneficial effects of manual loading of both the GTISTM and aluminium instruments on soft tissues. The mechanical loading of the instrument over the muscle applies an intense, specific localized stretch over the taut band which helps break down and separate actin-myosin cross fiber links (Schneider, 1994; Cary-Loghmani, 2003:55; Hammer, 2001), this reduces muscle spasm and deactivates the MTrPs (Gatterman and Goe, 1990; Thomson et al., 1991:444; Prentice, 1994:351). As a result the mobility between the tissue interfaces is restored and increases the extensibility of the structures (Cyriax, 1984:9; Hertling and Kessler, 1996:134).

The deep pressure also inhibits the incoming sensory input of pain; in addition it is thought that the pressure may also causes the release of the body's natural pain killers, i.e. endorphins (Schneider, 1994). In addition the decrease in pain levels can be explained by the "Gate Control Theory'' proposed by Melzack and Wall (1965). The theory proposes that a physiological "gate'' modulates the transmission of nerve impulses from the periphery to the central cells; this "gate'' mechanism is attributed to the substantia gelatinosa (SG). Afferent nerve impulses are transmitted through large and small nerve fibers, influencing the T cells and the ascending transmissions to the brain. These T cells may be inhibited by the SG which is influenced by the activity of the large and small diameter fibers (Melzack and Wall, 1965).

Stimulation of the smaller fibers carries impulses from the nociceptors (pain receptors) that "open" the gate allowing pain to be transmitted to the brain. The stimulation of the larger fibers "closes" the gate by over-riding the smaller fibers and therefore preventing the sensation of pain from reaching the brain (Melzack and Wall, 1965).

The mechanism of pain reduction in the treatment groups may act on this principle: the GTISTM and aluminium instrument may influence the larger fibers to close the "gate" and decrease the sensation of pain experienced (Lynch and Kessler, 1990:48).

In terms of algometer readings, levator scapula bilaterally showed significant differences in treatment effect over time (Figure 5 and 6). For these outcomes, the aluminium instrument would seem to be of greater benefit to GTISTM (stainless steel). The mean value of the treatment response of the aluminium group increased over time while that of the GTISTM group decreased. Therefore the null hypothesis is rejected, as there is a statistically significant difference in effectiveness of treatments.

However, this may not be a true reflection as the majority of the participants did not have both levator scapular MTrPs and therefore not all participants were included in the analysis, allowing for data skewing.

In addition the mean value after two treatments (T2) for the ***aluminium group*** indicates that the subjects' pain tolerance deceased which may indicate that the aluminium instrument may have aggravated the pain, suggesting that this instrument seems to be contraindicated for high frequency treatment application. In addition the improvement in pain at T3 (a one week follow up from T2) may be due to the natural history of the condition, without the irritant of the tool which resulted in the increased mean scores of the algometer.

The exception to the above discussion is the right trapezius where there was initial improvement followed by regression in the T2-T3 period with a subsequent overall decrease in algometer readings over time. This exception seems to be correlated with the handedness of the subjects, the majority of whom were right handed, with the most severe MTrPs on the right as a result. This could indicate that no matter the type of intervention, the patients would have improved initially due to mechanical stimuli to the area activating the "Gate Control Theory" (Melzack and Wall, 1965), with the possibility of being aggravated after this improvement (as related to the aggravation experienced in the less severe MTrPs (e.g. levator scapula) at the T1-T2 period), where the MTrP rating would have been less severe. The implication is that the aluminium instrument seems to act as an irritant for MTrPs that are of a less severe nature (as per the MFDS (Chettair, 2001) which is congruent with the

literature that indicates perpetuation/activation of MTrPs by mechanical abuse (Chaitow and DeLany, 2003; Travel and Simons', 1999).

There is a trend evident that ***GTISTM*** causes an initial improvement (T1 to T2). However this is followed by increase in the pain levels from T2 to T3. This trend was apparent in all the muscles from which algometer readings were taken (Figure 3-6). This supports GTISTM as a treatment modality used in high frequency treatment of MTrPs, which is in contrast to the inference made in respect of the aluminium treatment instrument, where it was indicated that it is not suitable for high frequency treatments.

As the instrument design, delivery method and technique were identical in each group, it therefore leads the researcher to assume that the only viable dissimilarity accountable for the differences between the groups could be related to instrument material.

5.3.2 Cervical Range of Motion (CROM)

The cervical range of motion goniometer (CROM), was used to measure flexion, extension, lateral flexion and rotation of the cervical spine, as these movements are most closely linked to the muscles under study (levator scapulae and trapezii) (Moore, 1999). The CROM goniometer has been found to be reliable, both intra and inter-tester, in the measurement of cervical range of motion (Rheault et al. 1992). Youdas et al. (1991) established the CROM goniometer to be highly reliable when compared to other cervical range of motion techniques such as universal or visual estimation.

A common trend is observed in the treatment effect from T1 and T2 in ***both groups***, the measurements for flexion (stretch of both muscles), extension (contraction of both muscles), right lateral flexion (left trapezius and levator scapula), left (left levator scapula and right trapezius) and right (right levator scapula and left trapezius) rotation all showed an improvement in range of motion. The exception was for flexion and extension where no improvement was noted in the aluminium group (Figure 7,8,10-12).

Between T2 and T3 however, the measurements decreased for left (left levator scapula and right trapezius) and right (right levator scapula and left trapezius) rotation in the aluminium group but the GTISTM group continued to increased.

Flexion (stretch of both muscles) and right lateral flexion of the GTISTM group measurement decreased in value between T2 and T3 (Figure7 and 10), whereas the treatment effects of the aluminium group continued to rise although it was marginal. Extension (contraction of both muscles) continued to improve in the aluminium as did the GTISTM (Figure 8).

The only measurement that did not follow a trend was left lateral flexion (Figure 9) in the GTISTM group, where a decrease in measurement between T1 and T3 was observed. The aluminium group showed an initial increase between T1 and T2, and then a slight decrease from T2 and T3.

For flexion, there was found to be a statistically significant interaction between time and group (Figure 7). GTISTM was found to be more effective than the aluminium instrument and so the null hypothesis can be rejected.

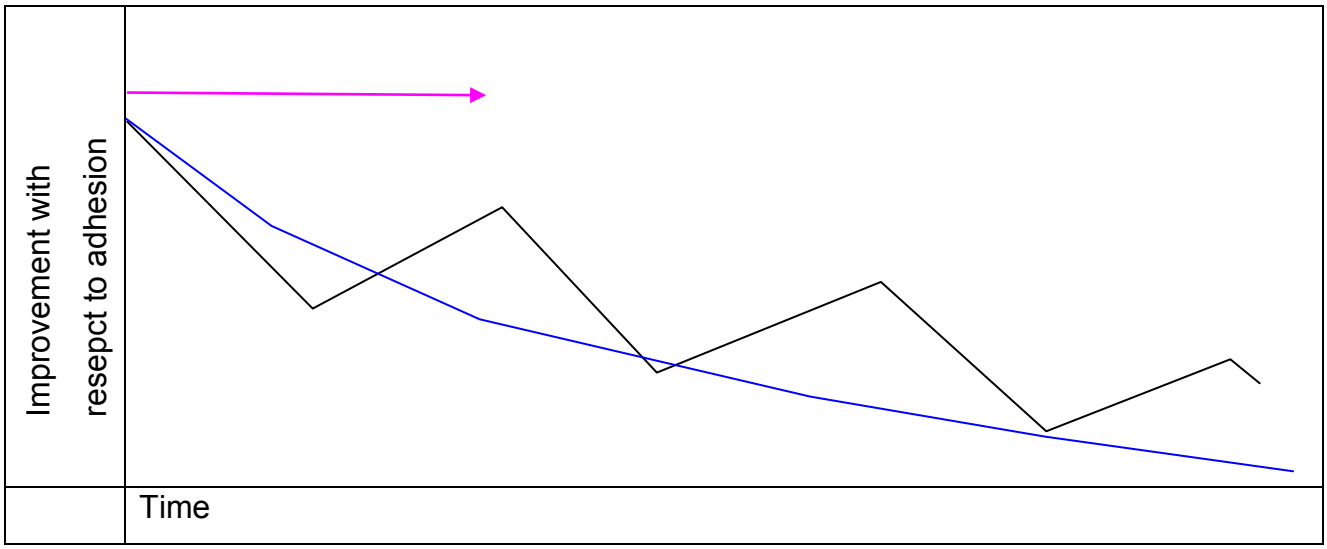
Based on the above, it would seem that the ***GTISTM group*** shows increased muscle extensibility (decreased muscle restriction due to MTrP) and/or contractility with respect to extension, left and right rotation. Right lateral flexion and forward flexion initially increase extensibility/contractility and then decrease, which may be related to the degree (with respect to both number and severity (tethering not pain)) of MTrPs on the right side as evidenced by the findings in the left lateral flexion recordings where there is a consistent decrease in the range of motion indicating decreased extensibility of the right trapezius (most commonly involved muscle).

