THE EFFECTIVENESS OF SPINAL MANIPULATIVE THERAPY AND TRANS-CUTANEOUS ELECTRICAL NERVE STIMULATION VERSUS SPINAL MANIPULATIVE THERAPY AND PLACEBO TRANS-CUTANEOUS ELECTRICAL NERVE STIMULATION IN THE TREATMENT OF MILD TO MODERATE CHRONIC TENSION-TYPE HEADACHE

A dissertation submitted to the Faculty of Health, Durban Institute of Technology, Natal, in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic

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I, Shane Warren Fonseca, do hereby declare this dissertation is representative of my own work, both in concept and execution, except where otherwise indicated in the text.

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DEDICATION

I dedicate this dissertation to my beautiful Mother. Thank you for your support in all my years of study, in particular, your invaluable help with my research. God bless you always.

ACKNOWLEDGEMENTS

I would personally like to thank Dr Andrew Jones, my Supervisor, for his time, patience and speedy marking. Your advice and support was greatly appreciated.

To all the subjects who participated in this study. Your contribution made this study possible.

To my friends, especially my sweet Laura, for all your encouragement and support throughout my years of study.

ABSTRACT

Headaches have been described as the most common medical complaint in society (Dalessia 1987:3), and Tension-type headaches constitute approximately 80% of these (Martin 1993:22). Although Episodic tension-type headache is more prevalent than Chronic tension-type headache and may have a greater societal impact, Chronic tension-type headache has by far a greater individual impact (Schwartz et al, 1998) on the patient. The exact causes of Chronic tension-type headaches are not known and, as a result, treatment is commonly symptomatic in nature and aimed at reducing pain. To date, treatment commonly involves the use of drugs and with it comes the threat of drug-induced side-effects (Bendtsen et al, 1996). The purpose of this study was to investigate two non-pharmacological treatments in the management of Chronic tension-type headaches, namely the relative effectiveness of Spinal Manipulative Therapy (SMT) in conjunction with Trans-cutaneous Electrical Nerve Stimulation (TENS), as compared with SMT and placebo TENS.

It was hypothesized that SMT in conjunction with TENS would provide a greater immediate and short-term benefit in comparison to SMT and placebo TENS in the treatment of mild

to moderate Chronic tension-type headache. The study was performed as a clinical trial conducted at the Durban Institute of Technology Chiropractic Day Clinic. Thirty patients presenting with Chronic tension-type headache were selected to participate in the study and randomly allocated into two equal groups.

Patients in both groups were treated four times over a period of seventeen days. Patients in group one received SMT and TENS, whereas patients in group two received SMT and placebo TENS.

The subjective responses of each patient were recorded by means of the Short-form McGill Pain Questionnaire (Melzack, 1987) and the Headache Diary (Nebe, Heier and Diener, 1995). The short-form McGill pain questionnaire was completed at the first, second and final treatments under the supervision of the researcher. The Headache Diaries were taken home by the patients after each treatment, completed and then returned to the Clinic. The data was analysed using the Friedman's t-test and Wilcoxon's signed ranks test for intra-group comparison with respect to each variable, while the Mann Whitney-U-test was used for inter-

group comparisons. The degree of significance was set at a 95% level of confidence (< = 0,05).

A statistically significant improvement in headache frequency and use of medication was recorded at the final consultation for both groups A and B. In terms of headache severity (Visual Analogue Scale) and the quality of headache pain (McGill), both groups A and B showed a statistically significant improvement from the initial to final consultation, although improvement in Group A was slightly more significant. Comparison of group A and group B for headache severity and the quality of the headache pain, from the initial to second consultation, revealed that although both were statistically significant, group A was highly significant. This indicates that Spinal Manipulative Therapy and Transcutaneous Electrical Nerve Stimulation brings about earlier benefit (in terms of pain relief), when compared to SMT and placebo TENS (i.e. SMT alone).

In terms of inter-group analysis, no significant changes were noted in terms of headache quality and severity, headache frequency and mean medication use per discrete headache episode at the initial consultation, the second

treatment and the final consultation between groups A and B.

In comparing the two different forms of treatment, Spinal Manipulative Therapy in conjunction with Transcutaneous Electrical Nerve Stimulation and Spinal Manipulative Therapy and placebo Transcutaneous Electrical Nerve Stimulation, Spinal Manipulative Therapy and Transcutaneous Electrical Nerve Stimulation was not found to be more effective than Spinal Manipulative Therapy and placebo Transcutaneous Electrical Nerve Stimulation, contrary to the proposed hypothesis. Both treatments however were successful in reducing the frequency of the headaches, the severity and quality of the pain experienced and the mean medication used per discrete headache episode. Therefore, both forms of treatment may be of some benefit in the management of Chronic tension-type headache and, since the combination treatment of Spinal Manipulative Therapy and Transcutaneous Electrical Nerve Stimulation provided earlier benefits than Spinal Manipulative Therapy alone, such a combination treatment is recommended for the treatment of Chronic tension-type headache.

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CHAPTER I

1. INTRODUCTION

1.1 The Problem and its setting

Headaches have been described as the most common medical complaint in society (Dalessio, 1987:3) and have an incidence of 66% to 83% of the population in developed countries (Martin, 1993:22). Of the 10-15% of headache sufferers that actually consult physicians, tension-type headaches constitute approximately 80% (Diamond, 1987:172).

Episodic tension-type headache is more prevalent than Chronic tension-type headache, constituting 95% of all tension-type headaches (Schwartz et al, 1998), and although it has a greater societal impact, Chronic tension-type headaches have a more significant individual impact. In a recent study, conducted in Maryland, USA, the overall prevalence of Chronic tension-type headaches was 2,2% with an overall sex prevalence ratio (women to men) of 2.0 in the same area (Schwartz et al, 1998). Subjects with Chronic tension type headaches reported more lost workdays (mean of 27.4 days vs 8.9 days for those reporting lost workdays) and reduced-effectiveness days (mean 20.4 vs 5.0 days for those reporting reduced effectiveness) compared with subjects with Episodic

tension-type headaches. A total of 11,8% of subjects with Chronic tension-type headaches reported actual lost workdays due to their headaches, while 46,5% reported reduced effectiveness days (Schwartz et al, 1998).

The exact causes of Chronic tension-type headaches are not known (Headache Classification Committee, 1988:30-31), with involuntary tightening in the pericranial muscles (Ashina et al, 1999), cervical subluxation complexes (Vernon, 1988) and psychological aetiologies (Headache classification Committee, 1988) being suspected. Jensen et al (1998), hypothesized that a pathophysiological evolution from an Episodic tension-type headache to a Chronic tension-type headache could occur. As Chronic tension-type headaches usually evolve from the Episodic form, it was suggested that prolonged painful input from the periphery may sensitize the central nervous system and that the pain in Chronic tension-type headache associated with a muscular disorder may, thus, be due to central misinterpretation of the incoming signals at the dorsal horn. Muscular disorders may, therefore, be of major importance for the conversion of Episodic into Chronic tension-type headaches (Jensen et al, 1998).

A wide variety of treatment for Chronic tension-type headaches is offered, that variety being due to various practitioners focusing on their field of expertise.

Since the exact causes of these headaches is not known, and there is no underlying organic disease or history of trauma, symptomatic relief medication is usually given (Anrig and Plaugher, 1998). To date one of the most common methods of treatment involves the tricyclic anti-depressant amitriptyline (Bendtsen et al, 1996), although a host of other medications are currently used, namely anti-emetics, ergotamines, S-HT agonists and dopamine antagonists (Anrig and Plaughter, 1998). According to Curl (1999), in order to counter the widespread prescription of medication that carries with it the continuous threat of iatrogenically induced side-effects, effective non-pharmacological management protocols must be found.

Gatterman (1995) is of the opinion that cervical spine dysfunction makes a significant contribution to the cause of a number of different headache types. Muller (1999) conducted a controlled clinical study of 80 patients, randomised into two groups, to investigate the prevalence of cervical spine dysfunction in tension-type headache subjects, as opposed to non-headache subjects. Patients in both groups were assessed for cervical spine dysfunction using the CROM goniometer, the algometer, motion palpation, dynamic flexion/extension intersegmental X-ray analysis and cervical spine sagital

curve alignment assessment. Inter-group comparisons found a statistically significant higher prevalence of cervical spine dysfunction in the 40 subjects suffering from tension-type headache, as compared to the 40 asymptomatic controls. Although present studies conflict with regard to spinal manipulation and its efficacy in the treatment of Chronic tension-type headache, Vernon and McDermaid (1998) found in a survey of chiropractors that cervical spine manipulation (especially of the upper cervical spine) is more commonly used, than any other form of therapy in the treatment of tension-type headaches. Furthermore, the use of chiropractic cervical manipulation in adults has been shown in studies to provide both immediate and long-term benefits to patients suffering from tension-type headache (Penter, 1992; Vernon, 1995; Boline et al, 1995).

Since the exact aetiologies of Tension-type headache are not known, treatment is commonly symptomatic in nature and aimed primarily at reducing pain (Haas, 1999). According to Liss and Liss (1996), the results of stimulating human subjects with high frequency electrical impulses include the increase in levels of CSF Seratonin and beta endorphin and the reduction of associated pain, spasticity and headache. The effects were documented in human subjects with measurements of the serum

concentration of various agents and assessments of the symptoms being performed before and after each stimulation. Since Trans-cutaneous Nerve Stimulation (TENS) provides such a high frequency electrical impulse, it could be used as an effective modality to complement SMT in the treatment of mild to moderate Chronic tension-type headaches.

A study by Farina et al (1986), concluded that TENS may induce a short-term bioelectrical inhibition of synapses of the small pain fibres in the spine by the larger fibres excited by the electrical stimulus, and as such may induce a hypoanalgesic state. The study also suggested that apart from its efficacy, TENS is free from side effects, not expensive and easy to apply (Farina et al, 1986).

The purpose of this study was to determine the relative effectiveness of chiropractic manipulation with TENS, as compared with chiropractic manipulation with placebo TENS, in the management of Chronic tension-type headache, with reference to the patient's subjective perception of the treatments through the use of the Short-form McGill Pain Questionnaire and a Headache Diary.

The wide variety of treatments used to manage Chronic Tension-type headache, and especially the use of excessive medication, points to the need for a more effective standardised method of treating the condition. Ideally the treatment should promote the symptom-free period the patient experiences, reduce the number of visits to the physician's office and reduce the overall cost of treatment through reducing patient consultations and reducing the medication consumed for symptomatic relief of the pain associated with Chronic tension-type headache. Furthermore, the extent of the side effects of the treatment and possible dependency on the treatment should also play a role in determining the most appropriate and effective treatment.

Chiropractic may offer a more effective and cheaper form of treatment by decreasing the overall number of patient consultations, while preventing both the side effects of, or dependency on, pain medication (De Busser, 2001). According to Stano (1993) in a study comparing health care costs of chiropractic and medical patients, preliminary results suggest significant cost savings for users of chiropractic care in respect of common musculoskeletal disorders.

Since SMT has been shown by clinical research to be effective in the treatment of Chronic tension-type headaches and Trans-cutaneous Nerve Stimulation has been shown to be effective in the management of chronic pain conditions such as headaches, this study aims to show that a combination treatment may be the more appropriate in the management of mild to moderate Chronic tension-type headaches.

1.1 **Statement of Research Objective**

To conduct a comparative clinical trial investigating the effects of Spinal Manipulative Therapy and Trans-cutaneous Electrical Nerve stimulation compared to Spinal Manipulaive Therapy and placebo Trans-cutaneous Electrical Nerve Stimulation in the treatment of mild to moderate Chronic tension-type headache.

1.1.1 OBJECTIVE

The objective is to determine the relative effectiveness of Spinal Manipulative Therapy and Trans-cutaneous Electrical Nerve Stimulation compared to Spinal Manipulative Therapy and placebo Trans-cutaneous Nerve Stimulation, in terms of subjective clinical findings.

1.2 **Hypothesis**

The hypothesis was that Spinal Manipulative Therapy of the cervical spine and Trans-cutaneous Electrical Nerve Stimulation applied pericranially would be more effective than Spinal Manipulative Therapy and placebo Trans-cutaneous Electrical Nerve Stimulation in the subjective clinical findings on analysis of the data.

CHAPTER II

2. Literature Review

Tension-type headache is the most common form of headache that a chiropractor will encounter in clinical practice (Davies, 2000). Although Chronic tension-type headache is not as prevalent as the Episodic tension-type headache type, it has a greater individual impact and accounts for more lost workdays and reduced effectiveness days (Schwartz et al, 1998). The management of the headache has differed greatly between medical professions, with varying success. It is thus important to review the relevant anatomy, physiology, differential diagnosis and treatment in respect to this condition (Vernon 1988:141).

2.1 Clinical Presentation

2.1.1 Classification of Chronic tension-type headache

The Headache Classification Committee of the International Headache Society in 1988, gave explicit diagnostic criteria for all headache disorders, where previous classifications lacked precision, included ambiguous expressions, and were non-operational, which resulted in vague criteria (Rasmussen and Olesen, 1994). Leone et al, 1995, (as quoted by Kidson, 2001),

assessed the reliability of the diagnostic criteria developed by the Headache Classification Committee of the International Headache Society. The clinical records for 100 consecutive outpatients were evaluated. The results revealed that the criteria developed by the Headache Classification Committee of the International Headache Society are satisfactorily applicable to high quality medical records (Leone et al, 1995, as quoted by Kidson, 2001).

The Headache Classification Committee of the Internal Headache Society has divided the classification of the tension-type headache into Chronic and Episodic tension-type headache (Headache Classification Committee, 1988:29).

Chronic tension-type headache has an average headache frequency of at least fifteen days per month, for a minimum of at least six months. Patients must present with at least two of the following pain characteristics:

i. Pressing (non-pulsating) quality
ii. Mild or moderate intensity (may inhibit but not prohibit activities)
iii. Bilateral location
iv. No aggravation by routine physical activity

As with Episodic tension-type headache, a disorder of the pericranial muscles may or may not be associated with the Chronic tension-type headache (Headache Classification Committee, 1988:31-32). Episodic tension-type headache requires a minimum of ten previous episodes with less than fifteen day per month frequency. Each episode may last from thirty minutes to seven days. This condition may or may not be associated with disorders of the pericranial muscles as determined by manual palpation, pressure algometer and elevated electromyography level of pericranial muscles at rest or during physiological tests (Headache Classification Committee, 1988:30-32).

Tension-type headache not fulfilling the operational diagnostic criteria for either Episodic or Chronic tension-type headache by one criterion, is temporarily defined as a tension-type headache until such time as it fulfils all the diagnostic criteria for either diagnosis (Headache Classification Committee, 1988:32-33).

2.2 **Epidemiology**

Chronic tension-type headaches are less prevalent than Episodic tension-type headache, constituting fewer than 5% of the overall tension-type headache sufferers.

However, "Chronic tension-type headaches have a greater individual impact than Episodic tension-type headache" (Schwartz et al, 1988).

2.2.1 Prevalence

The prevalence of tension-type headaches at the Technikon Natal Chiropractic Clinic was 30,8%, a prevalence mirrored by findings in private practice in South Africa (Drews, 1995). The overall prevalence of Chronic tension-type headache for Baltimore County, Maryland USA, was 2,2% (Schwartz et al, 1998). In a Thailand study, a prevalence of 27,3% was found for tension-type headache, with Chronic tension-type headache accounting for 36,7% of that prevalence (Srikiatkhachorn et al, 1996). A study by Jensen (1999) of one thousand subjects aged 25-64 years from eleven municipalities around Copenhagen, Denmark revealed a life-time prevalence of tension-type headache in the general population of 78% while one-year-period prevalence of 74%: 30% (223/735) had tension-type headache of more than fourteen days in the previous year while 3% were chronically affected i.e. had headaches more than fifteen days per month.

2.2.2 Age

Rasmussen (1993) identified the age of onset of tension-type headache in the second decade of life to be 49% in males and 58% in females, this being the largest single decade of onset. According to Raskin (1988:216), symptoms begin before the age of twenty years in 40% of patients suffering tension-type headache.

Schwartz et al, (1998) found that Chronic tension-type headache does not exhibit any clear differences in prevalence by age. However, the study did show that the proportion of patients over 50 years was higher for Chronic tension-type headache (men 18,8%, women 29,6%) than for Episodic tension-type headache (men 16,8%, women 19,5%). The prevalence of Chronic tension-type headache seems to increase with age (Abramson et al, 1980).

2.2.3 Gender

Women had a higher prevalence than men did at all ages (Rasmussen et al, 1992; Gobel et al, 1994; Rasmussen, 1995; Schwartz et al, 1998) with the sex prevalence

ratio (female to male) found to vary between 2:1 and 5:2 (Schwartz et al, 1998; Jensen, 1999). Lance (1982:102) stated that approximately 75% of Chronic tension-type headache patients are female. In clinical populations, women also outnumber men in the occurrence of Chronic tension-type headache, but this may be unproportional as women are more likely to seek care for their headaches than men (Rasmussen, 1995; Bove and Nilsson, 1998). According to Rasmussen (1995) this female preponderance of tension-type headache remains unexplained, although hormonal factors may play a role in the headache aetiology.

2.2.4 Duration and Frequency

Mootz et al (1994) reported on eleven men (18-40 years old) suffering from Chronic tension-type headache in a prospective case series analysis. Data was collected during a two week, no-treatment, baseline, period prior to initiation of care. Mean headache frequency was 3,1 headaches per two weeks, while mean headache duration was 6,7 hours per headache episode.

Langemark et al (1988) reported on the clinical characterisation of 148 patients suffering from Chronic tension-type headache, following a standardised

interview, neurological examination and evaluation of muscle tenderness and jaw movements. The mean reported duration of headache problems was ten years, while mean headache frequency was 30 days per month.

2.2.5 Severity

According to the International Headache Society Criteria (Headache Classification Committee, 1988), the intensity of pain in tension-type headache is typically mild to moderate. No distinction between Episodic and Chronic tension-type headache is made. In a study by Rasmussen et al (1992) of 488 subjects diagnosed with tension-type headache, it was noted that the subjects who had an increased frequency of tension-type headache, complained of headaches more severe. He found that 76% of 488 subjects with tension-type headache of more than 30 days per year, reported moderate or severe intensity compared to 50% of those with less frequent headaches.

2.2.6 Assessment of Disability

A total of 11,8% of patients with Chronic tension-type headache reported lost workdays due to their headaches, with an average of 27,4 lost workdays being reported

per person per year. Patients with Chronic tension-type headache also reported 46,5% reduced-effectiveness days with an average of 20,4 reduced-effectiveness days per person per year. Lost workdays in the past year were estimated as the number of headaches reported per year that caused the subject to miss part or all of a workday. Reduced effectiveness days were estimated from the product of headache frequency and duration, and the proportion of headaches that cause a decreased effectiveness level and the average proportion reduction in effectiveness at work, home or school (Schwartz et al, 1998).

2.2.7 Provoking Factors and Precipitants

The most common provoking factors for both types of tension-type headache were stress and mental tension. Precipitants (also called trigger factors and promoters) are factors that alone or in combination with other exogenous or endogenous exposures induce attacks in susceptible individuals (Kidson, 2001:9). Precipitants especially noted in tension-type headaches were smoking, weather changes, alcohol and menstruation (Rasmussen, 1995). Kidson (2001) found stress to be the predominant precipitating factor (65% of the subjects) in tension-type headache. Other precipitating factors

included light (26.67% of the subjects); heat (16.67% of the subjects); computers (15.0% of the subjects) and sound (10% of the subjects). The literature review did not reveal any specific information on Chronic tension-type headache.

2.3 Signs and Symptoms

In tension-type headache, unlike migraine, there should be no vascular symptoms such as visual disturbance present. Nausea, vomiting and anorexia, which are common in migraine, are rarely present. Dizziness, fatigue and tiredness commonly accompany tension-type headache and depression is quite prevalent in the Chronic tension-type headache form (Kunkel, 1991). In a series of 402 patients with tension-type headache, associated symptoms included tiredness (81%), poor sleep (53%) and light-headedness (51%) (Chun, 1985).

On examination, rigid neck and shoulder muscles (Davies, 2000), and a high prevalence of tender points (myofascial trigger points) especially in the mid- and upper cervical region are readily recognised on palpation (Jansen, 1998; Muller, 1999; Travell, Simons and Simons, 1999).

According to the International Headache Society (Headache Classification Committee, 1988), the clinical features of Chronic tension-type headache are defined as follows:

A. "Average headache frequency of more than fifteen day per month for over six months
B. Headache must last from thirty minutes to seven days
C. The headache must have at least two of the following pain characteristics:
    - Pressing or tightening quality (non-pulsating)
    - Mild or moderate intensity (may inhibit, but does not prohibit the patient's activities)
    - Bilateral location
    - No aggravation by routine activity
D. The headache must have both of the following qualities:
    - No vomiting
    - No more than one of the following: Nausea, Photophobia or Phonophobia
E. The headache must have at least one of the following:
    - The history, physical or neurological examinations do not suggest one of the following disorders: migraine headache, cluster headache, increased

intracranial pressure-type headache, decreased intracranial pressure-type headache, local lesion-type type headache, vasodilator-type headache and headache with stabbing head pains.

- The history and/or physical and/or neurological examinations do suggest such a disorder as outlined above, however, it is ruled out by appropriate examinations.
- If such a disorder is present, the headache does not occur for the first time in close temporal relation to the disorder". (Headache Classification Committee, 1988:29-30).

2.4 Mechanism and pathophsiology of Chronic tension-type headache

As stated previously, the exact causes of Chronic tension-type headaches are not known. However, various mechanisms are postulated as outlined below:

2.4.1 Vascular Hypothesis

Bogduk as cited by Vernon et al, (1992) noted that mechanical irritation of the vertebral artery, vertebral nerve and ascending sympathetic chain can initiate an "autonomic barrage" sufficient to cause cerebral vasospasm, and agreed with the hypothesis that subluxation of the cervical apophyseal joints might

compromise these structures. The mechanical derangement of the cervical apophyseal, craniocervical synovial joints produces the headache, and is characterised by a "chronic hypomobility". Vernon et al, (1992) found no positive findings of vertebrobasilar insufficiency while assessing cervical spine dysfunction in tension-type and migraine headache subjects. The role of vertebrobasilar insufficiency, due to cervical spine dysfunction, resulting in tension-type headache, has not been found to have a high prevalence in the tension-type population.

Consequently, tension-type headaches may be associated with vertebrobasilar insufficiency but currently there are no tests that are sensitive enough to demonstrate the insufficiency. There was no specific information regarding Chronic tension-type headache and this particular hypothesis.

2.4.2 The Continuum Hypothesis

The continuum hypothesis by Nelson (1994) discusses the possibility that tension-type headaches and migraine headaches do not exist as distinct physiological entities but form a continuum. This model is designed specifically for chronic headaches. The evidence proposed that tension-type headaches and migraines are different expressions of a common disorder:

- Pathophysiological similarities. There is autonomic instability evident in both headache types, and the central pain-modulating system is important to the pathophysiology of both tension-type headache and migraine (Schoenen et al, 1991).
- Epidemiological studies. There are similarities in the tension-type headache and migraine populations. Women outnumber the men by approximately 2:1, and the age distribution is similar with a peak in the 25-45 age group, in both headache populations (Pryse-Phillips, et al, 1992).
- Psychological similarities. Both tension-type headache and migraine patients show similar psychological trends, with increased incidence of affective disorders (e.g. depression) and personality traits (e.g. hysteria and hypochondriasis). (As quoted by Nelson, 1994).
- Symptomatic similarities. Patients diagnosed with either tension-type headache or migraine consistently manifest symptoms that are associated with the other type of headache (Messinger et al, 1991).
- Diagnostic overlap. Applying the diagnostic criteria of the Headache Classification Committee of the International Headache Society, many patients fulfil the criteria for both tension-type headache and migraine (Messinger et al, 1991).

- Therapeutic overlap. A variety of therapeutic approaches with very different modes of action have been shown to be effective in the treatment of both tension-type headache and migraine, including antidepressants (Boline et al, 1995), anti-inflammatory agents (Miller et al, 1987) and spinal manipulation (Vernon, 1995; Boline et al 1995; Angus, 1997).

Rasmussen (1995) expressed similar findings in terms of an overlap of symptoms existing in migraine and tension-type headache in his study on the epidemiology of headache. However, he indicated that although migraine symptoms do occur in tension-type headache, they are neither common nor severe and tend to occur in clusters rather than singly. From his research he concluded that the two headache types are separate, although they may co-exist and interrelate.

2.4.3 **Psychological hypothesis**

It is unknown whether headache is primary or secondary to psychopathology (Biondi and Portuesi, 1994). In patients suffering headache as a primary complaint while receiving psychological assessment, 95,5% suffered from Chronic tension-type headache (Sebit, 1996). Anxiety, insomnia and depression are often associated with Chronic tension-type headaches (Biondi and Portuesi, 1994) and, in fact, a number of studies have made use of amitriptyline, a tricyclic ant-depressant for the treatment of Chronic tension-type headaches (Boline et al, 1995; Mitsikostas et al, 1997).

There are three hypotheses pertaining to the psychopathological features in tension-type headache:

- The headache is primary, and the psychological changes that are noted in tension-type headache patients are a secondary reaction
- The tension-type headache is secondary to the primary psychological disorders.
- The initial distress and gradual model, suggests the patient's distress peaks within the first three years

of illness, and gradually subsides as the patient adapts and develops coping mechanisms (these coping mechanisms are not specified). The headache is not removed by these strategies, but there is diminished psychopathology (Biondi and Portuesi, 1994).

Although current medical knowledge cannot ascertain whether psychological factors are a cause or symptom of Chronic tension-type headache, they can be viewed as a close association. As such, psychological factors should not be overlooked when treating Chronic tension-type headache patients (Biondi and Portuesi, 1994).

2.4.4 Muscular hypothesis

Diamond (1987) suggested that the mechanism of tension-type headache is similar to that of chronic muscle contraction in other parts of the body as a result of muscle spasm linked to the central nervous system involving three pathologic reflex arcs and four consecutive steps:

1. Muscle spasm is initiated usually by a multisynaptic reflex of withdrawal. Stimulation is caused by a local pathological process and the impulse is transmitted to the spinal cord, then to the ventral

roots and next, via efferent nerves, to the neuromuscular junction, with resulting painful muscular contracture.

2. The initial impulse is conducted up the spinal cord via polysynaptic spinal pathways and the lemniscal system, to the thalamic and central levels. At these areas the stimulus is perceived as painful.
3. The brain next transmits impulses through the reticulspinal system to activate the gamma efferent neurons, which thus contract the muscle spindle.
4. During this contraction, a monosynaptic stimulus is evoked, travelling to the ventral horn. Efferent peripheral nerve discharge is augmented, as is the muscle contraction. (Diamond, 1987).

In the third reflex arc i.e. muscle spindle contraction, is a monosynaptic pathway and is related to tendon stretch reflexes. The contracting muscle would ordinarily inhibit the firing of the muscle spindle, thus terminating the stretch reflex and causing muscle relaxation. The gamma motor system's activity level determines the degree of muscle tone. If the gamma efferent system continues to fire, the muscle spindle remains tight and will continue contracting until the contraction itself becomes painful. (Diamond, 1987).

The theory that head and neck muscular contraction may play a pathogenic role in patients with tension-type headache is reflected in various studies:

Jensen (1996), studied the pericranial tenderness of tension-type headache sufferers and found increased tenderness of these muscles in the subjects compared to normal controls. Patients with Chronic tension-type headaches were more tender than both the Episodic tension-type headache patients and the controls. It was also found that the pericranial tenderness increased during headache, but there was no change in the electro-myographic readings (a four channel electromyograph recorded the temporal and trapezius signals bilaterally). As pressure pain thresholds were unaffected by the headache state, while thermal pain detection and tolerance thresholds decreased selectively in the temporal region, this indicated that the actual headache episode may be associated with a segmental central sensitisation and/or decrease antinociception. Although this study failed to record the muscle tenderness in the posterior cervical musculature, several studies support the major involvement of these muscles in the pathomechanics of Chronic tension-type headaches (McMennell, 1992; Jansen, 1998; Travell, Simons and Simons, 1999).

Jensen's hypothesis was further highlighted in a study by Jensen and Oelsen (1996) where headaches were induced in a group of volunteers by several hours of tooth clenching. Pericranial myofascial tenderness was found to precede headache by several hours. This study suggested the following mechanism of activation of Tension-type headache: involuntary contraction of muscles, due to mechanical or psychological stress, causes activation and chemical sensitisation of the myofascial mechanoreceptors and their afferent fibres. This increased peripheral input may result in a state of hypersensitivity. Normally increased peripheral nociceptive input is counteracted by increased activity in the antinociceptive system and no headache arises. However, in some individuals and under some circumstances this homeostatic mechanism does not function. An abnormal sensitisation arises and, combined with an impaired central antinociceptive mechanism, an episode of tension-type headache may develop (Jensen & Olesen, 1996).

Jensen et al (1998) found increased tenderness, but normal thermal thresholds at cephalic and extracephalic locations in Chronic tension-type headache patients with associated muscular disorders of the pericranial

muscles. This indicates that a central sensitisation may be mediated by low threshold mechanosensitive afferent neurons projecting to the dorsal horn neurons. However, the mechanisms of pain for the tension-type headache without associated percranial muscle dysfunction cannot be explained by simple allodynia or hyperalgesia as both mechanical and thermal pain thresholds from these patients were elevated, indicating a decreased pain tolerance as compared to controls. Consequently other mechanisms, possibly the central modulation of pain, must be considered.

The hypothesis of Jensen et al, (1998) creates an attempt to explain the pathophysiological evolution of the tension-type headache. It is suggested that prolonged painful input from the periphery may sensitise the central nervous system and the pain associated with muscle disorders may be as a result of central misinterpretation of the incoming signals at the dorsal horn or trigeminal level. Muscular disorders may consequently be responsible for the conversion of Episodic into Chronic tension-type headache. Central Supraspinal involvement is also probably involved as the precipitating factors leading to tension-type headache are stress, mental tension and fatigue (Rasmussen, 1993). It is also possible that

pericranial muscular disorders are the result of Chronic tension-type headache as opposed to the cause (Jensen et al. 1998).

There remains considerable controversy surrounding the pathogenic mechanism in tension-type headache. Contraction of the pericranial muscles and possibly increased pain sensitivity are thought to play a role in the pathogenesis of tension-type headache. The predominant theory, historically, has been that tension-type headaches are due to sustained muscle contraction of the cervical and pericranial muscles (Headache Classification Committee, 1988). However, electromyographic studies over the last 10-15 years do not support a muscle contraction mechanism in tension-type headaches (Chapman, 1986; as quoted by Travell, Simons and Simons, 1999), but rather evidence exists implicating localised myofascial trigger point pain as the aetiological source of pain in these headaches (Jaeger, 1995).

Olesen (1991) proposed a model that is supportive of the role of myofascial trigger points in headache. In this model, the cranial vasculature and pericranial muscles (myofascial trigger points) are the two primary nociceptive sources and supraspinal (emotional,

psychological) factors either increase or decrease pain. The final common pathway is through the second order pain transmission neuron upon which Olesen speculates, the inputs from the primary afferent nociceptives of intracranial and extracranial vasculature, extracranial musculature (trigger points) and supraspinal-on-off cells converge. The strength of input from each converging neuron determines which headache picture emerges clinically. A nociceptive predominance from myofascial trigger points will produce a tension-type headache picture. This model also helps to explain why patients may have both tension-type headaches and migraines (Olesen, 1991). It is likely, therefore, that identification and treatment of myofascial trigger points will decrease the incidence of the progression to chronicity of the headache-like pain (Travell, Simons and Simons, 1999).

2.4.5 Myofascial considerations

Many studies have documented the presence of pericranial muscle tenderness and referred pain patterns in tension-type headache sufferers (Olesen, 1982; Langemark and Olesen, 1987), with the abnormal tenderness being clinically determined using manual

palpation and pressure algometers (Jensen et al, 1997; Jansen, 1998; Muller, 1999).

The overlapping pain referral patterns from pericranial and cervical myofascial trigger points produce a characteristic tension-type headache picture especially when bilateral (Travell, Simons and Simons, 1999). Even the "steady, deep aching" quality of trigger point pain is comparable to the "pressing tightening" quality of tension-type headache as described by the International Headache Committee in 1988 (Travell, Simons and Simons, 1999).

Jansen (1998) conducted a controlled clinical trial involving 1 041 headache patients, 569 suffering from tension-type headache. The study included a standardised questionnaire for patient demographics and an examination, by palpation, of the relevant postural muscles i.e. posterior cervical muscles, trapezius muscles, suboccipital muscles and the sternocleidomastoid muscles. Analysis of the presence of active trigger points in the posterior cervical muscles revealed that the prevalence was 61,7%, 62,7% and 66,6% for trigger points one, two and three respectively. Analysis of active trigger points in the upper trapezius muscle revealed a prevalence of 37,1%,

while a prevalence of 49,7% and 23,1% was noted for the suboccipital and sternocleidomastoid (upper) muscles respectively.

Vernon et al (1992) found 85% of all tension-type headache patients have at least one myofascial trigger point of the posterior cervical muscles. This was supported by McMenell (1992) who stated that trigger points are a great source of tension-type headaches and that ten muscles, whose overlapping patterns of pain, are commonly involved in the cause of Chronic tension-type headaches. These muscles include: the trapezius, sternocleidomastoids, masseters, splenius cervicis, cervical capitus, frontalis, occipitals and the external ptyergoid muscles. The aetiological formation of these trigger points may include mechanical joint problems of the upper cervical spine (McMenell, 1992).

A myofascial trigger point is defined by Travell, Simons and Simons (1999) as a "hyperirritable focus within a taut band of skeletal muscle, located in the muscular tissue and/or its associated fascia". The spot is painful on compression and can evoke characteristic referred pain and autonomic phenomena. Myofascial trigger points are defined as either active or latent. An active myofascial trigger point causes

the patient pain. "A latent myofascial trigger point is clinically silent with regard to pain, however, may cause restriction of movement and weakness of the affected muscle." Apart from causing local and referred pain, myofascial trigger points in hypertonic muscles are also considered responsible for causing joint fixation. This is due to ligamentous shortening and articular adhesions that occur with muscle hypertonicity (Gatterman, 1990). The concept of restricted segmental movement due to muscle hypertonicity it popular with a number of authors (Gatterman, 1990; Mennell, 1990; Muller, 1999; Haldeman, 2000; De Busser, 2001).