By default this could be as a result of a decrease in the tethering effect of the MTrPs (with respect to both number and severity (tethering not pain) in especially those muscles presenting with fewer MTrPs (left side and right levator scapula) as opposed to the right trapezius where the majority of MTrPs

were found. This seems to imply that the GTISTM instrument has a greater effect on muscle/fascial extensibility and therefore this supports the literature which indicates that the GTISTM is thought to break adhesions/tethering and thereby increase the ROM within the muscles treated.

This trend seems to be applicable to the ***aluminium group*** as well, when assessing the readings T1-T2, where flexion and extension remain the same and all other readings improve. It is however noted that during the T2-T3 readings, that left lateral flexion as well as left and right rotation decrease, indicating a decrease in the respective muscle extensibility and/or contractility. This follows the pattern of decreased tethering of the muscle as discussed in the GTISTM group above, but also seems to indicate that there are increased points of tether which have formed in the time lapse between the last treatment and the final reading, which has allowed for increased tethering of the muscles presenting with the most MTrPs (right trapezius), without any negative consequences for those muscles with fewer MTrPs (right and left levator scapulae and left trapezius), resulting in either continued or subsequent improvement.

In a schematic summary :



Blue = GTISTM

Black = Aluminium

Pink = Research period for this research

From the above graph, the implications would be that there is a decrease in the reactivity of the trigger points post treatment 1 for both groups.

With the GTISTM group as compared to that of the aluminium group, both result in breaking of adhesions/tethering resulting in reactive inflammation. With this initial inflammation there is still an improvement in the overall ROM recorded as functional activity improves between treatments 1 and 2.

At the second treatment, the depth attained by the researcher in terms of applying GTISTM and aluminium to the muscle and its adhesions was decreased due to the residual effects of the inflammation that occurred post treatment 1. This therefore results in the researcher only being able to break the newly formed adhesions (inflammation as developed as a result of the previous treatment) and also some of the old adhesions, which shows flattening in the overall rate of improvement. The degree to which inflammation is present seems however to be different between the GTISTM and aluminium groups, where the rate of inflammation is less in the GTISTM group. This we suspect could be related to the instrument material, where the GTISTM instrument seems to maintain its temperature (and thereby negate the inflammation reaction created to a degree), where the aluminium instrument by virtue of its composition is not able to achieve this (**Elert, 2005).**

Therefore as expected, the values of the readings taken prior to treatment 3 decreased (reading for effect of treatment 2), as the treatment penetration was less than the penetration of the previous treatment given.

With the decrease in the depth of applied treatment at treatment 2, there is a reduction in the development of inflammatory processes. This allowed the researcher to access the adhesions within the muscle more readily at treatment 3. Thus at the third treatment the researcher was able to access deeper into the muscle allowing for older adhesions to be removed and there is therefore a further rate of improvement (similar to the response as found at treatment 1), giving a greater response in terms of ROM improvement.

Therefore when range of motion is taken into consideration in terms of the algometer findings, it would suggest that even though the GTISTM group for the most part decreased in tenderness overall, the extensibility of the tissues increased with the exception of the following:

- Increased tenderness of the right levator scapula region with decreased left lateral flexion, which are associated with each other and affect each others outcomes, which may have required more intervention as it is suggested that patients receiving GTISTM should have between six to eight treatments.

In the aluminium group there where no associations between the range of motion and the algometer readings, it is noted that the right trapezius showed a decrease in algometer readings and therefore an increased tenderness with time. This is congruent with the decrease in left lateral flexion, right and left rotation at reading T2-T3, which was however not to the same level as the increase that preceded it, therefore not allowing for the decrease to become apparent overall.

This confirms the researchers experience during the research where it was found that the GTISTM group seems to have improved consistently although incrementally as opposed to the aluminium which improved significantly to start with but reverted to outcomes scores close to the initial readings taken.

5.4 DISCUSSION OF SUBJECTIVE DATA (GTISTM vs. ALUMINIUM)

5.4.1 NRS-101

Numerical Rating Scale – 101(NRS-101) was used to assess the perceived level of pain intensity that the patient experienced (Jenson et al., 1986). A reduction in the mean score indicates a reduction in pain whereas an increase in the mean score indicates increased pain perception.

Both groups showed a significant decrease in scores over time, and the overall rate of decrease in NRS-101 score was similar in both groups, with the GTISTM group achieving marginal improvement (Figure 13).

The benefits in both groups can be attributed to the "Gate Control Theory" (Melzack and Wall, 1965), through the stimulation of the large nerve fibers which inhibit the smaller nociceptive fibers. The application of both the GTISTM and aluminium instruments results in mechanical loading of the tissues which aids in separating the muscle fibers and causes a localized stretch of the taut band (Schneider, 1995; Cary-Loghmani, 2003:55). This reduces muscle spasm and deactivates MTrPs which is associated with decreased pain levels (Gatterman and Goe, 1990; Thomson et al., 1991:444; Prentice, 1994:351).

Furthermore the instruments may have additional benefits such as:

- Instrument "cooling effect" as suggested in 2.10.2
- Increased range of motion and therefore proprioceptive and mechanical stimuli
- Decreased MTrP pain referral even though there is increased tenderness.
- In addition the effects of observe-response (Hawthorne) (Mouton, 2002) are not excluded, but it is assumed that this would be applicable in both groups.

5.4.2 CMCC Neck Disability Index

The CMCC Neck Disability Index was used to assess subjective information regarding the degree to which the patient's pain influenced their daily activities. The CMCC Neck Disability Index has been described in chapter three, along with its level of reliability and internal consistency (Vernon and Moir, 1991).

The scores of each section of the CMCC were summed to produce a total score. Table 19 indicates that there is no evidence of any treatment effect between the two groups over time. Graphically, figure 14 suggests that the score decreased at a faster rate for the aluminium group, however this was insignificant and therefore the null hypothesis could not be rejected.

As already discussed (2.7), MTrPs are characterized by a taut band within the muscle which results in restricted range of motion, painful muscle contraction, muscle weakness and referred pain (Travell and Simons', 1999; Chaitow and DeLany, 2003). These characteristics affect daily activities such as driving, working, sleeping and lifting.