2.4.6 Cervicogenic considerations

Various authors have implicated cervical spine dysfunction as a possible cause of headache. Muller (1999) conducted a controlled clinical study of 80 patients, randomised into two groups, to investigate the prevalence of cervical spine dysfunction in tension-type headache subjects, as opposed to nonheadache subjects. Patients in both groups were assessed for cervical spine dysfunction using the CROM goniometer, the algometer, motion palpation, dynamic flexion/extension intersegmental X-ray analysis and cervical spine sagital curve alignment

assessment. Inter-group comparisons found a statistically significant higher prevalence of cervical spine dysfunction in the 40 subjects suffering from tension-type headache, as compared to the 40 asymptomatic controls. Vernon et al, (1992) define cervical spine dysfunction as impaired or altered function of related components of the cervical spine, including skeletal, arthrodial and myofascial structures, resulting in the following aspect of cervicogenic dysfunction:

i. Inter-segmental Hypomobility:

A common clinical phenomenon is the hypomobility lesion, so-called because it presents as a restriction in movement in a spinal joint. Such restrictions of movement frequently accompany spinal pain (Bogduk, 1985). Pain arising from within or around any synovial joint may result in reflex muscle spasm in an attempt to prevent painful movement of the joint (Mennell, 1990). Both pain and muscle spasms are symptoms of Chronic tension-type headache. Many occupations require incorrect neck posture e.g. static muscle load and awkward working environments, all of which result in disturbances in the joints and musculature (Gatterman, 1990; Travell, Simons and

Simons, 1999). Vernon et al, (1992) found that there were no tension-type headache subjects that did not present without cervical spine dysfunction. 16 % had a fixation at only one level, 54% had fixations at two levels and 30% had fixations at three or more levels. Muller (1999) found hypomobile motion palpation findings in 97,5% of patients suffering from tension-type headache. These findings were confirmed by decreased active inter-segmental motion X-ray findings (especially at the C1-2 and C2-3 levels).

ii. Tender points in the soft tissue/trigger points

Lesions involving the neck muscles at their attachment to the occiput have frequently been cited as a cause of headache (Vernon, 1995:313). These areas of tenderness or trigger points can occur in any muscle, including those innervated by the upper three cervical nerves, which include the sternocleidomastoid muscles, the trapezius muscles and the intrinsic neck muscles attached to the occiput (Bogduk, 1985). The greater occipital nerve (the dorsal primary division of the 2nd cervical nerve) may be implicated in the aetiology of tension-type headaches (Travell, Simons and

Simons, 1999). The greater occipital nerve in its pathway to supply sensory branches to the scalp, and motor branches to the semispinalis capitis muscle, penetrates through the semspinalis capitis and trapezius muscles near their attachments to the occipital bone. Entrapment symptoms develop when trigger point (TrP) activity in one of the muscles that it penetrates produces taut bands of muscle fibres that compress the nerve as it penetrates the muscle. Symptoms associated with such compression include diffuse pain that is referred through the head; a continuous pressure-like pain that radiates into the forehead - similar to tension-type headache (Travell, Simons and Simons, 1999). The pain is often relieved by inactivation of the trigger points in the posterior occipital and trapezius muscles (Travell, Simons and Simons, 1999). This mechanism of tension-type headache aetiology was previously highlighted in a study by Kellgren 1938 (as quoted by Travell, Simons and Simons, 1999), in which a hypertonic saline solution was injected into the sub-occipital muscles resulting in a pain felt by the patient deep within the head as a headache.

The upper trapezius, posterior cervical and sternocleidomastoid muscles frequently exhibit myofascial tendencies causing headache (Travell, Simons and Simons, 1999).

iii Reduced regional ranges of motion

A finding associated with muscle tenderness is increased muscle stiffness (Vernon, 1995:314). The development of regional muscle stiffness and reduced cervical spine range of motion was reported on by Kidd and Nelson (1993). They found in their controlled, blinded study, comparing neck range of motion in 74 patients, 37 with and 37 without tension-type headache, that the headache sufferers had a statistically significant reduction of two or more cervical ranges of motion. These findings were further highlighted by Jansen (1998). Analysis of motion palpation on the left and right, in 569 patients suffering from tension-type headache, revealed that 93,9% and 94,1% respectively had fixated cervical spinal segments and a reduced cervical range of motion.

iv Radiographic findings of:

a. Static misalignment - cervical lordosis

b. *Dynamic inter-segmental abnormality*

c. *Static malposition of the head and neck*

(specifically anterior carriage and low round shoulders)

a. *Static misalignment/cervical lordosis* -

Nagasawa et al's, (1993) study disclosed that a large proportion of tension-type headache patients had straightened cervical spines, suggesting that sustained contraction of the neck flexors in tension-type headache patients interferes with maintenance of the physiologic cervical spine lordosis and results in straightened cervical spine. This may, in turn, exert a slight anteflexion of the cervical spine and cause passive loading of the occipitalis muscle. Such a tendency becomes more pronounced with increasing age. If the mechanism of tension-type headache is taken to be the result of muscle spasm linked to the central nervous system involving neural pathways and reflex arcs (Diamond and Dalessio, 1992:124), this passive loading may predispose the subject to tension-type headache (Nagasawa et al, 1993).

b. *Dynamic inter-segmental abnormality*

Pfaffenrath et al (1988) found a statistically higher incidence of restriction at Co-C1 in 15 cervicogenic headache patients as compared to eighteen normal controls. In a descriptive study on cervicogenic dysfunction in nineteen tension-type headache and twenty-eight migraine headache patients, Vernon et al, (1992), 97% of all tension-type headache patients exhibited on X-ray at least one significant abnormality of segmental mobility from Co to C7, while 43% exhibited abnormalities at four or more segments. Segmental hypomobility at Co-C1 was shown for 90% of the patients in flexion and 70% in extension. Muller (1999) found decreased active intersegmental motion X-ray findings (especially at C1-C2 and C2-C3 levels) in 97,5% of the patients suffering from tension-type headache.

c. *Static malposition of the head and neck*

Nagasawa et al, (1993) in an investigation of the prevalence of rounded shoulders in 372 tension-type headache patients, as opposed to 225 normal control subjects, found a statistically higher

number of rounded shoulders in tension-type headache patients (57,5%) versus control (41,8%). "Rounded Shoulders" referred to cases where the first thoracic vertebra were clearly visualised on lateral X-ray view.

In addition to the above model of cervicogenic dysfunction as a cause of tension-type headache, further studies highlight the cervicogenic hypothesis: Gatterman (1995) argues the hypothesis that cervical spine dysfunction makes a significant contribution to the cause of headache, while Muller (1999) found a significant incidence of cervical dysfunction in those suffering tension-type headache, as compared to the asymptomatic controls.

The possible sources of a headache of cervical origin are any of the structures innervated by the first three cervical nerves (Bogduk, 1992), as listed below:

- C1-C3 rami: Atlantooccipatal joint; lateral atlantoaxial joint; longus capitis; longus cervicus; rectus capitis anterior; rectus capitis lateralis; trapezius;

sternocleidomastoid; dura mata of posterior fossa; vertebral artery.

- C1-C3 Sinuvertebral nerves: Median atlantoaxial joint; transverse ligaments; alar ligaments; dura mater of spinal cord; dura mata of clivus; C2-C3 intervetrbral disc.
- C1-C3 dorsal rami: C2-C3, C3-C4 zygopophysial joints; suboccipital muscles; semispinalis capitis; semispinalis cervicis; multifidus; longissimus capitis; splenius capitis (Bogduk, 1992).

Hence, all these may be components of myofascial dysfunction and pain referral likely to be operative in tension-type headache (Vernon, 1995), but if the subject has an optimally functioning antinociception system, mild, moderate or even severe cervical spine dysfunction may not give rise to a headache (Nelson, 1994).

Gatterman (1995) stated that the neurophysiological basis of headache referral from the neck, particularly from inflammatory pain arising from the posterior occipital muscles and joints, can be explained by the phenomenon of central sensitisation and neuroplastic changes that these second order

neurons undergo in prolonged peripheral deep somatic pain. These are mechanisms thought for many years by Chiropractors to arise from a dysfunctional state of the vertebral motion segment (Gatterman, 1995).

2.4.7 Pathomechanics of pain in tension-type headache

Vernon (1998) proposed the vertebrogenic model of headache, with four categories:

- Extrasegmental, referring to the long regional myofascial structures, the ligamentum nuchae, and the interface between the occiputofrontalis muscle and the regional cervicothoracic structures.
- Intersegmental, referring to the three joint complexes of C2-C4 and the articulations of CO-C2, with their associated ligaments and deep intersegmental muscles.
- Infrasegmental, referring to the nerve structures within and surrounding the intervetebral foramina.
- Intrasegmental, referring to the spinal cord and medullary dorsal horn with trigeminocervical nucleus.

This model was previously revised by Vernon (1995). He proposed that in the mechanism of tension-type headache, the trigemino-cervical-nucleus plays an important role.

The trigemino-cervical-nucleus is an amalgamation of the caudal end of the trigeminal nucleus and the rostal ends of the horsal horns of the upper three cervical spinal nerves. Thus, the central nervous system cannot differentiate whether the source of pain is from the cervical spinal nerves or from the trigeminal system (Nilsson, 1994). Vernon (1995:309), explains that the trigimino-cervical-nucleus by virtue of its intimate relationship with the trigeminal nerve and cervical afferent nerves, is sensitive to nociceptive inputs. These can then facilitate or strengthen normal converging input resulting in hyperfacilitation. This may explain the formation of the headache and of deep tissue pain and hyperalgesia of the surrounding cutaneous areas. Hence, all these phenomena are component of myofascial dysfunction and pain referral likely to operate in tension-type headache (Vernon, 1995).

Gatterman (1990:252) discusses the arthrokinetic reflex which involves the intra-articular nociceptors: when the nociceptors are irritated by either mechanical or chemical stimulus (produced by joint pain), the reflex initiates arthrogenic muscle spasm with referred pain due to activation of convergent neutrons. Joint fixation and hypomobility may also initiate the reflex.

2.4.8 Central nervous system involvement

Pain in tension-type headache is similar to myofascial pain but whether it is strictly localised to muscle tissues or to other deeper tissues is still uncertain (Jensen, 1999). Clinically, the pain resembles that from the myofascial tissue, however components of both peripheral and central origin may contribute (Jensen 1999).

Tenderness of pericranial muscles is influenced by the actual headache state. But patients outside of the headache episode also have markedly increased tenderness compared with healthy controls (Bove & Nilsson, 1999). Pericranial muscles are therefore likely to play an important role in the pathophysiology of tension-type headache (Jensen & Olesen, 1996).

The initiating stimulus may be either a condition of mental stress, a physiological motor stress, a local irritative process with release of various peptides, or a combination of the above. The slightly increased motor activity and insufficient relaxation in the pericranial and shoulder muscles may contribute to maintaining the pain (Jensen & Olesen 1996; Jensen,1999). With increased nociceptive activity,

central sensitisation may be induced. Central nociceptive perception and modulation may become disturbed and widespread, thus prolonged secondary hyperalgesia may result (Jensen & Olesen, 1996).

Once central sensitisation is sufficiently strong and widespread, pain becomes chronic as a result of self-perpetuating disturbances in pain perception. A vicious cycle sets in and results in an abnormal reaction to incoming peripheral stimuli, often maintained long after the stimulus/stressor ceased (Jensen & Olesen 1996). In Jensen's (1999) study there was shown to be highly increased tenderness, slightly increased EMG activity and impaired pain sensitivity in patients with Chronic tension-type headache. Since Chronic tension-type headache often evolves from Episodic tension-type headache, it is suggested that prolonged painful input from the periphery may sensitise the central nervous system. Langemark et al (1988) proposed that the pain in Chronic tension-type headache with associated muscular disorder, may be due to a central misinterpretation of incoming signals at the dorsal horn or trigeminal level. This mechanism may be of importance in the conversion of Episodic

tension-type headache to Chronic tension-type headache in tension-type headache associated with pericranial muscle disorder (Jensen et al, 1998).

2.5 Treatment

Treatment of tension-type headaches commonly involves the use of various medications (Bendtsen et al, 1996). Although our present knowledge of medication habits in headache sufferers is poor, only 13% of all tension-type headache sufferers are managed without medication (Rasmussen, 1995). Schnider et al, (1994) conducted a study on the use of analgesics in 80 patients suffering from tension-type headache for an average of 21 years. Patients reported taking approximately six different drugs on average with cumulative doses reaching several kilograms. Most drugs were classified as only 'moderately effective' by patients. 21% of the group showed signs of possible analgesic-induced headache, and interestingly, many drugs with no known lasting effect on tension-type headache were prescribed. Furthermore, drugs with a considerable potential for addiction were frequently prescribed (Schnider et al, 1994).

Consequently, non-pharmacological management protocols should be explored as an alternative form of treatment.

2.5.1 Chiropractic Intervention

Vernon (1992), in a prospective study of chiropractic treatment of eighteen tension-type headache patients, found statistically significant reductions in headache activity as measured by frequency, duration and intensity. The results were obtained in an average of nine treatment sessions of chiropractic manipulation, directed principally at the cervical spine.

Mootz et al, (1994) reported on eleven men suffering from Chronic and Episodic tension-type headache. Treatment consisted of cervical spine manipulation, myofascial trigger point therapy and moist heat packs carried out over an eight week period of sixteen interventions. A statistically significant reduction in headache frequency (6,4 headaches to 3,1 headaches per two weeks) and duration (6,7 to 3,9 hours per headache) was observed, as was a strong reduction in headache intensity.

Boline et al, (1995) conducted a clinical trial of 150 patients with Chronic tension-type headache. Patients were randomised into two groups, one receiving spinal manipulation for six weeks and the other anti-

depressive medication (Amitriptyline) for six weeks. Four weeks after the cessation of therapy, the spinal manipulative group showed a 32% reduction in headache intensity, a 42% reduction in headache frequency and a reduction by 30% in analgesic use, whereas the Amitriptyline group showed no improvement in any of the variables.

2.5.1.1 Indications for manipulation

The primary indication for manipulation is a reversible mechanical de-rangement of the intervertebral joint that produces a barrier to normal motion. This is called a joint fixation (Gatterman, 1990).

Vernon et al (1992) demonstrated a high occurrence of cervical joint dysfunction during headache. This high occurrence of cervical joint dysfunction was further highlighted in tension-type headaches by the following studies: Vernon (1992); Kidd and Nelson (1993); Jansen (1998); Muller (1999). Bogduk (1992) extrapolated that joint dysfunction (subluxation) affecting the upper cervical synovial joints may play a role in the source of the headache. Although the exact pathology that occurs in these joints has yet to be clearly understood, the presence of abnormal palpatory and

motion findings, as well as relief from headache upon anaesthetisation of the responsible joint, strongly implicates these joints in those headache types that have a cervicogenic component e.g. tension-type headaches.

If cervical joint dysfunction is related to headache, then three theories of subluxation must be considered (Haldeman, 2000):

a) The nerve compression theory, in which abnormal biomechanic relations among vertebrae can cause compression of spinal nerve roots that in turn cause interference with normal nerve root function resulting in pain and other clinical symptoms or pathology. This theory, however, is still not well established scientifically

b) The reflex theory proposed that subluxation is caused by aberrant biomechanic relations, which stimulate receptors in the spinal and paraspinal tissue (including muscles, ligaments and facets). Neural reflex centres within the spinal cord or higher centres are activated by stimulation of these spinal structures, which in turn causes somato-somatic responses resulting in muscle spasm.

c) Finally the pain relief theory suggests that the adjustment can result in hypoalgesia. Often this theory is explained in terms of a singular cause for spinal pain e.g. facet fixation or muscle spasm. However, the relative importance of each of the various spinal structures still needs to be established.

Despite a need for further investigations into the subject, Haldeman (2000) concluded that the neurological effects of the adjustment can no longer be disputed. According to Gatterman (1990), a joint fixation can best be determined clinically by motion palpation or stress radiographs. Motion palpation has been found to have good intra-examiner reliability, but, inter-examiner reliability results have been inconclusive (Bergmann, et al 1993:739-739). The term adjustment is a unique term describing a chiropractic manipulation and entails the use of a specific, short-lever, high velocity, controlled forceful thrust by hand aimed at individual articulations (Gatterman, 1995:12).

Schafer and Faye (1990:40) cited the following indications for manipulation:

- Increased spinal mobility

- Break adhesions
- Extend shortened tendons and ligaments.

Others include:

- Restoring intervertebral discs and formina to their normal boundaries

Contra-indications to manipulation as stated by Gatterman (1990:67-68) include the following:

a) Vertebral-basilar artery insufficiency
b) Atheroschelerosis of major blood vessels
c) Aneurysm
d) Tumours (lung, thyroid, breast, bone)
e) Bone infections (tuberculosis, osteomyelitis)
f) Traumatic injuries (fractures, instability or hypermobility, severe sprains or strains, unstable spondylolisthesis)
g) Arthritis (rheumatoid, ankylosing spondylosis, psoriatic arthritis, unstable stage and later stage osteoarthritis, uncoarthritis)
h) Metabolic disorders (clotting disorders, osteoporosis, osteomalacia)
i) Neurologic complications (disc lesions with advancing neurological deficits, space-occupying lesions)

2.5.1.2 Effect of manipulation

There appears to be a composite of cervical spine dysfunction which may play a role in the aetiology of, or is associated with tension-type headache (Vernon et al, 1992). The high potential for upper cervical pain to occur in Chronic tension-type headache suffers creates sufficient opportunities for cranial referred pain (Vernon, 1995). Vernon (1995) stated that uncontrolled studies with regard to chiropractic manipulation, when taken together, indicated a 75%-90% success with the reduction of tension-type headaches. This may indicate that Chiropractic manipulation affects some of the underlying causative mechanisms of tension-type headache, including the Chiropractic subluxation (Boline and Nelson, 1992).

Fitz-Ritzen (1990) and Green (1997) attests that manipulation of the cervical spine causes an increase in the range of motion at the involved segment, reduction in pain and reduction in muscle tone as muscle spasm is reflexly relieved by stimulation of the facet mechanoreceptors. Curl (1994) discusses that the therapeutic effects of manipulation can be

explained by mechanical and reflex mechanisms involving mechanoreceptor stimulation, stretching of the muscle spindles, breaking of articular adhesions and increase in active and passive joint motion. Following manipulation, there is reflex inhibition of pain, inhibition of muscle spasm and stimulation of the autonomic nervous system. This is further highlighted by the Korr model (Butler, 1994) which suggests that the intrafusal fibres and golgi tendon organ receptors provide the mechanism whereby hypertonicity of the muscles producing joint fixation is relieved by manipulation. The intrafusal fibres and golgi tendon organ receptors act as breaks and limit excessive joint movement by initiating a reflex inhibition of motor activity in muscles operating over the joint. It is feasible that a high velocity thrust performed at the extreme of the restricted joints range of motion activates the golgi tendon organ receptors inhibiting muscle activity thereby reducing hypertonicity.

A study by Muller (1999), on the cervical spine dysfunction in tension-type headache subjects, found that on objective clinical examination the tension-type headache patients showed statistically significant improvements in cervical spine

dysfunction, including increased joint mobility, increased cervical lordosis, decreased tender point finding and increased cervical range of motion, following Chiropractic manipulation to the cervical spine. These results, revealed the relative efficacy of Spinal Manipulative Therapy in the treatment of tension-type headache.

2.5.2 Treatment utilizing Trans-cutaneous Electrical Nerve Stimulation

Since the exact aetiologies of tension-type headaches are not known, treatment is commonly symptomatic in nature and aimed primarily at reducing pain (Haas, 2000). According to Liss (1996), the results of stimulating human subjects with high frequency electrical impulses include the increased levels of CSF serotonin and beta endorphin and the reduction of associated pain, spacticity and headache. The effects were documented in human subjects with measurements of the serum concentration of various agents and assessments of the symptoms being performed before and after each stimulation. Since Trans-cutaneous Nerve Stimulation (TENS) provides such a high frequency electrical impulse, it could be used as an effective modality to complement SMT in the treatment of mild to

moderate Chronic tension-type headache. In a multicentre double blind study, population size 100, Solomon et al, (1989), reported on the safety and effectiveness of cranial electrotherapy in the treatment of tension-type headaches. Treatment consisted of extremely low level (≤ 2mA), high frequency current (≥ 150 Hz) applied transcranially with pain scores being recorded before and after twenty minute treatment periods, it was found to be safe and patients reported an average reduction in pain intensity of 35%.

TENS is a low level (0-60mA) biphasic, asymmetrical square wave with a variable frequency ranging from 0-600 Hz and provides pain relief by two different mechanisms. The first, based on the Gate Control hypothesis of Melzack and Wall (1965) proposes that activity in coarse afferent AB nerve fibres inhibits impulse transmission in pain pathways to the spinal cord level. The coarse nerve fibres have a low threshold for electrical stimulation and are therefore simple to activate by stimulation using electrodes placed on the skin.

The target fibres for TENS are the large AB fibres. These fibres are susceptible to electrical stimulation, while noxious impulses such as pain are conducted by A-delta or C-fibres. Both these groups of fibres have an influence of a system of neurones known as the Substantia Gelatinosa (SG). Melzack and Wall (1965) proposed that the SG has a largely inhibitory influence on the onward transmission of information to the second neurone in the spinal cord. It was proposed that when there is a noxious stimulation e.g. pain in the periphery, the A-delta and C fibres are active and the inhibitory function of the SG is diminished or stops. Thus pain is transmitted across the first synapse which acts as a physiological "gate" in the open position. When the large AB fibres are activated, e.g. by TENS the inhibitory function of the SG is enhanced and the "gate" is closed causing a diminution of pain or a cessation of the pain stimulus.

Secondly, TENS when applied cutaneously for a period of time, (> 15-20 minutes) can increase the release of endogenous opiods (serum endorphins) thereby relieving pain (Lazzari et al, 1983; Farina, 1986). It is proposed that TENS can facilitate pituitary endorphen release as well as enhance descending inhibition of pain by the activation of the periaquaductal grey matter and

Raphe nucleus. It is suggested that the analgesic effect of TENS is due to increased activity in serotonin producing fibres through the Raphe nucleus. Serotonin activity produces its effect at the post-synaptic level (Solomon, 1985).

Farina et al (1986) conducted a study on the treatment of headache with Trans-cutaneous Electrical Nerve Stimulation. TENS was applied to 35 patients with chronic muscle-contraction and tension-type headache. A high frequency current (100 Hz) was applied to the cervical spine in daily sessions of 30 minutes for 10 days. Headache improvement was > 60% in 70%-80% of the patients; > 40-60% in 22,9% of the patients and < 40% only 2,8% of the patients (i.e. one case). The results suggested that apart from its efficacy, TENS was free from side-effects, inexpensive and easy to apply and, as such, should be considered in the management of headache patients.

Studies pertaining specifically to the placement of electrodes for the treatment of headaches are sparse. According to the text "Pain Management: a practical guide for clinicians" by Kirsch, D and Lerner, F (1998) pericranial placement of electrodes, commonly over the occipital nerve pathway or over the temples or forehead,

is both safe and effective for the treatment of headaches. These placements are further supported by the text TENS: Clinical Applications and related theory" by Walsh, D (1997) which shows that a low level, high frequency current is both safe and effective for the treatment of headaches.

2.5.2.1 Indications for TENS (Ottosen, 1988), *relevant to study*

- Chronic neck and back pain
- Headaches (Farina et al, 1986)
- Improvement of muscle function by reducing spasm and associated muscle pain

2.5.2.2 Contra-indications to TENS (Ottosen, 1988)

a) Pacemakers

b) Broken or fragile skin, or dermatosis, or infection of the application site

c) Epilepsy

d) In the first three months of pregnancy

e) Patients on anti-coagulent medication e.g. Wafarin

2.5.3 Conclusion

The literature reflects that tension-type headache is a universal condition, which has both an individual and societal impact. Although not as prevalent as Episodic tension-type headache, Chronic tension-type headache has a more significant individual impact on the patient often leading to the excessive and detrimental over-use of medication.

To counter such overuse of medication and the definite threat of drug-induced side-effects, this study aims to provide evidence that chiropractic treatment is both efficient and cost effective in the treatment of Chronic tension-type headache.

Since Spinal Manipulative Therapy has been shown by clinical research to be effective in the treatment of Chronic tension-type headache and Trans-cutaneous Electrical Nerve Stimulation has been shown to be effective in the management of chronic pain conditions such as headaches, this study aims to show that a combination treatment may be more effective than a single treatment protocol in the management of mild to moderate Chronic tension-type headache.

CHAPTER III

3. MATERIALS AND METHODS

3.1 Introduction

The object of this study was to determine the relative effectiveness of each treatment protocol in terms of subjective measurements. The study attempted to identify whether the combination of Spinal Manipulative Therapy and Trans-cutaneous Electrical Nerve Stimulation had a greater effect in the management of Chronic tension-type headache than Spinal Manipulative Therapy and placebo Trans-cutaneous Electrical Nerve Stimulation. This chapter describes the methods used for collection of the subjective data, as well as the methods used for statistical interpretation and presentation.

3.2 Study design and protocol

The study was designed to be a single blinded, comparative, randomised controlled clinical trial. Patients (15) in Group A received Spinal Manipulative Therapy (SMT) to any level of the cervical spine and Trans-cutaneous Electrical Nerve Stimulation (TENS) applied pericranially. Group B (15 patients) received SMT to the cervical spine and placebo TENS. Firstly, intra-group changes were analysed for the two groups and

secondly, inter-group differences were analysed to determine which of the two protocols were, if at all, more effective.

3.3 Data

Two types of data were used in this study: primary and secondary data:

3.3.1 Primary data

The primary data was obtained by way of a standardized case history, physical and cervical regional examination according to the Durban Institute of Technology Chiropractic Day clinic forms (Appendices 3, 4, 5), as well as subjective questionnaires, namely the short-form McGill Pain Questionnaire (Appendix 6) and a Headache Diary (Appendix 7).

3.3.2 Secondary data

The secondary data was collected from a search of the related literature.

3.4 Research Methodology and Materials

Candidates suffering from Chronic tension-type headache were recruited by means of advertisements in the local newspapers, health shops, clinics and at the Durban Institute of Technology Campus. It was advertised that

free treatment was available for those patients suffering from Chronic tension-type headache who were willing to participate in the study and who agreed to abide by the treatment restrictions as defined by the experiment design. Patients who presented at the Chiropractic Clinic with suspected Chronic tension-type headache, or who replied telephonically, were briefly informed of the aim of the study and screened accordingly. Following this, an initial consultation was arranged for willing and suitable subjects.

3.4.1 **Inclusion and Exclusion Criteria**

Only those patients who fulfilled the following inclusion criteria were considered for examination:

1) Only those patients diagnosed as suffering from Chronic tension-type headaches defined by the Headache Classification Committee of the International Headache Society (1988:29-30), and who presented with no additional pathology contra-indicating spinal manipulative therapy or TENS, were considered for the study.

2) Must have suffered from at least 15 headache episodes per month for at least six months duration (International Headache Society, 1988).

3) Patients were required to present with a cervicogenic component to be considered for this study. The presence of a cervicogenic component was determined during the cervical regional examination. Zygophophyseal joint dysfunction was located by means of motion palpation (Schafer and Faye 1989:100-109).

4) Patients were required to be without manual treatment for three weeks prior to the commencement of this study. This was to induce patient naivety. Due to time constraints, this period was to be used as opposed to the more accepted six months. This naivety period - where no manual therapy is performed preceding the study - has been shown by Assendelft et al, (1992) to be an accepted substitute to the blinding process. Patients were required to be without drug therapy for two days prior to the commencement of this study. (This is an acceptable wash-out period for medication.)

5) Patients were asked about any use of muscle relaxants, anti-inflammatories and/or analgesics for the relief of the tension-type headaches. Drug names, amounts taken and frequency at which they are taken were initially recorded prior to commencement of the study. Drug use was then monitored during the treatment programme as a way of rating patient improvement.

Candidates were excluded from the study if they presented with any of the following exclusion criteria:

1) Below the age of 18 or above the age of 65 years.

- Patients younger than 18 years of age require parental consent.

- Patients older than 65 years of age are excluded because phase III degeneration is usually present in the cervical spine (Kirkaldy-Willis, 1992).

2) Any contra-indications to Spinal Manipulative Therapy as outlined by Gatterman (1990:55-69).

3) Any contra-indications to Trans-cutaneous Electrical Nerve Stimulation as outlined by Ottosen (1988).

4) Patients suffering from any of the following:

- High Blood Pressure

- Patients with cancer

- Patients presenting with hard neurological signs

- Patients requiring X-rays

5) Any patients developing secondary illnesses that may affect, perpetuate or cause their tension-type headaches will be excluded from the study e.g. influenza, sinusitis (Crompton and McHardy, 1993).

3.4.2 **Procedure**

The subjects who were considered for the study were informed as to the nature and reasons for the study in a cover letter (Appendix 1) after which they completed and signed an informed consent form (Appendix 2) which explained the terms of the study. Participants underwent a full case history (Appendix 3), relevant physical examination (Appendix 4) and cervical regional examination (Appendix 5). During the cervical regional examination, facet joints with restricted motion segments i.e. joint fixations, were located in the cervical spine by means of motion palpation (Schafer and Faye, 1989:100-109).

A. *Randomisation*:

Those patients meeting the stated criteria were then randomly allocated into group A or group B. Thirty pieces of paper were used for this purpose, 15 with group A written thereon and 15 pieces with group B written thereon. Patients, at the initial consultation, randomly drew a piece of paper from a plastic bag containing the original thirty pieces, thereby determining their group.

B. *Intervention*

Group No. 1 received cervical spine manipulation (Diversified technique (Szaraz, 1984) to the level of,

and in the direction of the fixation, and Trans-cutaneous Electrical Nerve Stimulation (151Hz, 2mA, 16 min). Treatment by TENS involved two phases (eight minutes each). Phase one involved placement of the self-adhesive electrode pads (Set A) in the following manner: Red lead pad was placed over the temporal fossa, lateral to outer canthus; the black lead pad was placed suboccipitally on the ipsilateral side. Electrode pads (Set B) mirrored the above placements on the contralateral side. Solomon et al, (1989) showed cranial electrotherapy, in the form of a low level (≤2mA), high frequency (≤150Hz) current applied transcranially, to be safe and effective in ameliorating the pain intensity of tension headaches. Although the above study uses transcranial electrode application, the pericranial electrode placement used in this study was done to reduce any risks associated with transcranial electrotherapy, although no contra-indications using the above frequency and intensity have, to date, been found.

Phase 2 involved placement of the electrode pads (Set A) in the following manner: Red lead pad was placed suboccipitally; the black lead pad was placed over the upper trapezius muscle on the ipisilateral side (placements according to D. Ottoson, T. Lundeberg, 1988). In order to standardize the point of electrode placement

on the upper trapezius muscle, a point corresponding to trapezius TP2 was used: caudal and posterior to the free border of the upper trapezius muscle (Travell, Simons and Simons, 1999). In accordance to accepted principles of electrode placement, pads may be placed over trigger points (Melzack et al, 1977). Electrode pads (Set B) mirrored above placements on the contralateral side.

Prior to electrode pad placement, the involved skin area was cleaned using alcohol and the electrodes were placed as close to the bare skin as possible, in an area absent of hair. The patients were closely monitored throughout the procedure to ensure there was no discomfort caused by the TENS.

Group 2 received spinal manipulation followed by placebo TENS (OHz, OmA, 16 min). In order to test the efficacy of a combination treatment (i.e. SMT and TENS) in the management of Chronic tension-type headache, an appropriate placebo control group is essential (Jamison, 1996). Placebo is important in a clinical study to accurately determine the effectiveness of that under investigation (Sullivan, 1993). Pad placement and treatment procedure in Group 2 was the same as for Group 1.

All participants in both groups were treated four times over a period of seventeen days.

3.5 Measurements and Observations

Subjective measurements were taken to record any changes arising from the treatment, with regard to Chronic tension-type headache.

3.5.1 Subjective measurement

The Short-form McGill Pain Questionnaire was completed at the initial, second and final treatments. The Headache Diary was filled in between the initial and second treatments, between the second and third treatments and between the third treatment and final consultation.

3.5.1.1 Short-form McGill Pain Questionnaire

The Short-form McGill Pain Questionnaire (Melzack, 1987) (Appendix 6) was used to provide subjective information on the sensory, affective and overall intensity of pain. The questionnaire consists of 15 descriptors which are rated on an intensity scale: 0 = none; 1 = mild; 2 = moderate; 3 = severe. The sum of the completed questions gave a total possible score of 45. This system of questionnaire has been shown to

be sufficiently sensitive to demonstrate differences to treatment at statistical levels (Melzack,1987).

3.5.1.2 **Headache Diary**

Andrasik (1992:353) maintains that subjective ratings of head pain including frequency, intensity and duration have become the 'gold standard' with regard to quantifying headache activity in both research and clinical settings. A headache diary adapted from Nebe, Heier and Diener (1995) was used to measure the first two parameters.

- Headache frequency pertains to the number of Chronic tension-type headache episodes experienced over the specified interval, recorded between each treatment on the Headache Diary. Frequency was calculated by dividing the number of discreet headache episodes experienced during the study, by the number of days over which the patient was treated. This could then be compared with the patients average headache frequency recorded at the initial consultation.

- Headache intensity was recorded using a visual analogue scale (VAS). The patients' initial average headache intensity was recorded at the initial consultation. Average headache intensity of the headache episodes experienced by the patient during

the study were then recorded by VAS on the Headache Diary, completed between each successive treatment.

Therefore, improvement in headache intensity could be (a) monitored from one treatment to the next and (b) monitored overall i.e. from the initial to final consultation.

With regard to headache duration, the average headache duration of the patients headaches were recorded at the initial consultation, but because the study allowed the patients to continue to use analgesics for the relief of their headaches, duration of headache episodes occurring during the study, were not able to be recorded. Drug names (and type), amounts taken and frequency at which they are taken were initially recorded prior to the commencement of the study. Drug use was then monitored during the treatment programme as a means of rating patient improvement. Patients were informed only to use analgesics or other headache medications once the headache intensity had been accurately determined and recorded on the Headache Diary after each headache episode.

The Headache Diary was completed by the patient after the initial, second and third treatments. The Headache Diary at the initial consultation also included questions about

the patient's normal headache characteristics. These included:

- Usual number of headaches (in days per month)
- Average number of headache episodes per day
- Usual headache duration in hours
- Usual headache intensity (VAS)
- Usual character of the pain
- Localisation of the pain
- Any accompanying symptoms e.g. nausea, vomiting, photo/photophobia

Blanchard et al, (1981) compared ratings obtained from the relatives of treated headache patients with the daily diary ratings made by the patients themselves, and the results were found to be statistically significant. Thus providing the social validity of the headache diary.

3.5.2 **Admissibility of Data**

The whole initial assessment for each subject was completed on the same day. Only the results of those subjects that met the criteria of the study were utilized.

3.5.3 Ethical Considerations

Ethical criteria were instituted as recommended by the Durban Institute of Technology Ethical Committee for patient orientated research.

3.6 Statistical Analysis

3.6.1 Method of data analysis

The sample size of the study was fifteen per group. Statistical analysis of the following data was collected:

1. The scores from the Short-form McGill Pain Questionnaire
2. The scores from the Headache Diary represented in terms of intensity (Visual Analogue Scale), frequency and use of medication.

Non-parametric methods were used to analyse the subjective data. Intra-group data was analysed using Friedman's t-test and Wilcoxon's signed ranks test. For the Freidman's t-test,if the null hypothesis (Ho) is rejected ($p \leq 0.05$) the Dunn Procedure (multiple comparison procedure) was applied to determine which of the treatments were significantly different. Inter-group data was analysed using the Mann Whitney-U-Test. All data was analysed at the 5% level of

significance, and decisions made using the appropriate p-values.