In treating MTrPs the GTISTM and aluminium instruments cause a localized stretch which splays and separates the local muscle fibers and cross links (Schneider, 1995; Cary-Loghmani, 2003:55). This stretch decreases muscle spasm, deactivating the MTrP and alleviating the taut band (Gatterman and Goe, 1990; Thomson et al., 1991:444; Prentice, 1994:351). This strecth increases mobility of the muscle resulting in improved range of motion (Cyriax, 1984:9; Hertling and Kessler, 1996:134). The effect of these therapies is evident in the improvement in daily activities such as lifting, driving, work and recreation.

The presence of MTrPs results in pain on contraction of the muscle; this is most noticeable during activities such as lifting and driving. Through deactivating the MTrP and the taut band, muscle strength is restored and pain is reduced resulting in improved function. Similarly through treating the MTrPs, the patient will no longer experience the associated referred pain, resulting in decreased frequency and intensity of headaches (Travell and Simons', 1999).

The improvement of pain and discomfort levels demonstrated in the CMCC can further be attributed to Melzack and Walls "Gate Control Theory" (1965). Through the mechanical stimulation of the tools the large fiber input increases, resulting in decreased nociceptive transmission and lowering of the pain

levels. Lower pain levels would be associated with improved function as reflected in the CMCC.

Notwithstanding the above results it is interesting to note that the activities of muscle contraction (lifting (Figure 4.4.2.4), working (Figure 4.4.2.8)) seem to favour the GTISTM group, which supports the previous discussion (5.3.1), where such demands on the muscle would have been less restricted by the presence of lower levels of inflammation within the muscle groups concerned, over the aluminium group where more inflammation is suggested to occur after the treatment application (T1-T2). With the suggestion that the aluminium group does not decrease the adhesions to the same extent as the GTISTM group over time, the ability for the aluminium group to restore full functional activity at the T2-T3 reading would be less than for the GTISTM group, supporting the assertions of GTISTM breaking more adhesions.

This is probable even in the face of the decreased pain, as pain and the presence or absence of adhesions does not follow a linear relationship.

5.5 DISCUSSION OF INTRA-GROUP CORRELATIONS BETWEEN SUBJECTIVE AND OBJECTIVE FINDINGS

All correlations where taken at the final readings.

Table 1: A discussion on the positive and negative correlations between subjective and objective changes in the GTISTM group (n=15)

Reading 1	Correlation	Reading 2	Discussion
NRS-101	Significantly negative	L lat flex R lat flex L rotation	A decrease in NRS-101 scores represents decreased pain levels which is associated with increased ROM. Subjects would initially have reported the most severe pain on the right. Following treatment this would have resulted in improved movements (stretch and contraction of the right trapezius) as associated with decreased pain.
CMCC	Significantly negative	R lat flex L Trapezius R Lev scapula L Lev scapula	Increased movement and decreased tenderness of muscles improves neck function which is indicated by a decrease in the CMCC score. Therefore with increased ability to perform work the CMCC decreases. This is associated with decreased MTrPs on the associated muscles (as stated) and therefore by implication an increase in right lateral flexion (stretch (left trapezius and lev scap)) as well as contraction (right lev scap). The right trap may not have been significant as the treatment time may have been insufficient (see 5.3.2)
Left lateral flexion	Positive	L rotation	Both of these movements involve the same muscles (left trapezius and levator scapula); therefore an increase in the one movement is expected to be associated with an increase in the other.

Right lateral flexion	Positive	L rotation R trapezius	Deactivation of MTrPs in the right trapezius causes decreased pain and increased ROM of that muscle, therefore the increase in lateral flexion on the same side and rotation to the opposite side can be expected.
Right Trapezius	Positive	R lev scapula L lev scapula	Decreased pain level in the right trap correlates with decreased pain levels in the right lev scap as the muscles overlie one another and function synergistically with another therefore treatment of one will affect the other. In addition the right lev scap correlates with the left lev scap due to neurological cross-over, where treatment effects may affect the other muscle on a neurological reflex pathway (Koceja et al., 1991 and Urbach et al., 1999)
Left Trapezius	Positive	L lev scapula	The muscles overlie one another and function synergistically with the other, therefore treatment of one will affect both.
Right Levator Scapula	Positive	L lev scapula	The right lev scap correlates with the left lev scap due to neurological cross-over (Koceja et al., 1991 and Urbach et al., 1999) as well as highlights the synergistic role of the muscles in flexion and extension.

Table 2: A discussion on the positive and negative correlations between subjective and objective changes in the Aluminium group (n=15)

Reading 1	Correlation	Reading 2	Discussion
NRS-101	Significantly positive	CMCC	As both these readings are subjective measurements of pain and/or disability, this correlation can be expected.
NRS-101	Significantly negative	Extension L Lat flex R rotation L lev scapula	Contraction of the left levator scapula containing MTrPs can be painful. Deactivation of these MTrPs results in decreased pain levels and increased ROM in the contracted position (extension and left lateral flexion) as well as the stretched position (right rotation).
CMCC	Significantly negative	L rotation	Increased ROM is associated with improved function in daily activities and is most closely associated with right trapezius muscle, through its symptoms it affects the degree of movement (increase) as well as activity (decrease as per CMCC = increased functional ability).
Extension	Positive	L lat flex	As for NRS-101 relationship with extension, left lateral flexion and right rotation.
Left lateral flexion	Positive	R lat flex	In deactivating the MTrPs of the trapezii, greater extensibility and contractile strength is achieved. This results in an increase in lateral flexion on the same side (contractile ability) and on the opposite side (extensile ability).
Right lateral flexion	Positive	L rotation R rotation L trapezius	Deactivation of MTrPs in the left trapezius causes decreased pain and increased ROM of that muscle, therefore the increase in right lateral flexion. Left rotation and right lateral flexion would be associated with the increased pliability of the muscle and therefore its stretch.

Right rotation	Positive	R trapezius L trapezius R lev scapula L lev scapula	With respect to the antagonistic relationship of the muscles involved, it would appear that optimal function between them is dictated by the degree of decreased tenderness in all muscles. This function seems to be most closely related to and represented by right rotation (principally resolution of the MTrPs in the levator scapula as most subjects presented with right sided MTrPs).
Right trapezius	Positive	L trapezius R lev scapula	Decreased pain level in the right trap correlates with decreased pain levels in the right levator scapula as the muscles overlie one another; therefore treatment of one will affect the other. The right trap correlates with the left trap due to neurological cross-over with respect to muscle relaxation and decreased pain (Koceja et al., 1991 and Urbach et al., 1999)
Left trapezius	Positive	R lev scapula L lev scapula	With respect to the antagonistic relationship of the muscles involved, it would appear that optimal function between them is dictated by the degree of decreased tenderness in all muscles. This function seems to be most closely related to and represented by right rotation (principally resolution of the MTrPs in the levator scapula as most subjects presented with right sided MTrPs). In addition the right lev scap correlates with the left lev scap due to neurological cross-over effects (Koceja et al., 1991 and Urbach et al., 1999)
Right Levator Scapular	Significantly positive	L lev scapula	The right lev scap correlates with the left lev scap due to neurological cross-over effect (Koceja et al., 1991 and Urbach et al., 1999) as well as the relationship with the left trapezius which would influence this relationship.

Table 3: A discussion on the positive and negative correlations between subjective and objective changes in the Placebo group (n=15)

The following correlations are based on the assumption that the subjects improved based on one of the following:

- "Hawthorne effect" (Mouton, 2002). Therefore by implication the subjective measures versus the objective measures as related to the reported findings may be skewed.
- "Treatment" via the application of cold in terms of the ultrasound gel/ultrasound head.
- Improvement via natural history.