3.6.2 Procedure of Statistical Analysis of subjective data

Friedman's t-test was used to determine if there was significant improvement within the two groups for the Short-form McGill Pain Questionnaire and the Visual Analogue Scale scores. The data compared was taken from:

- The first treatment, the second treatment and the final consultation; i.e.

GROUP A

- 1^{ST} treatment $\leftrightarrow$ 2^{nd} treatment $\leftrightarrow$ Final Consultation

GROUP B

- 1^{ST} treatment $\leftrightarrow$ 2^{nd} treatment $\leftrightarrow$ Final Consultation

In each test, the null hypothesis states that there is no improvement between the two related samples being compared at the alpha (α) = 0,05 level of significance. The alternative hypothesis states there is an improvement at the same level.

Decision rule: The null hypothesis is rejected at the α level of significance if p, which is the observed level of significance, is less than α. Otherwise, the null hypothesis is accepted at the same level.

If the null hypothesis (Ho) is rejected and the alternative (H_1) hypothesis is accepted for the Friedman's t-test, then the Dunn Procedure will have to be applied to identify treatments that are significantly different. The multiple comparison procedure uses the following formula:

If $|Rj - Rj^1| \geq z \sqrt{\frac{bk\ (k+1)}{6}}$ then Rj and Rj^1 are declared significant.

Wilcoxon's signed ranks test was used to compare results from related samples within Group A and Group B with respect to mean headache frequency and the mean medication used per discrete headache episode. The data compared was taken from:

- The initial and final consultation; i.e.

  GROUP A

  1^{st} treatment ⟷ Final consultation

  GROUP B

  1^{st} treatment ⟷ Final consultation

The Mann Whitney-U-Test was used to determine if there was a significant difference between the two groups at the first treatment, the second treatment and the final consultation. Each group was treated as being independent of the other (unpaired) in order to determine if there was any significant difference between the two groups at a 95% confidence level. The data compared was taken from:

- The first treatment (Tx 1) of group A and group B
- The second treatment (Tx 2) of group A and B
- The final consultation (Fin. Cons) of group A and group B; i.e.
  - Group A (Tx 1) ⟷ Group B (Tx 1)
  - Group A (Tx 2) ⟷ Group B (Tx 2)
  - Group A (Fin. Cons.) ⟷ Group B (Fin. Cons.)

In each test, the null hypothesis states that there is no difference between groups A and B with respect to the variable of interest, at the $\alpha = 0,05$ level of significant. The alternative hypothesis states that there is a difference at the same level.

According to Zar (1996), the Mann Whitney-U-Test is one of the most powerful non-parametric tests.

Decision rule: The null hypothesis is rejected at the α level of significance if p, which is the observed level of significance, is less than α. Otherwise, the null hypothesis is accepted at the same level.

Selected visual summaries of analytical findings are given by use of bar charts to compare groups A and B with respect to the variables of interest. Average (mean) readings will be used to construct the charts.

3.6.3 Statistical Packages

The Statistical package SPSS was used for entry and analysis of data.

3.7 The specific treatment of each objective

3.7.1 Objective

The objective of this study was to investigate the relative effectiveness of Spinal Manipulative Therapy and Transcutaneous Electrical Nerve Stimulation as compared to Spinal Manipulative Therapy and placebo Transcutaneous Electrical Nerve Stimulation in terms of subjective clinical findings, in order to determine the more effective treatment in the management of mild to moderate Chronic tension-type headache.

3.7.1.1 The data required

The data required for testing the hypothesis of objective one was obtained from the Short-form McGill Pain Questionnaire (Appendix 6) and the Headache Diary (Appendix 7).

3.7.1.2 How the data was secured

Data was collected from the participating patients at the Durban Institute of Technology Chiropractic Day Clinic. The data was collected by the researcher and recorded in each patient's file. The Short-form McGill Pain

Questionnaire was completed under the supervision of the researcher, while the Headache Diary was explained to each patient and then completed by the patient at home between subsequent treatments.

3.8 Conclusion

Thirty patients, aged 18-65, suffering from Chronic tension-type headache were selected for this study and received either Spinal Manipulative Therapy and Transcutaneous Electrical Nerve Stimulation or Spinal Manipulative Therapy and placebo Transcutaneous Electrical Nerve Stimulation. Each patient was assessed in terms of subjective clinical findings and the data was recorded for further statistical analysis.

CHAPTER IV

4. RESULTS

4.1 Introduction

In this chapter, the criteria governing the admissibility of the data will be outlined and the collected data from the study will be presented in tabulated form. Demographic data from the study will be presented, followed by the intra-group and inter-group data.

4.1 Criteria governing the admissibility of the data

Information obtained from the case history, physical examination, cervical regional examination, Short-form McGill Pain Questionnaire and the Headache Diary were used as the data for this study. The Short-form McGill Pain Questionnaire was completed under the supervision of the researcher. The Headache Diary was completed independently by each patient at home between subsequent treatments, and returned to the researcher.

The null hypothesis (Ho) states that there is no difference between the two groups with respect to the variable of interest. The alternative hypothesis (H_1) states that there is difference between the two groups.

For the following data, the level of significance (α) was set at 0,05 (5% level of significance). Therefore, the null hypothesis was rejected when $p < 0,05$, and the null hypothesis was accepted when $p \geq 0,05$.

P is the observed level of significance of the test.

The decision rule works as follows:

Reject Ho if $P < \alpha = 0,05$

Accept Ho if $P \geq \alpha = 0,05$

P is the observed level of significance of the test.

4.1.1 **Abbreviations**

Group A = Spinal Manipulative Therapy (SMT) and Trans-cutaneous Electrical Nerve Stimulation (TENS)

Group B = SMT and placebo TENS

S.D. = Standard deviation

Freq = Frequency

VAS = Visual Analogue Scale

MEDS = Medications used

n = Number

Tx = Treatment

NAD = No abnormalities detected

Cons. = Consultation

SFMPQ = Short-form McGill Pain Questionnaire

4.3 Demographic data table

	Group A	**Group B**
Size	n = 15	n = 15
Age range (years)	21-61	22-53
Mean age (years)	32,86	30,80
Male : Female	7 : 8	4 : 11
Race:		
White	14	13
Black	1	1
Indian	0	0
Coloured	0	0
Previous headache episodes over (years)	8,73	5,53
Mean headache duration of a single headache episode (hours)		
- At initial consultation	9,13	8,60
Mean headache frequency per month (28 days)		
- At initial consultation	20,067	19,067
- At final consultation	8,9920	7,8767
Mean number of discrete headache episodes per day	1,13	1,0
Associated signs and symptoms:		
None	3	6
Photophobia	10	4
Phonophobia	2	5
Nausea (mild)	1	1
Headache location:		
A. Bilateral	12	10
Unilateral	0	0
Mixed	3	5
B. Occipital	13	13
Frontal	9	10
Temporal	9	10
Vertex	7	6

	Group A		Group B	
Pain description				
▫ Dull, Aching, Throbbing	3		4	
▫ Constricting, Oppressive, Heavy	2		2	
▫ Both	10		9	
	tx 1	tx 4	tx 1	tx 4
Myofascial tenderness (trigger points) and/or **hypertonicity**				
Posterior Cervical:				
TP_3 Active	14	3	13	4
Latent	1	12	2	11
NAD	0	0	0	0
TP_2 Active	7	2	10	2
Latent	8	12	5	10
NAD	0	1	0	3
Trapezius				
TP_2 Active	11	2	10	3
Latent	4	10	5	11
NAD	0	3	0	1
Sternocleidomastoid				
Superior TP Active	8	0	7	1
Latent	6	5	7	4
NAD	1	10	1	10
	tx 1	tx 4	tx 1	tx 4
Level of Fixation				
Co/1	8	3	9	2
C2	8	7	8	3
C3	5	4	4	3
C4	6	1	7	3
C5	1	0	2	2
C6	0	0	0	1
C7	1	0	1	0

4.4 Intra-group data

The results from groups A and B are compared with respect to the subjective data collected over the research period.

4.4.1 Subjective data

Table 1: Statistical results of the subjective findings using the Friedman's t-test to compare visit one, visit two and the final consultation of the Short-form McGill Pain Questionnaire (McGill) in Group A and then Group B.

Group		Mean	Std. Deviation	P-value
A	McGill Tx1	16.47	4.39	.000 (< .001)
	McGill Tx2	7.20	2.91	
	McGill Tx4	6.00	2.83	
B	McGill Tx 1	13.40	4.37	0.001
	McGill Tx2	7.93	3.79	
	McGill Tx4	4.13	2.59	

In Group A, there is a very high level of significance of the p-value ($p < 0,05$). Thus, the alternative hypothesis is accepted.

In Group B, there is a very high level of significant of the p-value ($p < 0,05$). Thus the alternative hypothesis is accepted.

Since the null hypothesis (Ho) was rejected for Freidman's t-test, in both Group A and Group B, the Dunn Procedure was applied to determine which of the treatments were significantly different in each group.

Table 1a: Dunn Procedure for McGill values for Group A.

Treatment	Sum of Ranks	Computed Value
$R_1 - R_2$	17.55	11.61
$R_1 - R_3$	27.55	11.61
$R_2 - R_3$	9.90	11.61

In group A, from the Dunn Procedure we find:

- R_1-R_2 (17.55) $\geq$ 11.61. Therefore, there is an improvement in the quality of the headache experience (McGill) from treatment one to the second treatment.
- R_1-R_3 (27.55) $\geq$ 11.61. Thus, there is an improvement from the initial treatment to the final consultation.
- R_2-R_3 (9.9) < 11.61. Thus there is no improvement from treatment two to the final consultation (three full treatments).

Table 1b: Dunn Procedure for McGill values for Group B.

Treatment	Sum of Ranks	Computed Value
$R_1 - R_2$	13.95	11.61
$R_1 - R_3$	27.90	11.61
$R_2 - R_3$	13.95	11.61

In Group B, from the Dunn Procedure we find:

- R_1-R_2 (13.95) $\geq$ 11.61. Therefore there is an improvement in the quality of the headache experience (McGill) from treatment one to treatment two.
- R_1-R_3 (27.90) $\geq$ 11.61. Thus, there is an improvement from the initial treatment to the final consultation.
- R_2-R_3 (13.95) $\geq$ 11.61. Thus, there is an improvement from the second treatment to the final consultation.

Table 2: Statistical results using the Wilcoxon's signed ranks test to compare the mean headache frequency at the initial consultation (per 28 days) to the mean headache frequency over the treatment programme (per 28 days).

Group		Mean	Std. Deviation	P-value
A	Mean Headache Frequency at initial Cons. (per 28 days)	20.07	4.27	0.001
	Mean Headache Frequency over Tx period (28 days)	8.99	3.73	
B	Mean Headache Frequency at initial Cons. (per 28 days)	19.07	4.82	0.001
	Mean Headache Frequency over Tx period (28 days)	7.88	3.39	

In both group A and group B, the p-value ($p < 0,05$) for headache frequency from the initial consultation to the final visit is highly significant. Thus, the null hypothesis is rejected. The alternative hypothesis (H_1), which states that there is a significant difference between the two readings, is accepted.

Table 3: Statistical results of the subjective findings using the Wilcoxon's signed ranks test to compare mean medication used per discrete headache episode (recorded at the initial consultation) to the mean medication used per discrete headache episode over the research/treatment period.

Group		Mean	Std. Deviation	P-value
A	Mean Meds per Headache at Initial Cons	2.47	0.74	0.001
	Mean Meds over Cons period	1.21	0.86	
B	Mean Meds per Headache at Initial Cons	2.57	1.21	0.001
	Mean Meds over Cons period	1.30	1.15	

In both group A and group B, there is a very high level of significance of the p-value ($p < 0,05$). Thus, the null hypothesis is rejected and the alternative hypothesis is accepted.

Table 4: Statistical results of the subjective findings using the Friedman's t-test to compare the Visual Analogue Scale (VAS) scores at the initial consultation, the second treatment and the final consultation in Group A, and then in Group B.

Group		Mean	Std. Deviation	P-value	
A	VAS at Initial Cons	7.54	1.52	.000	(<.001)
	VAS at Tx2	4.05	1.73		
	VAS at Final Cons	2.75	1.45		
B	VAS at Initial Cons	6.89	1.11	.000	(<.001)
	VAS at Tx2	4.28	1.53		
	VAS at Final Cons	2.65	1.39		

In group A, there is a very high level of significance of the p-value ($p < 0,05$). Thus, the alternative hypothesis is accepted.

In group B there is a very high level of significance of the p-value ($p < 0,05$). Thus, the null hypothesis is rejected at this level of significance, and the alternative hypothesis may be accepted.

Since the null hypothesis (Ho) was rejected for Freidman's t-test, in both Group A and Group B, the Dunn

Procedure was applied to determine which of the treatments were significantly different in each group.

Table 4a: Dunn Procedure for the Visual Analogue Scale for Group A.

Treatment	Sum of Ranks	Computed Value
$R_1 - R_2$	18.00	11.61
$R_1 - R_3$	27.00	11.61
$R_2 - R_3$	9.00	11.61

In Group A, from the Dunn Procedure we find:

- R_1-R_2 (18.0) $\geq$ 11.61. Therefore there is an improvement in the severity of the headache experienced by the patients from the initial treatment to the second treatment.
- R_1-R_3 (27.0) $\geq$ 11.61. Thus, there is an improvement from treatment one to the final consultation (representing three full treatments).
- R_1-R_3 (9.0) $<$ 11.61. Thus, there is no improvement from treatment two to the final consultation.

Table 4b: Dunn Procedure for the Visual Analogue Scale for Group B.

Treatment	Sum of Ranks	Computed Value
$R_1 - R_2$	14.10	11.61
$R_1 - R_3$	25.05	11.61
$R_2 - R_3$	10.95	11.61

In group B, from the Dunn Procedure, we find:

- R_1-R_2 (14.10) $\geq$ 11.61. Therefore there is an improvement in the severity of the headache experienced by the patients from the initial treatment to the second treatment.
- R_1-R_3 (25.05) $\geq$ 11.61. Thus, there is an improvement from treatment one to the final consultation (representing three full treatments).
- R_1-R_3 (9.0) $<$ 11.61. Thus, there is no improvement from treatment two to the final consultation, although the improvement between these treatments was greater than that of Group A.

4.5 Inter-group data

The results from related data are compared with respect to the subjective data collected within group A and within group B over the research period.

4.5.1 Subjective Data

Table 5: Statistical results of the subjective findings using the Mann Whitney-U-test to compare the initial consultation (Tx 1), the second treatment (Tx 2) and the final consultation (Tx 4) of the Short-form McGill Pain Questionnaire of both group A and group B.

	Group A		Group B
	Mean	P-value	Mean
McGill (0-45) Initial Cons.	16.47	0.088	13.40
McGill (0-45) T x 2	7.20	0.933	7.93
McGill (0-45) Final Cons.	6.0	0.098	4.13

There are no differences ($p \geq 0,05$) in the value (means) between the initial consultation, the second treatment and the final treatment. Thus the null hypothesis is accepted. For graphic representation of the means values recorded above, refer to graph one.

Table 6: Statistical results of the subjective findings using the Mann Whitney-U-test to compare the mean headache frequency at the initial consultation and the final consultation of both group A and group B.

	Group A		Group B
	Mean	P-value	Mean
Mean headache frequency at initial Cons. (per 28 days)	20.0667	0.594	19.0667
Mean headache frequency over Tx period (per 28 days)	8.9920	0.520	7.8767

There are no differences ($p \geq 0,05$) in the values (means) between headache frequency (over 28 days) at the initial consultation and headache frequency over the treatment period (calculated to 28 days) of both group A and group B. Thus, the null hypothesis is accepted. For graphic representation of the above mean values, refer to graph two.

Table 7: Statistical results of the subjective findings using the Mann Whitney-U-test to compare mean medication used per discrete headache episode recorded at the initial consultation to mean medication used per discrete headache episode over the treatment programme of both group A and group B.

	Group A		Group B
	Mean	P-value	Mean
Mean meds per headache at initial Cons.	2.4667	0.789	2.5667
Mean meds per headache over Tx period	1.2073	0.850	1.2953

There are no differences ($p \geq 0,05$) in the values (means) between medication used per headache episode at the initial consultation and medication used per headache episode over the treatment period, of both group A and group B. Thus, the null hypothesis is accepted. For graphical representation of the above values, refer to graph three.

Table 8: Statistical results of the subjective findings using the Mann Whitney-U-test to compare the VAS scores of the initial consultation (Tx 1), the second treatment (Tx 2) and the final consultation (Tx 4) of both group A and group B.

	Group A		Group B
	Mean	P-value	Mean
VAS (Tx 1)	7.54	0.383	6.8933
VAS (Tx 2)	4.0533	0.819	4.28
VAS (Tx 4)	2.7533	0.546	2.6467

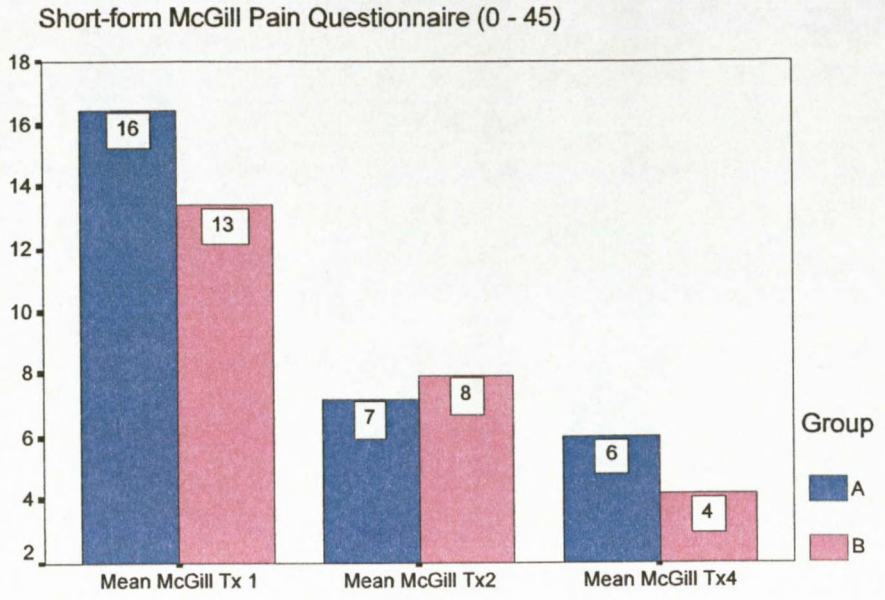
There are no differences ($p \geq 0,05$) in the values (means) between the initial consultation, the second treatment and the final consultation. Thus the null hypothesis is accepted. For graphic representation of the mean values represented above, refer to graph four.

4.6 Graphical Representation

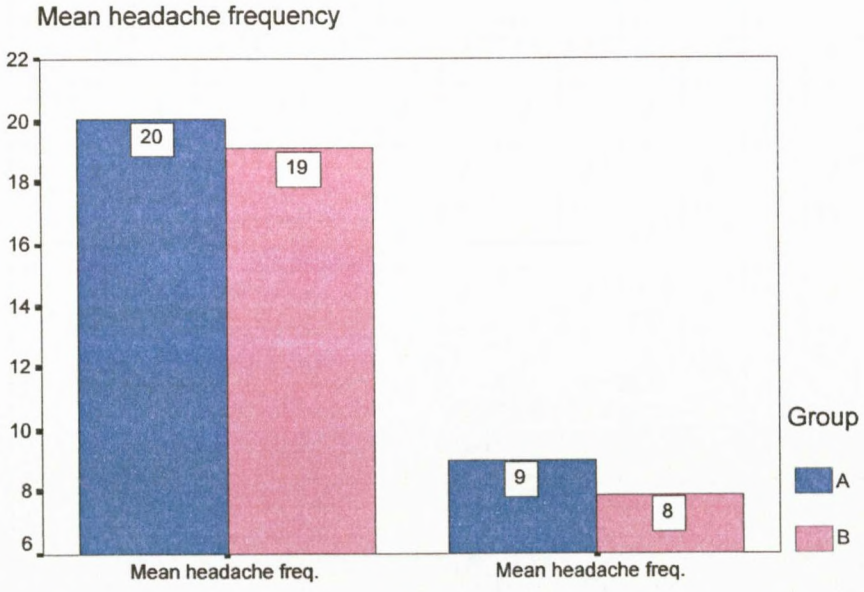
For graphical representation of the above results, refer to the pages at the end of this chapter.

4.7 Conclusion

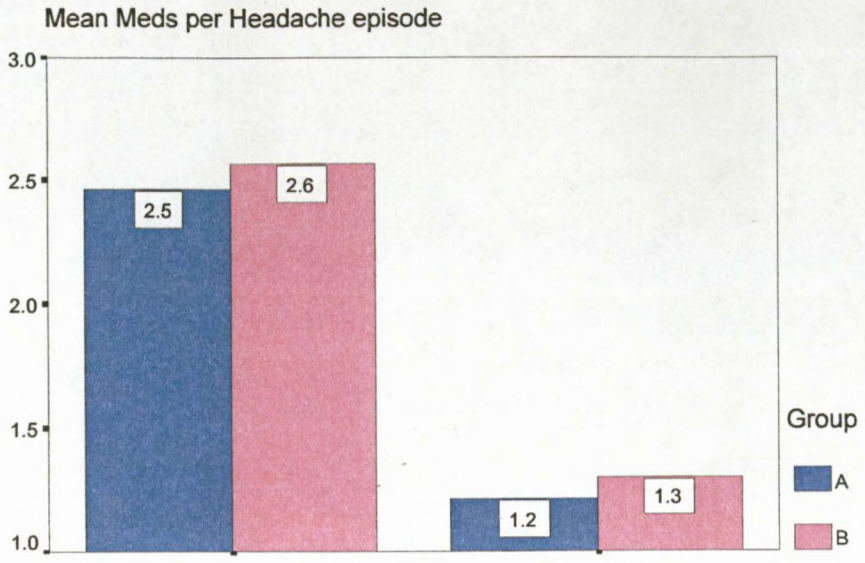
The data collected in this chapter was collected during the course of the study and represents the subjective measurements for both the intra-group and the inter-group comparisons. The data was statistically analysed using the SPSS Software Package.



Graph 1: Mean values recorded for the Short-form McGill Pain Questionnaire comparing Group A & B at treatments 1, 2 & 4

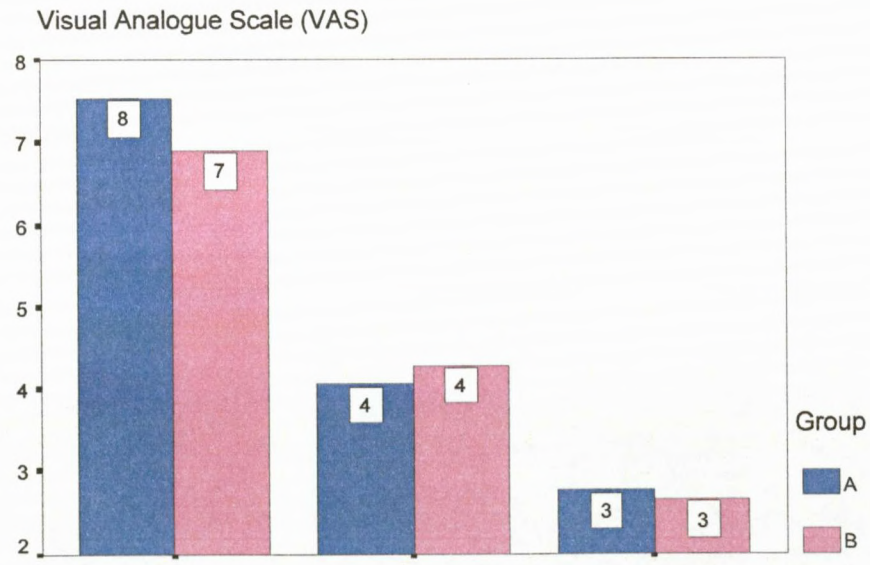


Graph 2: Mean Headache frequency values comparing group A & B at Initial Consultation and Final treatment



Graph 3: Mean medication used per discrete headache episode comparing

Groups A & B at Initial Consultation and Final treatment



Graph 4: Mean values recorded for the Visual Analogue Scale comparing

Groups A & B at treatments 1, 2 & 4

CHAPTER V

5. Discussion

5.1 Introduction

This chapter focuses on two main areas of analysis, namely, demographic data analysis and subjective data analysis. Analysis of the subjective data includes intra-group as well as inter-group comparisons. Results from this study were then compared with published research on the topic to determine whether this study compares favourably or not to documented trends.

5.2 Demographic data

Seventy-six candidates applied to be part of the study of whom thirty were accepted to participate. Patients were excluded for the following reasons:

1) Four subjects had sustained trauma to the cervical spine.
2) Three subjects had positive Wallenberg's test bilaterally.
3) Four subjects had excessively high blood pressure.
4) Two subjects were too old i.e. over 65 years of age.
5) Five subjects failed to keep their appointments within the stipulated 17 days.

6) Twenty-seven subjects were diagnosed with having another type of headache: Episodic tension-type headache (thirteen); migraine headache - eleven (6 patients had both tension-type headache and migraine); cluster headache (two) and Sinus headache (one).

The age range of group A was from twenty-one to sixty-one years of age with a mean age of 32,86 years, whilst the range of group B was from twenty-two to fifty-three years of age with a mean age of 30,80 years. The age range and mean age correspond with other studies in which the prevalence peaked in the 30-39 year old age group (Schwartz et al, 1998).

The male to female ratio was 7:8 for Group A and 4:11 for group B. This corresponds to the majority of literature in which women had a higher prevalence than men did at all ages (Gobel et al, 1994; Rasmussen, 1995; Schwartz et al, 1998). A total of nineteen women were treated in this study - representative of 63,3% of the total treatment group. This correlates to Bove and Nilssons (1998) study which proposed that in clinical populations, women outnumber men, and that this may be due to the fact that women are more likely to seek

care for their headaches than men. This was further highlighted by the fact that twenty three of the patients suffering from headaches (69,6%) who applied, but were not accepted onto the study, were female.

The subjects had suffered previous headache episodes of a range of six months to thirty-three years in group A, with a mean duration of 8,73 years. In group B subjects had suffered previous headache episodes of a range of six months to thirty years, with a mean duration of 5,53 years. These mean values do not correlate closely to the 10.0 years mean duration of episodes as reported by Langemark et al (1988) in his study on the "clinical characterisation of patients with Chronic tension-type headache". This may be due to the small sample size used in this study - thirty patients as opposed to 148 patients in Langemark et al (1988) study, or possibly due to the different demographical/geographical areas under which the studies were completed.

The mean headache duration of a single headache episode suffered by the participants and recorded at the initial consultation, ranged from three hours to forty eight hours in group A, with a mean value of 9,13 hours. In group B the mean duration of a single headache episode ranged from six hours to seventy two hours, with a mean value of 8,60 hours. These values correspond to other studies in which the headache

duration varied from several hours - 5,9 hours to 8,2 hours (Linet et al, 1989) to several days (Mootz et al, 1992).

The most common headache description in both groups was a combination of a "dull, aching" pain with a "heavy, constricting, oppressive" sensation. This description corresponds closely to the description of the headache sensation in other studies and literature (Headache Classification Committee, 1988; Travell, Simons and Simons, 1999; Kidson, 2001).

Headache location was similar between the groups with the majority of patients complaining of a sub-occipital headache (86,7% in both groups). However, most of these patients also complained that headache location began sub-occipitally but moved into the head to involve the frontal (60% group A, 67% group B); Temporal (60% group A, 67% group B) and Vertex areas (47% group A and 40% group B) of the head. These locations correspond closely to previous research (Langemark et al, 1988; De Busser, 2001), but especially the "muscular theory" that myofascial trigger points may be actively involved in the aetiology of tension-type headache since pain arising from these points in the posterior cervical

musculature commonly refers from the sub-occipital region into the forehead, temporal region and vertex of the head (Olesen, 1991; Vernon et al, 1992; Travell, Simons and Simons, 1999).

The possibility that Chronic tension-type headache arises from psychological stress cannot be refuted by this study. From data recorded in the Case History examination, stress was commonly indicated by participants to trigger a headache. Two patients had recently lost their jobs, one patient experienced the death of a family member, one patient was resigning from his job to emigrate overseas, one patient was recently divorced, three patients were in financial difficulty, two patients had been unemployed for several months and the seven students who participated in the study were preparing to or writing examinations. Other stresses mentioned included family tension and a dislike of their current jobs. In keeping with the findings of this study, Passchier and Orlebeke (1985) reported that of all headache triggers in their study, stress was mentioned most frequently. Smith (1995) indicated that psychological factors might precipitate or augment headache and in fact, a number of studies have made use of anti-depressants for the treatment of Chronic tension-type headache (Boline et al, 1995; Mitsikostas, 1997).

Other than stress, which was found to be the predominant precipitating factor in 63,3% of the participants, other

precipitating factors were: light (46,6%), sound (23,3%) and the use of computers (23,3%), with two patients reporting mild nausea in addition to photophobia. These values correspond closely to Kidson's (2001) study in which stress was found to be the predominant precipitating factor in 65% of the subjects, while other precipitating factors included light (26.67%); sound (10%) and computers(15% of the subjects). In the current study, menstruation was also found to play a role in headache occurrence and severity in 16.6% of the participants. This corresponds to Rasmussen's (1995) study in which menstruation (and alcohol) were found to be active precipitants in tension-type headache.

In both groups, subjects complained of associated neck or shoulder pain and/or tightness. Participants were palpated by the examiner as part of the cervical regional examination to determine trigger point involvement in the upper and middle posterior cervical muscles, the upper trapezius muscles and the upper sternocleidomastoid muscles. This was performed at the initial and final consultations.

In group A, hypertonicity and tenderness most commonly occurred in the upper posterior cervical muscles (93% of participants), the trapezius muscles (73% of participants), and the middle posterior cervical muscles (47% of participants). These findings correspond with Kunkel (1991)

and Davies' (2000) findings that patients with tension-type headache concurrently experience neck 'tightness' or 'stiffness' of the trapezius and suboccipital muscles. Hypertonicity also occurred in the upper sternocleidomastoid muscles in 54% of the participants. This correlates with Nagasawa et al's (1993) study in which 372 patients with tension-type headache were X-rayed to determine relationships between the cervical spine and tension-type headache. A great majority of the patients were found to have straightened cervical spines. It was proposed that a large portion of tension-type headache patients had sustained contraction of the neck flexors which, in turn, exerted a slight anteflexion of the cervical spine and caused passive loading of the posterior occipital muscles.

Group B had similar findings, with hypertonicity and tenderness occurring most commonly (in descending order) in the following muscles: the upper posterior cervical muscles (87%); the upper trapezius muscles (67%); the middle posterior cervical muscles (67%) and the upper sternocleidomastoid muscles (47%).

In both groups there was a reduction in the hypertonicity and tenderness experienced by the patient at the final consultation. In group A, the percentages of participants still having active myofascial involvement were as follows:

in the upper and middle posterior cervical muscles - 20% and 13,3% respectively; the upper trapezius muscles - 13,3%, and the upper sternocleidomastoid muscles - 0%. This was mirrored by the findings in Group B: upper and middle posterior cervical muscles - 26,7% and 13,3% respectively; the upper trapezius muscles - 20% and the upper sternocleidomastoid muscle - 6,7%. Fitz-Ritson (1990) and Green (1997) attest that manipulation of the cervical spine causes a reduction in muscle tone as muscle spasm is reflexly relieved by stimulation of the facet mechanoreceptors. The Korr model suggests that the intrafusal fibres and golgi tendon organ receptors provide the mechanism whereby hypertonicity of the muscle producing joint fixation is relieved by manipulation. The intrafusal fibres and golgi tendon and organ receptors act as breaks and limit excessive joint movement by initiating a reflex inhibition of motor activity in muscles operating over the joint (Butler, 1994). It is feasible that a high velocity thrust performed at the extreme of the restricted joints range of motion activates the golgi tendon organ receptors inhibiting muscle activity, thereby reducing hypertonicity (Butler, 1994 : 98-99). This improvement in the hypertonicity and tenderness of the cervical muscles following cervical manipulative therapy correlates to various other studies: Gatterman, 1990; Menell, 1990; Halderman, 2000.

Forty-three percent of the patients reported that initially their headaches occurred less frequently, thereby placing them in the Episodic tension-type headache category, as defined by the Headache Classification Committee (1988). They reported an initial headache frequency of less than 15 episodes per month, although this frequency increased over time to over 15 episodes a month, placing them into the chronic headache group. This correlates to Jensen et al (1997) which proposed that the conversion of Episodic tension-type headache to Chronic tension-type headache is highly probable. This is significant as Kidson (2001) found Spinal Manipulative Therapy alone very effective in the treatment of Episodic tension-type headache. The current study found Spinal Manipulative Therapy and Transcutaneous Electrical Nerve Stimulation to be more effective than SMT alone in the treatment of Chronic tension-type headache. As such, it can be postulated that such a combination treatment may be used to great effect in the treatment of Episodic tension-type headache, thereby reducing headache symptoms and possibly preventing the conversion from an Episodic to a Chronic tension-type headache. This would in turn reduce the individual and societal impact that the headaches have on the patients, while reducing lost workdays, thereby improving productivity and profitability in business.

The most common level of fixation in both groups was Co/1 (57%) followed very closely by C2 (53%)and then C4 (43%). Ng (1980) and Bogduk (1992) noted dysfunction of the upper cervical spine in adult headache sufferers and the results of the current study confirm the role of the upper cervical spine in the mechanism of Chronic tension-type headache. Vernon and McDermaid (1998) found upper and mid-cervical manipulation to receive the highest level of endorsement from chiropractors in the field. In both group A (29 fixations to 15 fixations) and group B (31 fixations to 14 fixations) there was a marked reduction in the number of fixations found between the initial consultation and the final consultation. This reduction corresponds to current knowledge that chiropractic manipulation will reduce joint subluxation (Gatterman, 1990; Haldeman, 2000).

5.3 Intra-group analysis

5.3.1 **The Subjective Data**

Short-Form McGill Pain Questionnaire

Comparing visit one to visit two, to the final consultation of the Short-form McGill Pain Questionnaire (Table 1) for Group A, the p-value was less than $\alpha = 0.05$, thus the alternative hypothesis (H_1), which states that there is significant improvement between the visits, was accepted.

The SFMPQ (Table 1) for group B showed statistically significant results at the 95% confidence level when comparing visit one to visit two, to the final consultation. At this level H_1 is accepted. This reveals that in both groups, treatment was able to reduce the headache symptoms, at a 95% level of confidence.

Since the null hypothesis (Ho) was rejected for Freidman's t-test when analysing the Short-form McGill Pain Questionnaire results, the Dunn Procedure was applied to determine if there was a significant improvement between treatments, and if so, which treatments.

In Group A (Table 1a), from the Dunn Procedure it was found that for R_1-R_2 the Sum of Ranks (17.55) $\geq$ Computed value (11.61), thus there was a highly significant reduction in the headache symptoms experienced by the participants from the first treatment to the second treatment.

In Group B (Table 1b), from the Dunn Procedure it was found that for R_1-R_2 the Sum of Ranks (13.95) $\geq$ Computed value (11.61), thus there was a highly significant improvement from the first treatment to the second treatment in terms of headache symptoms experienced by the participants, although not as significant as that experienced in Group A.