Reading 1	Correlation	Reading 2	Discussion
NRS-101	Positive	CMCC	As both these readings are subjective measurement of pain and/or disability, this correlation can be expected.
NRS-101	Negative	Flexion	Deactivation of MTrPs causes decreased pain levels and increased ROM in the levator scapulae as the principle extensors (i.e. flexion induces a stretch).
CMCC	Negative	R lat flex	Increased ROM is associated with improved function in daily activities, which would correspond with the increased need to utilize / contract the right trapezius for activities of daily living (ADL).
Flexion	Positive	R lat flex R trap	MTrPs in the right levator scapula and trapezius muscle restrict flexion and lateral flexion on the same side (i.e. muscle stretch versus contraction). Treating the MTrPs results in decreased pain and greater flexion and lateral flexion.
Extension	Positive	L lat flex R lat flex	Could be related to the levator scapulae improvement.
Left lateral flexion	Positive	R lat flex	In deactivating the MTrPs of the trapezii, greater extensibility and contractile strength is achieved. This results in an increase in lateral flexion on the same side (contractile ability) and on the opposite side (extensile ability).

Right Rotation	Positive	R trapezius R lev scapula L trapezius	As for flexion, extension, left lateral flexion, the right rotation is determined by a muscle that did not have a significant number of active MTrPs, therefore the association with the related muscles is determined for the most part by the stretch on contraction of those muscles associated with the identified movement.
Right trapezius	Positive	L trapezius R lev scapula	It would seem that the subjects showed either little or no improvement overall, nevertheless improvement in any one facet with respect to tenderness seems to have been mirrored in all muscles. This could be related to decreased referral/actual pain and resultant functional improvement with time (i.e. natural history).
Left Trapezius	Positive	R lev scapula L lev scapula	
Right Levator Scapular	Positive	L lev scapula	

Table 4: A discussion on the positive and negative correlations between subjective and objective changes in the Control group (n=15)

The following correlations are based on the assumption that the subjects improved based on one of the following:

- "Hawthorne effect" (Mouton, 2002). Therefore by implication the subjective measures versus the objective measures as related to the reported findings may be skewed.
- Improvement via natural history.

Reading 1	Correlation	Reading 2	Discussion
NRS-101	Positive	CMCC	As both these reading are subjective measurements of pain and/or disability, this correlation can be expected.
Extension	Positive	R rotation	Extension is principally a function of the levator scapulae, which seem to be related to the trapezii (as below) and thus a relationship with rotation could exist.
Left rotation	Positive	R rotation	Decreased pain level in the left trap correlates with decreased pain levels in the left lev scap as the muscles overlie one another therefore treatment of one will affect the other. Furthermore it would seem that the trapezii are related to one another, both in the number of trigger points (i.e. algometer reading) as well as the degree of functional ability of the muscles.
Right Trapezius	Positive	L trap L lev scapula	
Left Trapezius	Positive	L lev scapula	

5.6 DISCUSSION OF TREATMENT GROUPS vs. CONTROL GROUP

5.6.1 Objective Outcomes

5.6.1.1 Algometer

The data collected from the control group was used to assess the natural progression of patients with myofascial pain. These readings were used as a baseline for comparison with the data from the treatment and the placebo group (Mouton, 2002:159; Kienle and Kiene, 1998:21).

As the ***control group*** did not undergo any treatment, the MTrPs runs its natural course and can be expected to fluctuate with time. Daily activities such as lifting objects, driving and poor posture etc. may perpetuate active MTrPs and therefore continue to increase the pain levels.

The decease in pain levels observed in the ***treatment groups*** can be attributed to the beneficial effects of manual loading of both the GTISTM and aluminium instruments on soft tissues as discussed in section 5.3.1.

Two statistically significant effects of treatment versus the control group were observed:

- GTISTM of the left trapezius indicates a borderline significant effect (Table 36), and
- There was a significant effect of the aluminium instrument on the right levator scapula muscle (Table 38).

Although insignificant statistically certain trends were observed, improvements in pain levels over time were observed for right and left trapezius (Figure 25 and 29) and right levator scapula (Figure 33) in the GTISTM group. This is in contrast to the control group where increased pain levels were observed in the same muscle groups.

In conclusion, the GTISTM and the aluminium groups faired better than the control group with respect to the algometer findings and therefore it can be further concluded that for decreased tenderness the aluminium and the GTISTM both have beneficial effects.

5.6.1.2 CROM

Statistically there were no significant findings of treatment effects in either group versus the control group, certain trends however were observed.

The GTISTM group showed an increase in ROM for all measurements between T1 and T2 with the exception of left lateral flexion which decreased throughout the treatment protocol (Figures 41, 45, 49, 53, 61). Extension, left and right rotation continued to improve to T3 (Figures 45, 49 and 53). Flexion and right lateral flexion ROM decreased between T2 and T3 but had an overall improvement over time (Figure 41 and 61).

The aluminium groups showed an increase in all movements over time, but the treatment effects were statistically insignificant when compared to the control group. Flexion and extension showed no change at T2, however there was an increase at T3, with an overall increase in ROM between T1 and T3 (Figure 43 and 47). Left rotation, right rotation, left lateral flexion and right lateral flexion all showed an improvement at T2, but decreased at the one week follow up (T3); however there was an overall increase between T1 and T2 (Figures 51,55,59 and 63).

The readings from the control group were varied, with an increase in flexion, left rotation and right rotation at T2 (Figure 43, 53 and 55). All three of these measurements decreased to the same readings taken on the first consultation indicating that there was no improvement over time. Both extension and right lateral flexion decreased at T2, the lateral flexion continued to decrease to T3 whereas extension improved at T3 but still decreased in ROM from T1 and T3 (Figure 44 and 61). Left lateral flexion remained the same at T2 and improved fractionally at T3 (Figure 57).

The pressure the GTISTM and aluminium instruments apply over the MTrPs is believed to restore the abnormally contracted sarcomeres found in the contracted knot of a MTrP to their normal resting length (McPartland, 2004). Once the MTrPs have been inactivated, the increased extensibility of the involved muscles would promote an increase in ROM and prevent the development of muscular imbalances from occurring which may result in the evolution of chronic pain syndromes.

The control group results indicate that no improvement occurred in ROM over T1 and T3 in flexion, left and right rotation (Figures 42, 49 and 53). Extension and right lateral flexion actually decreased in movement over this time (Figures 45 and 61). This can be expected as no form of treatment was given during the duration of the study. MTrPs when left untreated result in a reduced extensibility of the involved muscle with a consequently decrease in ROM.

In conclusion, the GTISTM and the aluminium groups faired better than the control group with respect to the CROM findings and therefore it can be further concluded that for decreased tenderness the aluminium and the GTISTM both have beneficial effects.

5.6.2 Subjective Outcomes

5.6.2.1 NRS-101

When the treatment groups were compared to the control group, it was found that the effects of the treatment for the treatment groups were significantly more effective than the control group (Figure 65 and 67). The effects of the treatment have been discussed in section 5.3.1. and as a result one expects to see an improvements noted in these groups.

5.6.2.2 CMCC

When compared to the control group, the treatment effects of GTISTM were found to be significantly more effective than the control (Figure 69). The

treatment effects of the aluminium group were also apparent but were not statistically significant (Figure 71).

In conclusion we see that the GTISTM group improves more than the aluminium group in terms of the comparison with the control group overall. The most noted difference is with respect to the CMCC between the GTISTM and aluminium, with smaller differences between the groups (aluminium and GTISTM) with respect to NRS-101, CROM and algometer.