Looking at the descriptive statistics, the mean SFMPQ value in group A went from 16,47 at the initial consultation to 7,20 at treatment two, thus representing an improvement of 9,27. In group B mean SFMPQ values went from 13,40 to 7,93, representing an improvement of only 5,47. Therefore, the combined treatment of Spinal Manipulative Therapy (SMT) and Trans-cutaneous Electrical Nerve Stimulation (TENS) was more effective than SMT and placebo TENS at reducing the headache symptoms experienced by the patients after just one treatment.

Using the Dunn Procedure to compare visit one to visit four (final consultation) of the Short-form McGill Pain Questionnaire (Table 1a) for group A, the Sum of Ranks (27.55) ≥ Computed value (11.61), thus there was a highly significant reduction in headache symptoms experienced by the patients from the initial visit to the final consultation.

The SFMPQ (Table 1b) for Group B, showed equally statistically significant results at the 95% confidence level, when comparing visit one to the final consultation. For R_1-R_3, the Sum of Ranks (27.90) ≥ Computed value (11.61). Thus there was a significant improvement from the initial to final consultation. This revealed that in both groups treatments

were able to reduce headache symptoms at a 95% level of confidence.

On analysis of the descriptive statistics, mean SFMPQ value improvement from the initial treatment to the final consultation was 10,47 and 9,27 in Group A and Group B respectively. From the above values, it can be reasoned that a combination treatment of SMT and TENS is more effective than SMT and placebo TENS (i.e. SMT alone) in the reduction of headache symptoms in patients suffering from Chronic tension-type headaches. Furthermore, the mean improvement value in Group A from treatment one to treatment two was 9,27, the same as the mean improvement value for Group B (9,27) over the entire treatment period i.e. treatment one to treatment four. Therefore, it can be hypothesised that a single treatment with SMT and TENS is as effective as three treatments with SMT alone, although the difference between overall improvement is less pronounced.

Using the Dunn Procedure to compare visit two to the final consultation of the Short-form McGill Pain Questionnaire (Table 1a) for group A, the Sum of Ranks (9.9) $\leq$ Computed value (11.61). Thus there was no significant improvement in the quality of the headache from treatment two to the final consultation. Although a reduction in the headache symptoms was noted by the participants of Group A from treatment two to

the final consultation, the Dunn Procedure did not register the improvement as highly significant.

The SFMPQ (Table 1b) for Group B, showed statistically significant results at the 95% confidence level, when comparing visit two to the final consultation. For R_2-R_3, the Sum of Ranks (13.95) ≥ Computed value (11.61), thus there was a significant reduction in the headache symptoms from the second to the final consultation. This revealed that Group B was able to reduce headache symptoms between these treatments at a 95% level of confidence.

Between treatment two and the final consultation, improvement in group B was more statistically significant than in group A, suggesting that after the initial treatment with SMT and TENS (Group A), patient improvement plateaus somewhat. Thereafter, improvement continues slowly, albeit steadily. What is of interest, is that the Sum of Ranks for Group B (13.95) was constant for both R_1-R_2 and R_2-R_3. Thus, in Group B (SMT alone), improvement, although initially slower than the combination treatment of SMT and TENS, was constant and continued at a steady pace such that overall improvement after three treatments, between the two groups, was very similar.

Summary (short-form McGill Pain Questionnaire)

There were statistically significant differences recorded for the SFMPQ scores of both group A and group B, at the 95% level of confidence. Group A showed a more significant improvement from treatment one to two than group B, although overall improvement was similar. Thus, Spinal Manipulative Therapy, in conjunction with Trans-cutaneous Electrical Nerve Stimulation, provided both a rapid and lasting effect in the improvement of headache symptoms in patients suffering from Chronic tension-type headaches. Spinal Manipulative Therapy alone (placebo TENS) provided improvement in symptoms although significantly less rapid and slightly less effective than the combination treatment.

Headache Diary

For both group A and group B (Table 2), a statistically significant reduction in headache frequency was recorded when comparing the mean headache frequency recorded at the initial consultation (per 28 days) to the mean headache frequency recorded over the treatment period (calculated to 28 days), thus Ho was rejected and the alternative hypothesis (H_1) was accepted. Subjects experienced considerably fewer headaches over the research programme than normal.

The mean frequency of the headaches per month at the initial consultation in group A was 20,067 episodes, while in group B the headache mean frequency per month was 19,067 episodes. The groups were considered to be similar and comparable with regard to frequency of headache episodes, which strengthened the statistical results of this study. These values correspond to the mean range of frequencies, 12,8 episodes per month (Mootz et al, 1994) to thirty episodes per month (Langemark et al, 1988) as reported by the above researchers in patients suffering from Chronic tension-type headache. At the final consultation, mean frequency of the headaches per month was diminished in both groups. Group A reported a decrease in headache frequency per month of 20,067 episodes to 8,99 episodes following participation in the study. Group B reported a decrease in headache frequency per month of 19,067 episodes to 7,88 episodes following participation in the study. Both groups showed marked improvement from normal mean headache frequency per month to the number of headache episodes per month experienced by the participants during the study. This reduction in headache frequency corresponds to numerous studies: Vernon (1982) in a prospective study of chiropractic treatment for adult tension-type headache sufferers recorded a reduction in frequency from twelve to two headaches per month. Mootz et al (1994) found that after eight treatments of manipulation, myofascial trigger point

therapy and moist head packs, subjects in the study went from suffering 6.4 to 3.1 headaches per two weeks. Similarly Boline et al's (1995) study comparing spinal manipulation with anti-depressive medication, indicated a 42% decrease in frequency for the group receiving manipulation and no improvement for the medication group.

For both group A and group B (Table 3), a statistically significant reduction in medication used per discrete headache episode was recorded when comparing the normal mean medication used per headache episode at the initial consultation to the mean medication used per headache episode during the research programme. Thus, the Ho was rejected and the alternative hypothesis (H_1) was accepted.

In both groups over the counter analygesics were most commonly used for the treatment of the headache pain. These included Panado®, Myprodol®, Disprin®, Neurofen® and Stopain®. This correlates to current literature and research which states that Chronic tension-type headache is most commonly treated with medication, in particular over-the-counter analgesics and anti-inflammatories (Anrig and Plougher, 1998; Curl, 1999).

In group A the number of headache tablets (analgesics) taken per headache episode at the initial consultation, ranged from two to six tablets, with a mean value of 2,2 tablets per

discrete headache episode. This figure is probably below the true level of tablets consumed, as patients were reluctant to express an over-use of medication during patient examination. At the final consultation (reflecting drug use during the study) the number of headache tablets taken per headache episode ranged from 0 to 2,29 tablets per discrete headache episode, with a mean value of 1,21 tablets per discrete headache episode. This represents a 55% reduction in the use of medication by patients for the symptomatic relief of Chronic tension-type headache during the study.

In group B the number of tablets (analgesics) taken per headache episode, at the initial consultation, per headache episode ranged from 1 to 8, with a mean value of 2,5667 tablets per discrete headache episode. At the final consultation the use of tablets ranged from 0 to 4,5 tablets per headache episode with a mean value of 1,29 tablets. This reflected a 54,4% reduction in the use of analgesics for Chronic tension-type headache during the study.

Furthermore, since the mean headache frequency was reduced in both groups from the initial to final consultations, use of headache medication was even further reduced since patients experiencing fewer headaches required fewer "headache tablets". In group A, the mean headache tablet use per month was 40,86 tablets, while in group B it was 55,40 tablets per

month. At the final consultation (representing the treatment period) the mean headache tablet use per month was 12,72 and 12,14 in group A and group B respectively. This represents a 68,86% (group A) and a 78,1% (group B) reduction in the mean use of medication by patients suffering from Chronic tension-type headaches per month.

This reduction in the use of prescription medication for the symptomatic relief of pain in Chronic tension-type headache sufferers is important for two reasons. Firstly, by reducing the use of medication we reduce the risk of iatrogenically induced side-effects (Curl, 1999), as well as possible dependency on treatment (De Busser, 2001). Secondly, the reduction in usage of over-the-counter prescription drugs provides a more cost efficient approach to the treatment of mild to moderate Chronic tension-type headaches. This corresponds with Stano's (1993) findings that chiropractic may provide significant cost savings for users in respect of common musculoskeletal disorders.

The Visual Analogue Scale (VAS) scores for group A (Table 4) showed a highly significant improvement from the values recorded at the initial consultation (representing average normal headache intensity), the scores recorded at the second visit (representing VAS scores following one treatment) and the scores recorded at the final consultation (representing

three treatments). Thus, the Ho was rejected and the H_1 was accepted. Since the null hypothesis (Ho) was rejected for Freidman's t-test when analysing the Visual Analogue Scale scores, the Dunn Procedure was applied to determine if there was a significant improvement between treatments, and if so, which treatments.

In Group A (Table 4a), from the Dunn Procedure it was found that for R_1-R_2, the Sum of Ranks (18.0) $\geq$ Computed value (11.61). Thus, a highly significant degree of relief from pain and distress was achieved by the combination treatment of Spinal Manipulative Therapy and Transcutaneous Electrical Nerve Stimulation from the first consultation to treatment two, at a 95% level of confidence.

In Group B (table 4b), from the Dunn Procedure, it was found the Sum of Ranks (14.10) $\geq$ Computed value (11.61). Thus, there was a significant improvement between treatments. In Group B, subjects had a smaller Sum of Ranks, thereby revealing that although the treatment (SMT and placebo TENS) provided significant relief from pain, at a 95% level of confidence, the relief provided was not as significant as that provided by the combination treatment in group A over a period of one treatment.

Using the Dunn Procedure to compare visit one to the final consultation of the Visual Analogue Scale (Table 4a) for group A, the Sum of Ranks (27.0) ≥ Computed value (11.61), thus indicating that significant relief from pain was achieved by the combination treatment of SMT and TENS, at a 95% level of confidence, from the initial visit to the final consultation.

The Visual Analogue Scale (Table 4b) for group B, showed equally statistically significant results at the 95% confidence level when comparing visit one to the final consultation. For R_1-R_3, the Sum of Ranks (25.05) ≥ Computed value (11.61), thus there was a significant improvement between treatments. This revealed that in both groups, treatments were able to reduce the degree of pain and distress suffered by participants at a 95% level of confidence.

When comparing the Sum of Ranks of Group A and Group B, both groups had a very similar improvement from the initial to final consultations, although Group A (SMT and TENS) had a slightly more significant overall improvement than Group B (SMT and placebo TENS).

What is interesting is that these values re-affirm the McGill values which revealed that after one treatment, the combination treatment of SMT and TENS provides a rapid

improvement, but then plateaus and improvement is thereafter slow but steady. SMT alone provides a constant, steady improvement from the initial treatment which, although does of offer the immediate relief that a combination treatment does, provides a very similar improvement over three treatments.

Using the Dunn Procedure to compare visit two to the final consultation of the Visual Analogue Scale (Table 4a) for group A, the Sum of Ranks (9.0) ≤ Computed value (11.61). Thus there was no significant improvement in the severity of the headache pain from treatment two to the final consultation. However although the Dunn Procedure did not register the improvement as highly significant, a reduction in the severity of the headache pain and distress was noted by the participants. On analysis of the descriptive statistics, VAS scores did show an improvement from the second treatment to the final consultation.

The VAS (Table 4b) for Group B, showed similar findings to Group A when comparing the second treatment to the final consultation. For R_2-R_3, the Sum of Ranks (10.95) ≤ Computed value (11.61), thus there was no significant improvement between treatments. However, as in Group A, an analysis of the descriptive statistics revealed that the VAS scores did show an improvement from the second treatment to the final

consultation, thereby indicating that both groups did receive relief from pain between these treatments. The improvement of VAS scores in Group B (1.633) and the Sum of Ranks (10.95) indicate that the improvement using SMT alone (placebo TENS) was greater than that of a combination treatment of SMT and TENS between treatment two and the final consultation (1.33 and 9.0 for the VAS score improvement and the Sum of Ranks respectively).

This reaffirms the previous statement that treatment with SMT and TENS, plateaus after one treatment with further improvement occurring slowly, while treatment with SMT alone occurs steadily from the initial treatment to the final consultation.

These results compare favourably with findings by Hoyt et al (1979), in a study comparing manipulation to two placebo control groups in patients suffering from chronic headache, who indicated a decrease by 50% in headache severity. Boline et al (1995), in his study on spinal manipulation vs amitriptyline for the treatment of Chronic tension-type headache, indicated a 32% decrease in headache intensity in those patients receiving spinal manipulation. However, contradictory findings were recorded by Mootz et al (1994) where a trend towards reduction in severity was recorded but was not found to be statistically significant. Possible

reasons for this disparity in the literature may be that Mootz et al's (1994) study grouped both Episodic and Chronic tension-type headache sufferers, and that only male subjects were accepted into the research.

Summary (Headache Diary)

Analysis of the data indicated that both group A and group B showed statistically significant improvements in headache frequency. Group A and B both had a p-value of 0.001, thus demonstrating that both SMT and TENS, and SMT alone, is effective in reducing headache frequency in patients suffering from Chronic tension-type headaches.

A highly statistically significant improvement was recorded for both group A and group B in terms of mean medication used per discrete headache episode. Group A and group B both had a p-value of 0.001, thus indicating that both a combination treatment, or SMT alone, is effective in reducing medications used for pain relief in patients suffering from Chronic tension-type headache.

Analysis of the data indicated that both group A and group B showed statistically significant overall improvement in headache severity (pain and distress). Both Group A and Group B had a p-value of 0.000, thus demonstrating that both Spinal

Manipulative Therapy in conjunction with Transcutaneous Electrical Nerve Stimulation, and Spinal Manipulative Therapy alone (placebo Transcutaneous Electrical Nerve Stimulation), caused a reduction in headache severity in the treatment of Chronic tension-type headache.

5.4 Inter-group data

5.4.1 Subjective data

Short-form McGill Pain Questionnaire

Comparing the data obtained from the SFMPQ completed at the initial consultation for both groups A and B (Table 9) produced a p-value greater than $\alpha = 0,05$ and hence the Ho was accepted. Therefore, no statistically significant difference was observed.

The mean values of both groups were similar in terms of the quality of pain experienced and the groups were thus comparable. This assists in the analysis of any changes that may arise as a result of either form of treatment. Any reduction in the quality of pain would be indicative of the success of the treatment.

Analysis of statistical results comparing (a) visit two, and (b) the final consultation of groups A and B,

revealed in both cases a p-value greater than $\alpha = 0,05$. Therefore, in both cases, Ho is accepted and the alternative hypothesis rejected.

Summary (short-form McGill Pain Questionnaire)

Overall, the mean value of the two groups at visit one, visit two and the final consultation were very similar, indicating that neither treatment was more statistically beneficial than the other in reducing the quality of pain experienced by those headache sufferers.

Headache Diary

When comparing visit one of the Headache Diary for groups A and B (Table 10), no statistically significant difference was noted at the 95% level of confidence for mean headache frequency as recorded by the examiner.

At the final consultation, no statistically significant changes were noted when comparing the groups with respect to headache frequency (Table 10) and thus Ho was accepted and H_1 rejected. It would appear that both forms of treatment were equally beneficial with regard to improving the number of headache episodes experienced by the patient. Group A and B showed a significant

improvement in headache frequency, with a change in the mean number of headache days per month from 20,067 to 19,067 and 8,99 to 7,87 for groups A and B respectively.

When comparing visit one of the Headache Diary for groups A and B (Table 11) no statistically significant difference was noted at the 95% level of confidence for the mean medication used per discrete headache episode.

At the final consultation, no statistically significant changes were noted when comparing the groups, thus the alternative hypothesis was accepted and H_1 rejected. Both forms of treatment were equally beneficial with regard to improving the mean medication used per discrete headache episode. Group A and group B showed a significant improvement in the use of medication from treatment one to the final consultation, with both treatments providing similar overall improvements.

Comparing the data obtained from the Visual Analogue Scale (VAS) completed at the initial consultation for both groups A and B (Table 12) produced a p-value greater than $\alpha = 0,05$ and hence the Ho was accepted. Therefore, no statistical significance was observed.

The mean values of both groups were similar in terms of the intensity of pain experienced and the groups were thus comparable.

Analysis of statistical results comparing (a) visit two, and (b) the final consultation, of groups A and B revealed in both cases a p-value greater than $\alpha = 0,05$. Therefore in both cases, Ho is accepted and the alternative hypothesis rejected.

Overall, the mean values of the two groups at the initial consultation, treatment two and the final visit were very similar, indicating that neither treatment was more statistically beneficial than the other in reducing the intensity of the pain experienced by these headache sufferers. Although the reductions in headache intensity recorded from visit one to four, in group A and group B, indicates that both groups showed a significant (and similar) improvement in the intensity of the pain experience.

Summary (Headache Diary)

The two groups were comparable for all measurements at the initial visit and thus any changes in the p-value to an alpha value less than 0,05, would indicate the one treatment to be more effective than the other.

Comparisons of the groups at visit two and the final consultation, in terms of mean headache frequency, mean medication used per discrete headache episode and severity/intensity of pain experienced, illustrated no statistically significant differences. Thus the Ho was accepted and Hi rejected for this set of data. Therefore, neither form of treatment was more effective than the other.

5.5 Problems encountered with demographic and subjective data

In this study homogeneity was a problem. This author randomly allocated the patients into either treatment group in order to safeguard against selection bias. However, ideally matched pairs should be used where the subject is matched with someone of the same or similar age, sex, race and history (Fitz-Gibbon and Morris 1987 : 109). In this particular study owing to the clinical setting and time constraints, it was not possible to

achieve this ideal. It is possible that the heterogeneity of the two groups used in this study may have affected the outcome.