This supports the assertions that the GTISTM is the more beneficial tool in terms of treatment frequency as well as in terms of the stimulation of the physiological processes in order to establish normalcy in the muscles containing MTrPs (i.e. inflammation).

5.7 DISCUSSION OF TREATMENT GROUPS vs. PLACEBO GROUP

The similarities in the application of ultrasound to the treatment groups were the reasoning for using this modality as the placebo; both treatments involve the use of a metal surface and a form of lubrication over the area being treated.

5.7.1 Objective Outcomes

5.7.1.1 Algometer

There were no statistically significant differences between the treatment groups and the placebo group, except for the positive effect of the aluminium instrument on the pain intensity of the left levator scapula muscle (Table 41). The decreased pain levels observed in the treatment groups are expected and have been discussed in section 5.3.1.

Figures 26,28,30,32,34,36,38,40 indicate that the pain intensity of the placebo decreased at T2 for all the involved muscles, however only the right and left Trapezius continued to decrease in pain to T3 (Figures 26,28,30 and

32), the right levator scapular remained the same at T3 but showed an overall improvement between T1 and T3 (Figures 34 and 36). The pain intensity of the left levator scapula muscle increased between T2 and T3 with a resultant increase between T1 and T3 (Figures 38 and 40).

The improvements observed in the placebo group may be due to a number of factors:

- Due to natural history, pain and discomfort decrease over time with the healing and strengthening of an injury (Lachmann and Jenner, 1994:28).

- The increased mechano-receptive activity as a result of the stimulation of the ultrasound head on the skin causes a reduction in the amount of pain transmitted as per the "Gate Control Theory" (Melzack and Wall, 1965:971; Lynch and Kessler, 1990:48).

- Placebo effect – the patient's perception of pain may altered by the influence the treatment intervention has on the psychology of the patient. The improvement is not however based on a physiological response associated with healing, and therefore this perception is altered with time as the patient does not respond physiologically to the treatment and maintains the same level of dysfunctional ability. (Mouton, 2002)

- "Hawthorne effect" – this is caused by the presence of the Doctor which influences the patients' response to be more favorable. The patients try to please the Doctor with a well intentioned but false subjective improvement that does not correlate with their objective response. In the case of the algometer measurements, patients may have delayed their response in order to give the results the patient thinks are the desired results. This effect is negated with time as the patient does not

> respond physiologically to the treatment and maintains the same level of dysfunctional ability. (Mouton, 2002)

Therefore in summary the GTISTM and aluminium seem to be no better than the placebo in terms of the measured tenderness as recorded algometer, however it must be noted that tenderness results from an inflammatory process or irritation to the structures underlying the area in which the algometer is applied, therefore application that would result in a change in this pathophysiology would affect the recorded tenderness. In this case the probability of the ultrasound gel/ultrasound head cooling the area could be perceived as a form of therapy, thereby negating the “placebo effect” within the group.

This seems to be particularly relevant in view of the discussion (2.10.2), where it is indicated that the cooling effect (Elert, 2005) of the instruments (GTISTM and aluminium) may be responsible for the differences between the two groups.

In addition to the above it must also be acknowledged that the application of the treatment in the short term may not reflect any better than placebo as a result of the increased pathophysiological reactions (e.g. inflammation) that are induced by treatment application. This may in the short term increase the tenderness of the tissues, but resolve the clinical picture with which the patient reports (as patients do not report tenderness, only overt pain).

It is therefore recommended that future research looks at the frequency of treatment over a prolonged period before a determination can be made with respect to the efficacy of either the GTISTM or aluminium in terms of the algometer findings.

5.7.1.2 CROM

Statistically there is no significance between the treatment groups and the placebo group (Tables 43, 45, 47, 49, 51 and 53). Although insignificant the

GTISTM group improved at a quicker rate than the placebo group for left and right rotation (Figure 50 and 54). The improvements observed in the treatment groups have been discussed in section 5.6.1.2.

The same discussion in respect of the effects of the current placebo can be found under 5.7.1.1.

It is therefore recommended that future research looks at the frequency of treatment over a prolonged period before a determination can be made with respect to the efficacy of either the GTISTM or aluminium in terms of the CROM findings.

5.7.2 Subjective Outcomes

5.7.2.1 NRS-101

Both the GTISTM and the aluminium group did not show a significant treatment effect when compared to the placebo group (Table 55). All three groups reported a decrease in the CMCC score which is an indication that neck function has improved, however this was not statistically significant and when assessed in light of the findings above (5.7.1.1), it becomes apparent the effect of the perceived treatment was related to a greater degree to the cooling effect of the ultrasound gel and not the effect of the detuned ultrasound.

5.7.2.2 CMCC

There were no significant differences found between the three groups (Table 57). The changes in scores over time were similar in all three groups.

This must however be taken into consideration with view to the fact, that the application of the treatment in the short term may not reflect any better than placebo as a result of the increased pathophysiological reactions (e.g. inflammation) that is induced by treatment application. This may in the short

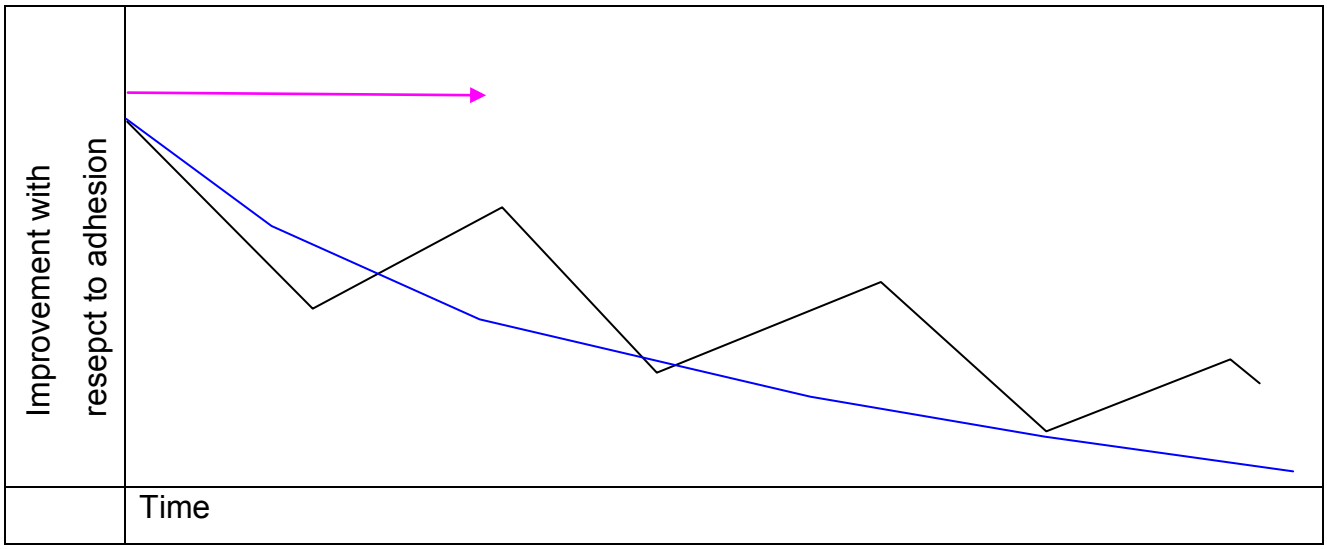
term increase the tenderness of the tissues, affecting the activities, but resolve the overall clinical picture with which the patient reports (as patients do not report tenderness, only overt pain).

5.8 SUMMARY AND CONCLUSIONS

Based on the above presentation, it would seem that the ***GTISTM group*** shows increased muscle extensibility (decreased muscle restriction due to MTrP) and/or contractility. By default this could be as a result of a decrease in the tethering effect of the MTrPs (with respect to both number and severity (tethering not pain) in especially those muscles presenting with fewer MTrPs. This seems to imply that the GT instrument has a greater effect on muscle/fascial extensibility and therefore this supports the literature which indicates that the GTISTM is thought to break adhesions/tethering and thereby increase the ROM within the muscles treated.

This trend seems to be applicable to the ***aluminium group*** as well, when assessing the readings T1-T2. It is however noted that the T2-T3 readings, indicate a decrease in the respective muscle extensibility and/or contractility. This does not follow the pattern of decreased tethering of the muscle as discussed in the GTISTM group above, but rather seems to indicate that there are increased points of tether (adhesions) which have formed in the time lapse between the last treatment and the final reading, which has allowed for increased tethering of the muscles.

In a schematic summary :



Blue = Graston

Black = Aluminium

Pink = Research period for this research

From the above graph, the implications would be that there is a decrease in the reactivity of the trigger points post treatment one for both groups.

With the GTISTM group as compared to that of the aluminium group, both result in breaking of adhesions/tethering resulting in reactive inflammation. With this initial inflammation there is still an improvement in the overall ROM recorded, as functional activity (CMCC, NRS-101) improves between treatments 1 and 2.

At the second treatment, the depth attained by the researcher in applying GTISTM and aluminium to the muscle and its adhesions was decreased due to the residual effects of the inflammation that had occurred post treatment 1. This therefore results in the researcher only being able to break the newly formed adhesions (inflammation as developed as a result of the previous treatment) and also some of the old adhesions, showing flattening in the overall rate of improvement. The degree to which inflammation is present seems however to be different between the GTISTM and aluminium groups, where the rate of inflammation is less in the GTISTM group. This we suspect

could be related to the instrument material, where the GTISTM instrument seems to maintain its temperature (and thereby negate the inflammation reaction created to a degree), where the aluminium instrument by virtue of its composition is not able to achieve this.

Therefore as expected, the readings taken prior to treatment 3 (reading for effect of treatment 2), were less than those for the previous treatment given.

With the decreased depth of applied treatment at treatment 2, there is a reduced development of inflammatory processes at treatment 3. This allowed the researcher to access the adhesions within the muscle more readily at treatment 3. Thus at the third treatment the researcher was able to access deeper into the muscle allowing for older adhesions to be removed and there is therefore a further rate of improvement (similar to the response as found at treatment 1), giving a greater response in terms of clinical improvement.

This process is supported by the results found in the “placebo group” where similar results where found. It was not expected at the outset of this study that an instrument “cooling” effect could be present; therefore a placebo emulating the treatment groups was taken as the most consistent placebo reflecting the actual treatment. However at the conclusion of this study we find ourselves in a position where the gel and stainless steel (ultrasound) application in the placebo group seem to support the suggestion made in this study that the GTISTM group has better clinical outcomes over time (i.e. frequency of application and reduction of adhesions) than the aluminium group, which would seem to be related to the instrument applying a cooling effect over the initiated pathophysiological reactions (e.g. inflammation) initiated by both the aluminium and GTISTM instruments resulting in the difference between the outcomes in the aluminium and GTISTM groups.

5.8.1 The first hypothesis

The stainless steel GTISTM instrument would be more effective than the aluminium instrument terms of objective clinical findings, in the treatment of myofascial trigger points.

The above is *accepted in terms of* the increased benefit with respect to treatment frequency (as noted by algometer findings) and treatment effect (limited inflammation) for the GTISTM group as compared to the aluminium group.

5.8.2 The second hypothesis

The stainless steel GTISTM instrument would be more effective than the aluminium instrument terms of subjective clinical findings, in the treatment of myofascial trigger points.

The above hypothesis remains *undetermined* as the effects of the GTISTM, aluminium and the placebo show the same trends indicating that the measurement tools in terms of subjective reporting were not sensitive enough to discriminate between the groups.

5.8.3 The third hypothesis

Trends would be evident between the objective and subjective clinical findings, demonstrating a relationship between these findings.

The above hypothesis is *accepted* as similar trends were found between the two treatment groups in terms of treatment application and its effect on the MTrPs even though the clinical outcomes obtained indicated different modifying agents (instrument material).

5.8.4 The fourth hypothesis

The GTISTM and aluminium instruments would be more effective than the control group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

The above hypothesis is *accepted* as both treatment groups faired better than the control group.

5.8.5 The fifth hypothesis

The GTISTM and aluminium instruments would be more effective than the placebo group in terms of objective and subjective clinical findings, in the treatment of myofascial trigger points.

The above hypothesis is *accepted with reservation* as both treatment groups and the placebo group had similar outcomes which seemed to have been related to the method of application of the ”intervention” where it seems that the placebo may have had a therapeutic effect.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 INTRODUCTION

This chapter will discuss the outcomes of the research as well as make recommendations with regards to further research.

6.2 CONCLUSIONS

The purpose of this study was to determine if there was a clinical difference between the GTISTM instruments and instruments of the exact design but of a different material (i.e. aluminium) as well as whether these instruments showed any difference to a placebo control and natural history processes.

It could be stated in conclusion that the GTISTM instruments show better clinical outcomes when applied frequently over the regions of the MTrPs as opposed to the aluminium instruments which show decreased clinical outcomes. It is proposed that the cooling effect of the GTISTM instrument is principally related to this clinical phenomenon, as in principle both instrument groups work at the same mechanical level. This is supported by the results obtained in the placebo group where it is suspected that the cooling effect of the ultrasound gel and/or stainless steel head resulted in similar findings.

In terms of the outcomes between the treatment groups and the placebo and natural history groups, it was found that both instruments were better in obtaining improved clinical outcomes over the natural history group.

There were correlations between the improved clinical outcomes between the GTISTM and the placebo, which seems be related to the cooling effect of the two “treatment” modalities utilized. The aluminium group improved when compared to the placebo and natural history groups, but to a lesser extent

than the GTISTM group. The effect of the intervention is on a mechanical level and allows for some clinical improvement above natural history but similar to that of the placebo which seems to have affected the clinical syndrome of MTrPs by a physiological mechanism as opposed to a mechanical one.

Therefore the outcomes of this research support the clinical use of the GTISTM above that of aluminium as the GTISTM has a two fold effect (mechanical and physiological/cooling) as compared to the aluminium which has only one mechanism of action (mechanical).

6.3 RECOMMENDATIONS

1) Lack of blinding could have resulted in researcher bias. Having a peer intern or clinician to take objective and subjective measures may result in more reliable readings.

2) A larger sample size is suggested to improve the validity of the study and for the results to be more statistically significant.

3) The Graston Technique (GT) = GISTM + exercise. For the purposes of this research, participants did not receive the full GT protocol. It is important to note, that GISTM should be used in conjunction with a cardio warm-up, targeted stretching and strengthening exercises and post treatment cryotherapy. By following this comprehensive treatment approach, the full benefit/effect of GISTM can be realized.

4) Increasing the frequency and number of treatments may provide more accurate information as to the effectiveness of the GTISTM instrument.

5) Equal sample stratification in terms of age, race, gender between the four groups may give a more accurate reflection of the effectiveness of the instruments.

6) Due to the possible cooling effect of the gel, it is suggested that lazer be used as an alternative to the detuned ultrasound as the placebo intervention.