The problems experienced in recording the subjective data occurred firstly in the completion of the Short-form McGill Pain Questionnaire. It is the author's opinion that some patients tended to exaggerate the quality of the pain experienced due to their headache at visit one (perhaps to justify their wanting to participate in the study and to convince the examiner of the severity of their headache experience) and underplay the quality of pain experienced at the final consultation. The examiner hypothesized that this was perhaps done so as to not offend the researcher.

The second problem experienced was the recording of mean medication used by the patient at visit one. It is the author's opinion that several patients underplayed the amount of medication they used for pain relief, some offering only rough estimates to perhaps avoid admitting to the over-use of, or even addiction to, analgesics. All patients generally successfully completed the Headache Diary and no problems arose from the actual recording of the data. However, during the study, several patients reported stressful changes in their

lifestyle: two patients lost their jobs, one patient experienced the death of a family member and one patient was resigning from his job to emigrate. These 'stressors' tended to cause headaches of greater frequency and intensity and the patients required increased medication. Thus, such lifestyle changes may have influenced research statistics.

As with the Short-form McGill Pain Questionnaire, it is the author's opinion that some patients tended to exaggerate the severity of the pain experience when recording scores on the Visual Analogue Scale at the initial consultation, while underplaying scores at the final consultation. The examiner hypothesized that the patient's initial high scores were an attempt by the patient to justify inclusion into the study, while low scores at the final consultation may have been to prevent embarrassment to the patient by not improving after several treatments.

A minor problem with the Headache Diary was that since the questionnaire was an adapted one, there was no previous validity testing. As a result, validity testing of this Headache Diary is needed to further strengthen the results.

Another problem encountered in the study was the fact that patients were treated over differing time intervals. This lack of homogeneity may have affected research results as some patients had exaggerated gaps between treatments while others were seen over shorter intervals e.g. one patient was seen every two days until completion of the study (treatment was over 8 days), while another took the full 17 days to complete the study.

It is the author's opinion that standardising the treatment intervals would allow for statistically more accurate comparisons between patients and hence more accurate results.

CHAPTER VI

6. Conclusions and recommendations

6.1 Conclusions

6.1.1 Subjective data

Analysis of the results indicates statistically significant improvements in both groups with regard to headache frequency and mean medication used per discrete headache episode. Both groups also showed statistically significant overall improvements with regard to the quality of the headache experience (SFMPQ), although improvement in group A after a single treatment was equivalent to three treatments in group B.

There were statistically significant improvements in both groups with regard to headache severity (VAS). Although both groups showed statistically significant overall improvements with regard to the severity of the headache experience, group A showed a greater improvement after the initial treatment than group B, and a slightly greater overall improvement from visit one to treatment four, than group B.

Inter-group analysis did not demonstrate any significant differences between groups A or B and thus neither form of treatment was seen to be more effective than the other in the management of Chronic tension-type headache, with regard to the patient's perception of headache.

6.1.2 **Final conclusion**

In conclusion, in comparing the two different forms of treatment - Spinal Manipulative Therapy (SMT) and Transcutaneous Electrical Nerve Stimulation (TENS) with SMT and placebo TENS, SMT and TENS was not found to be more effective than SMT alone (placebo TENS) in the management of Chronic tension-type headache.

However, it was found that the combination treatment gave faster relief from symptoms when compared to SMT alone and, as a consequence, is recommended as the treatment of choice in the management of Chronic tension-type headache. Possibly, future treatment should make use of a combination of Spinal Manipulative Therapy and Transcutaneous Electrical Nerve Stimulation for the initial one to two treatments, after which Spinal Manipulative Therapy

alone should be sufficient for the continuation and maintenance of improvement.

Due to the small sample size, there is a high probability of type 2 error having occurred. It is therefore possible that statistically significant differences existed that were not detected by the statistical analysis.

6.2 Recommendations

The diagnostic criteria for Chronic tension-type headache are clear, concise and easy to apply, and is recommended for future studies involving Chronic tension-type headache.

A larger sample size is recommended in order that a trend in the results may be more apparent and sensitive to subtle changes in data. This study with a sample size of thirty and treatment groups of fifteen cannot carry the weight that a larger sample size could. Possibly, future similar research could be conducted outside of the Durban Institute of Technology where time constraints are absent. As such, more time could be dedicated to improving the

homogeneity of samples and providing for an adequate pre- and post-treatment evaluation.

More homogeneity in the two groups is recommended. Ideally matched pairs should be used where the subject is matched with someone of the same/similar age, race, sex and history. This would make the results more accurate and statistically valid. However, due to the time constraints of the Durban Institute of Technology undergraduate research programme, this was not feasible.

A pre-treatment evaluation for a minimum of four weeks using headache diaries is recommended to record base line levels and to plot the natural course of the headache. Similarly, post-treatment evaluation is recommended to provide a more accurate measure of any changes arising in headache behaviour following treatment.

Since the Headache Diary lacked validity testing, it is recommended that such validation be acquired, or a more standardised Diary be used for future studies involving Chronic tension-type headache. This would create greater homogeneity, thereby strengthening

results and enabling closer and more accurate comparisons between studies.

Previous research has not adequately examined the relationship between Chronic tension-type headache and migraine headache. According to the Continuum hypothesis of Nelson (1994), tension-type headache and migraine do not exist as distinct physiological entities but form a "continuum". With such in mind, a recommendation for future research would be to repeat the study using migraine headache sufferers, to determine a) if such treatment protocols are as effective in the treatment of migraines, and b) if there really does exist a "continuum" relationship between the two headache types with respect to treatment.

Although precipitants such as stress were touched upon in this study, psychological factors are important in the headache pathophysiology and should not be overlooked when treating Chronic tension-type headache patients (Bondi and Portuesi, 1994). As such, this researcher recommends that further attention be given to factors such as anxiety, depression and insomnia when assessing possible headache aetiologies. Such information could be

obtained through a specific questionnaire in the Headache Diary.

It is suggested that assessment of disability caused by Chronic tension-type headache be researched. The current study failed to obtain data from the sample groups regarding the effect such chronic headaches have on patient efficiency at work, and lost workdays due to the headache experience. This loss of productivity is an important economic consideration, and as such should be researched further, with the aim that current treatment may decrease reduced effectiveness days and/or lost workdays - both of which impact negatively on productivity in business. Such data could be obtained through a headache diary, in which specific questions relate to the above.

A further way of strengthening this study would be the inclusion of an objective measurement e.g. a Surface EMG. This would provide greater insight into the pericranial muscle involvement in the pathomechanics of Chronic tension-type headache.

It is recommended that future studies examine the cost effectiveness of Chiropractic treatment for the

management of Chronic tension-type headache vs more conventional treatment e.g. medication. Kidson (2001) in his study on Episodic tension-type headache, concluded that cervical spine manipulation gives faster relief from symptoms than medication (acetysalicyclic acid), thereby proposing that Chiropractic may prove the more cost efficient approach in the treatment of tension-type headache. Further research is warranted.

Lastly, it is recommended that future studies could examine other modalities in combination with Spinal Manipulative Therapy to determine possible improved treatment protocols for the management of Chronic tension-type headache.

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APPENDIX 1

CHIROPRACTIC RESEARCH ON TENSION-TYPE HEADACHES

TITLE: The effectiveness of Spinal Manipulative Therapy and Trans-cutaneous Electrical Nerve Stimulation versus Spinal Manipulative Therapy and placebo Trans-cutaneous Electrical Nerve stimulation in the treatment of mild to moderate chronic tension-type headache.

Dear Patient

Thank you for enrolling in the research programme. The aim of this study is to compare two treatment protocols and their relative effectiveness in the short term treatment of mild to moderate chronic tension-type headaches.

Sixty people will be required to complete this study and participants will be divided into two equal groups. Group one will receive a combination treatment consisting of cervical spine manipulation and Trans-cutaneous Electrical Nerve Stimulation (TENS). Group two will receive a treatment consisting of cervical spine manipulation and placebo TENS. Participants have a 50% chance of being in the placebo TENS group, although treatment in the form of manipulation will be administered to all patients. A placebo is when a patient receives a sham treatment. This is done in research studies in order to provide a control for the comparison of two treatment protocols.

Cervical spine manipulation has been shown to be effective in the treatment of chronic tension-type headaches by promoting normal biomechanics of the cervical spine. TENS is a form of electro-therapy that when applied over an area of pain, helps to reduce pain intensity, and hence, it is postulated, will reduce the intensity of chronic tension-type headaches.

As with all treatments, the above treatment protocols may produce mild side effects – although rare. Side effects of cervical spine manipulation may include dizziness and may induce mild, short-term muscle tension. Side effects of the electrotherapy may include mild skin irritation and a mild short-term increase in pain experience at the sight of stimulation. Patients presenting with these side effects may leave the study at any time.

This study hopes to evaluate the above treatment protocols with the aim of finding an effective non-medical approach to the treatment of chronic tension-type headaches; and to determine if a combination treatment is the more effective approach.

You will be required to undergo four treatments over a seventeen day period. All treatments will be performed under the supervision of qualified chiropractors, free of charge, at the Technikon Chiropractic Day Clinic. You will be required to keep changes in your lifestyle to a minimum for the duration of the study. Use of medication will not warrant you being excluded from this study. Confidentiality will be maintained at all times, and you are free to withdraw from the study at any stage.

Please feel free to ask about any other concerns.

Yours sincerely

SHANE FONSECA
CHIROPRACTIC INTERN

APPENDIX 2

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CONFIDENTIAL PATIENT INFORMATION

Date: _____ Male/ Female: _____

Surname: _____ Title: _____

First name: _____ Initials: _____

Birthdate: _____ I.D..number: _____

Occupation: _____ Marital status: _____

Medical aid: _____ M/A number: _____

Med doctor: _____ Last visit: _____

Chiropractor: _____ Last visit: _____

Postal address: Residential address:

_____ _____

_____ _____

_____ _____

Tel - work: _____ Tel - home: _____

Employer: _____

Employer's address:

_____

_____

_____

Intern: _____

P.T.O

TECHNIKON NATAL 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:** .....

All Conditions met in Visit No.:.....

To be signed into PTT:.....

Signature:..... **Date:** .....

Signed off:.....

Intern's Case History:

1. **Source of History:**

2. **Chief Complaint : (patient's own words):**

3. **Present Illness:**

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

4. **Other Complaints:**

5. **Past Medical History:**

▹ General Health Status

▸ Childhood Illnesses

▸ Adult Illnesses

- Psychiatric Illnesses
- Accidents/Injuries
- Surgery
- Hospitalizations

6. Current health status and life-style:

- Allergies
- Immunizations
- Screening Tests incl. 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

TECHNIKON NATAL

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient:_____File#: _____Date:_____
Clinician:_____Signature:_____
Intern:_____Signature:_____

1. VITALS

Pulse rate:
Respiratory rate:
Blood pressure: R L
Temperature:
Height:
Weight:

2. GENERAL EXAMINATION

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

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

1) Is this patient in **Cardiac Failure** ?
2) Does this patient have signs of **Infective Endocarditis** ?
3) Does this patient have **Rheumatic Heart Disease ?**

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

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

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

Percussion: - borders of heart

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

4. RESPIRATORY EXAMINATION

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

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

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

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

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

5. ABDOMINAL EXAMINATION

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

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

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

- Pupillary light reflexes = Direct:
  = Consensual:
- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

V a. Sensory - Ophthalmic:
- Maxillary:
- Mandibular:

b. Motor - Masseter:
- Jaw lateral movement:

c. Reflexes - Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

VII a. Motor - Raise eyebrows:
- Frown:
- Close eyes against resistance:
- Show teeth:
- Blow out cheeks:

b. Taste - Anterior two-thirds of tongue:

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

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

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

XII Inspection of tongue (deviation):

Motor System:

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

- Forearm = Supination & Pronation:
- Fingers = Extension (Interphalangeals & M.C.P's):
- Thumb = Opposition:
- Hip = Flexion & Extension:
  = Adduction & Abduction:
- Knee = Flexion & Extension:
- Foot = Dorsiflexion & Plantar flexion:
  = Inversion & Eversion:
  = Toe (Plantarflexion & Dorsiflexion):

b. Tone
- Shoulder:
- Elbow:
- Wrist:
- Lower limb - Int. & Ext. rotation:
- Knee clonus:
- ankle clonus:

c. Reflexes
- Biceps:
- Triceps:
- Supinator:
- Knee:
- Ankle:
- Abdominal:
- Plantar:

Sensory System:

a. Dermatomes
- Light touch:
- Crude touch:
- Pain:
- Temperature:
- Two point discrimination:

b. Joint position sense
- Finger:
- Toe:

c. Vibration:
- Big toe:
- Tibial tuberosity:
- ASIS:
- Interphalangeal Joint:
- Sternum:

Cerebellar function:

Obvious signs of cerebellar dysfunction:
= Intention Tremor:
= Nystagmus:
= Truncal Ataxia:

Finger-nose test (Dysmetria):
Rapid alternating movements (Dysdiadochokinesia):
Heel-shin test:
Heel-toe gait:
Reflexes:
Signs of Parkinsons:

8. SPINAL EXAMINATION:(See Regional examination)

Obvious Abnormalities:
Spinous Percussion:
R.O.M:
Other:

9. BREAST EXAMINATION:

Summon female chaperon.

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

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

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

Patient: _____ File: _____

Date: _____ Intern/Resident: _____

Clinician: _____ Sign: _____

OBSERVATION:

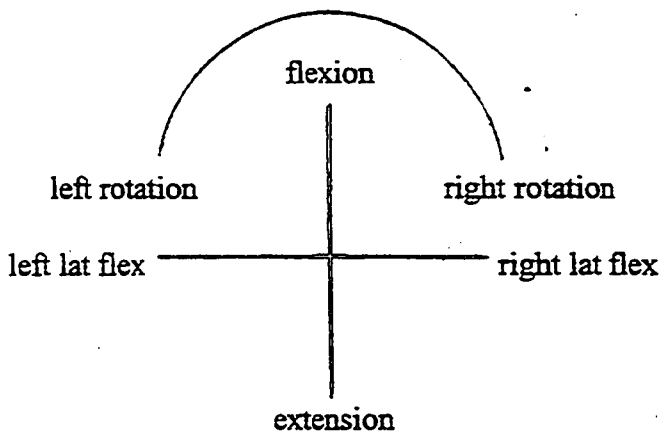
Posture
Swellings
Scars
Discolouration
Hair Line
Bony & Soft Tissue Contours

Shoulder position:
Left:
Right:
Muscle spasm
Facial expression

RANGE OF MOTION:

Flexion (45'):
L/R Rotation (70'):

Extension (70'):
L/R Lat Flex (45'):



PALPATION:

Lymph Nodes
Thyroid Gland

Trachea

ORTHOPAEDIC EXAMINATION:

Tenderness
Trigger Points: SCM, Scalenii, Post Cervicals, Trapezius, Lev Scap

Doorbell sign
Kemp's test
Cervical distraction
Halstead's test
Hyperabduction test
Shoulder abduction test

Cervical compression
Lateral compression
Adson's test
Costoclavicular test
Eden's test
Shoulder depression test

Dizziness rotation test
Brachial plexus tension

Lhermitte's sign

NEUROLOGICAL EXAMINATION:

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

VASCULAR:

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

MOTION PALPATION & JOINT PLAY:

Left: Motion Palpation:
Joint Play:

Right: Motion palpation:
Joint Play:

Basic Exam: Shoulder:
Case History:

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

Upper T horacics:
Motion Palpation:
Joint Play:

Basic Exam: Thoracic Spine:
Case History:

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

APPENDIX 6

MEASUREMENT OF PAIN

Short-form McGill Pain Questionnaire (SF-MPQ)

Ronald Melzack (1984)

Date:_____ File no.:_____ Visit no:____

Patient name:_____

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

No pain |——————————————————| Worst possible pain

PPI

0	NO PAIN	_____
1	MILD	_____
2	DISCOMFORTING	_____
3	DISTRESSING	_____
4	HORRIBLE	_____
5	EXCRUCIATING	_____

FIGURE 10.5 The short- form Mc Gill Pain Questionnaire. Descriptors 1 - 11 represent the sensory dimension of pain experience and 12 - 15 represent the affective dimension. Each descriptor is ranked on a scale of 0 = none. 1 = mild. 2 = moderate. 3 = severe. The Present Pain Intensity (PPI) of the standard long form MPQ and the Visual Analogue Scale are also included to provide overall pain intensity scores.

APPENDIX 7

HEADACHE DIARY (Treatment One)

Name : .....

Gender : .....

Age : .....

Body weight (kg): .....

Usual number of headaches (in days per month) .....

Number of headache episodes per day (average) .....

Usual headache duration per episode (hours): .....

Usual headache intensity (VAS):

Usual character of the pain: Dull, Oppressive, Pulsating, Throbbing, Stabbing

Localization of the pain: Unilateral, Bilateral

Accompanying symptoms: Nausea, Vomiting, Photophobia, Phonophobia

Additional remarks: .....

.....

APPENDIX 7

HEADACHE DIARY

VISIT 1-2
2-3
3-4

NAME: .....

DATE: .....

VISIT: .....

NUMBER OF HEADACHE EPISODES BETWEEN TREATMENTS
(This includes any headache experienced at consultation)

* Tick next to the appropriate block as a headache episode occurs

ONE	
TWO	
THREE	
FOUR	
FIVE	

USUAL/AVERAGE HEADACHE INTENSITY (VAS) OF THE ABOVE HEADACHE EPISODES:

No pain _____ Worst pain possible

MEDICATION TAKEN FOR ABOVE HEADACHE EPISODES:

DRUG NAME/TYPE	AMOUNT TAKEN	FREQUENCY