7) The objective and subjective measures used in this study were indirect measures of MTrPs, further research should consider using more direct measures such as EMG or diagnostic ultrasound.

8) In future studies it is recommended that a comparative analysis of the baseline differences between groups for the variables algometer, CROM, NRS-101 and CMCC is conducted. This analysis would demonstrate if there was significant variation with respect to the baseline levels of these variables.

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Appendix A

ARE YOU BETWEEN THE AGES **18** AND **55** AND SUFFER FROM

NECK PAIN AS A RESULT OF MUSCLE KNOTS IN THE NECK AND UPPER SHOULDERS?

RESEACH IS CURRENTLY BEING CARRIED OUT AT THE DURBAN INSTITUTE OF TECHNOLOGY CHIROPRACTIC DAY CLINIC

FREE TREATMENT

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

FOR FURTHER INFORMATION CONTACT MARCUS ON 204 2205/2512

Appendix B

Letter of information

Dear Participant

Welcome to this study

Title of the study

The influence of component materials on Graston Technique effectiveness during the treatment of myofascial pain syndrome.

Supervisor: Dr C Korporaal Contact number: (031) 204-2611
(M.Tech:Chiropractic, CCFC, CCSP,ICSSD)

Research Student: Marcus Georgiou Contact number (031) 204-2512

Purpose of study
The aim of this study is to determine the influence of component materials in the clinical outcome of Graston Technique in the management of myofascial pain syndrome in patients with trigger points in the levator scapular and trapezius muscles in terms of subjective and objective findings.

Procedures:
At the initial consultation you will be screened for suitability. Suitable patients will then be randomly allocated into four groups. Two of the groups will receive treatment while the third group will make up the placebo group and the fourth group will form the control group. Clinical measurements will also be taken on the initial consultation. A total of 3 treatments will take place over a period of two weeks. The second and third clinical assessment will take place at week 2 and 3 respectively of the research period.

Risks/ Discomforts
The application of the Graston instruments may produce some discomfort and/or bruising, but is temporary in nature and does not cause any harm. The applied pressure over the affected area may be modified to suite the patient; however some discomfort may be necessary to release muscle restrictions and treat the trigger points.

Benefits
According to current hypotheses you will benefit from the treatment of myofascial pain syndrome. Your participation will also assist in establishing the effectiveness of the Graston technique instruments.

New findings
Any new findings during the course of the study will be made available to you.

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

- If you are unable to attend all your appointments.
- If during your participation in this study you have made changes in your lifestyle that may affect the outcome of the study e.g. medication, supplements or other forms treatment.

Confidentiality:

All patient information is confidential. The results of the study will be made available in the Durban Institute of Technology Library in the form of a mini-dissertation.

You are free to withdraw from the study at any stage. Please don't hesitate to ask questions on any aspect of the study. Your full co-operation will assist the Chiropractic profession in expanding its knowledge of this condition and the instruments used to treat it.

Your participation in this study is greatly appreciated.

Yours sincerely

……	……
Marcus Georgiou	Dr C Korporaal
(Research Student)	(Supervisor)

Appendix C

Informed Consent Form

Title of research project: "*The influence of component materials on Graston Technique effectiveness during the treatment of myofascial pain syndrome"*.

Name of Supervisor: Dr. C. Korporaal (M.Tech:Chiropractic, CCFC, CCSP, ICSSD)
Tel: 031 2042611

Name of research students: Marcus Georgiou
Tel: (031) 204-2512

Date: _____

Please circle the appropriate answer

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 answer to your questions? Yes / No
4. Have you had an opportunity to discuss this study? Yes / No
5. Have you received enough information about this study? Yes / No
6. Who have you spoken to anyone? , if yes, who? Yes / No

_____

7. Do you understand the implications of your involvement in this study? Yes / No
8. Do you understand that you are free to withdraw from this study? Yes / No
   a) at any time
   b) without having to give any reason for withdrawing, and
   c) without effecting your future health care.

9. Do you agree to voluntarily participate in this study? Yes / No

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

_____ _____

Patient Signature Guardian Signature

_____ _____

Date Date

Appendix D

DURBAN INSTITUTE OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient: _____ Date: _____

File # : _____ Age: _____

Sex : _____ Occupation: _____

Intern : _____ Signature _____

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: Signature :

Case History:

Examination:

Previous: Current:

X-Ray Studies:

Previous: Current:

Clinical Path. lab:

Previous: Current:

CASE STATUS:

PTT:	Signature:	Date:

CONDITIONAL:
Reason for Conditional:

Signature: Date:

Conditions met in Visit No:	Signed into PTT:	Date:
Case Summary signed off:		Date:

Intern's Case History:

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

3. **Present Illness:**

	Complaint 1	**Complaint 2**
▸ Location ▸ Onset : Initial: Recent: 1. Cause: ▸ Duration ▸ Frequency ▸ Pain (Character) ▸ Progression ▸ Aggravating Factors ▸ Relieving Factors ▸ Associated S & S ▸ Previous Occurrences ▸ Past Treatment ▸ **Outcome:**		

4. **Other Complaints:**

5. **Past Medical History:**

- General Health Status
- Childhood Illnesses
- Adult Illnesses
- Psychiatric Illnesses
- Accidents/Injuries
- Surgery
- Hospitalizations

6. Current health status and life-style:

- Allergies
- Immunizations
- Screening Tests incl. xrays
- Environmental Hazards (Home, School, Work)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
  Analgesics/week:
- Tobacco
- Alcohol
- Social Drugs

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. **Review of Systems:**

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

Appendix E

Durban Institute of Technology
PHYSICAL EXAMINATION: SENIOR

Patient Name : _____ **File no :** **Date :** _____
Student : **Signature :**

VITALS:				
Pulse rate:			Respiratory rate:	
Blood pressure:	R	L	Medication if hypertensive:	
Temperature:			Height:	
Weight:	Any recent change? Y / N		If Yes: How much gain/loss	Over what period

GENERAL EXAMINATION:		
General Impression		
Skin		
Jaundice		
Pallor		
Clubbing		
Cyanosis (Central/Peripheral)		
Oedema		
Lymph nodes	Head and neck	
	Axillary	
	Epitrochlear	
	Inguinal	
Pulses		
Urinalysis		

SYSTEM SPECIFIC EXAMINATION:

CARDIOVASCULAR EXAMINATION

RESPIRATORY EXAMINATION

ABDOMINAL EXAMINATION

NEUROLOGICAL EXAMINATION

COMMENTS

Clinician: **Signature :**

Appendix F

DURBAN INSTITUTE OF TECHNOLOGY
REGIONAL EXAMINATION - CERVICAL SPINE

Patient: _____ File No: _____

Date: _____ Student: _____

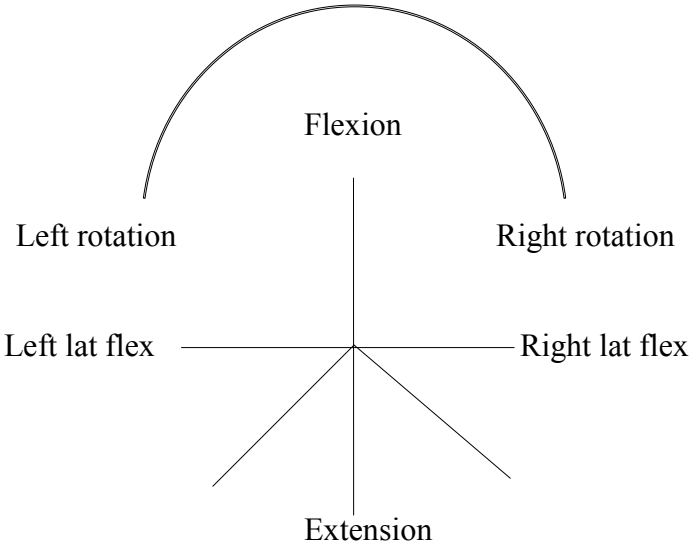
Clinician:_____ Sign: _____

OBSERVATION:

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

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

RANGE OF MOTION:
Extension (70º):
L/R Rotation (70º):
L/R Lat flex (45º):
Flexion (45º):



PALPATION:
Lymph nodes
Thyroid Gland
Trachea

ORTHOPAEDIC EXAMINATION:

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

	Right	Left		Right	Left
Doorbell sign			Cervical compression		
Kemp's test			Lateral compression		
Cervical distraction			Adson's test		

Halstead’s test			Costoclavicular test		
Hyper-abduction test			Eden’s test		
Shoulder abduction test			Shoulder compression test		
Dizziness rotation test			Lhermitte’s sign		
Brachial plexus test					

NEUROLOGICAL EXAMINATION:

Dermatones	**Left**	**Right**	**Myotomes**	**Left**	**Right**	**Reflexes**	**Left**	**Right**
C2			C1			C5		
C3			C2			C6		
C4			C3			C7		
C5			C4					
C6			C5					
C7			C6					
C8			C7					
T1			C8					
			T1					
Cerebellar tests:		Left		Right				
Disdiadochokinesis								

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

MOTION PALPATION & JOINT PLAY:

Left: Motion Palpation:
Joint Play:

Right: Motion Palpation:
Joint Play:

Upper Thoracics:
Motion Palpation:
Joint Play:

BASIC EXAM: SHOULDER:
Case History:

BASIC EXAM: THORACIC SPINE:
Case History:

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

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

Appendix G

MYOFASCIAL DIAGNOSTIC SCALE

DURBAN INSTITUTE of TECHNOLOGY

Patients Name: _____

Muscle: _____

Treatment No: _____

Signs:

1. Soft tissue tenderness

Grade		
0	No tenderness	0
i	Tenderness to palpation WITHOUT grimace or flinch	1
ii	Tender WITH grimace and/or flinch to palpation	2
iii	Tenderness with WITHDRAWAL (+ "Jump sign")	3
iv	Withdrawal (+ "Jump sign") To non-noxious stimuli (ie. Superficial palpation, pin prick, gentle percussion	4

2. Snapping palpation of the trigger point evokes a local twitch response 4

3. The trigger point is found in a palpable taut band. 4

4. Moderate, sustained pressure on the trigger point causes or intensifies pain in the reference zone 5

Total _____

Appendix H

CERVICAL RANGE OF MOTION READINGS

Patient Name _____

File No. _____

Consultation Date	Flexion	Extension	Left Lat. Flexion	Right Lat. Flexion	Left Rotation	Right Rotation
1.						
2.						
3.						

Appendix I

ALGOMETER READINGS

Patient Name _____

File No. _____

Consultation Date	Affected muscle	Readings		
		1.	2.	Ave.
1.	Right Trap Tp1 Right Trap Tp 2 Right Levator Scapular Tp1 Right Levator Scapular Tp 2 Left Trap Tp1 Left Trap Tp 2 Left Levator Scapular Tp1 Left Levator Scapular Tp 2			
2.	Right Trap Tp1 Right Trap Tp 2 Right Levator Scapular Tp1 Right Levator Scapular Tp 2 Left Trap Tp1 Left Trap Tp 2 Left Levator Scapular Tp1 Left Levator Scapular Tp 2			
3.	Right Trap Tp1 Right Trap Tp 2 Right Levator Scapular Tp1 Right Levator Scapular Tp 2 Left Trap Tp1 Left Trap Tp 2 Left Levator Scapular Tp1 Left Levator Scapular Tp 2			

Appendix J

CMCC NECK DISABILITY INDEX

This questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage everyday life. Please answer every section and mark in each section only ONE box as it applies to you. We realize you may consider that two of the statements in any one section could relate to you, but please just mark the box which most closely describes your problem.

Section 1 - Pain Intensity

2. I have no pain at the moment.
3. The pain is very mild at the moment.
4. The pain is moderate at the moment.
5. The pain is fairly severe at the moment.
6. The pain is very severe at the moment.
7. The pain is the worst imaginable at the moment.

Section 2 - Personal Care (Washing, Dressing ...)

- I can look after myself normally without causing extra pain.
- I can look after myself normally but it causes extra pain..
- It is painful to look after myself and I am slow and careful.
- I need some help but manage most of my personal care.
- I need help every day in most aspects of self care.
- I do not get dressed, I wash with difficulty and stay in bed.

Section 3 - Lifting

☐ I can lift heavy weights without extra pain.
☐ I can lift heavy weights but it gives extra pain.
☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table.
☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
☐ I can lift only very light weights.
☐ I cannot lift or carry anything at all.

Section 4 - Reading

☐ I can read as much as I want to without pain in my neck.
☐ I can read as much as I want to with slight pain in my neck.
☐ I can read as much as I want with moderate pain in my neck.
☐ I cannot read as much as I want because of moderate pain in my neck.
☐ I can hardly read at all because of severe pain in my neck.
☐ I cannot read at all.

Section 6 - Concentration

- I can concentrate fully when I want to with no difficulty.
- I can concentrate fully when I want to with slight difficulty.
- I have fair degree of difficulty in concentrating when I want to.
- I have a lot of difficulty in concentrating when I want to.
- I have a great deal of difficulty in concentrating when I want to.
- I cannot concentrate at all.

Section 7 - Work

- I can do as much work as I want to .
- I can do only my usual work, but no more.
- I can do most of my usual work, but no more.
- I cannot do my usual work.
- I can hardly do any work at all.
- I cannot do any work at all.

Section 8 - Driving

☐ I can drive my car without any neck pain.
☐ I can drive my car as long as I want with slight pain in my neck.
☐ I can drive my car as long as I like with moderate pain in my neck.
☐ I cannot drive my car as long as I want because of moderate pain in my neck.
☐ I can hardly drive at all because of severe pain in my neck..
☐ I cannot drive at all.

Section 9 - Sleeping

☐ I have no trouble sleeping.
☐ My sleep is slightly disturbed (<1 hour sleep loss).
☐ My sleep is mildly disturbed (1-2 hours sleep loss).
☐ My sleep is moderately disturbed (2-3 hours sleep loss).
☐ My sleep is greatly disturbed (3-5 hours sleep loss).
☐ My sleep is completely disturbed (5-7 hours sleep loss).

Section 5 - Headaches	**Section 10 - Recreation**
☐ I have no headaches at all. ☐ I have slight headaches which come infrequently. ☐ I have moderate headaches which come infrequently. ☐ I have moderate headaches which come frequently. ☐ I have severe headaches which come frequently. ☐ I have headaches almost all the time.	☐ I am able to engage in all my recreation activities with no neck pain at all. ☐ I am able to engage in all my recreation activities, with some pain in my neck. ☐ I am able to engage in most, but not all of my usual recreation activities because of pain in my neck. ☐ I am able to engage in a few of my usual recreation activities because of pain in my neck. ☐ I can hardly do any recreation activities because of pain in my neck. ☐ I cannot do any recreation activities at all.

Vernon/Hagino, modified from Foubister et al.,Physiotherapy

Appendix K

Numerical Rating Scale –101 Questionnaire

Patient name: _____ File No.: _____

Date: _____

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