

**A CLINICAL TRIAL TO INVESTIGATE THE RELATIVE EFFECTIVENESS  
OF ACETAMINOPHEN WITH CAFFEINE AS OPPOSED TO CERVICAL  
MANIPULATION IN THE TREATMENT OF TENSION – TYPE HEADACHE.**

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

By

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I, Deborah Anne Thomson, do hereby declare that this dissertation is representative of my own work, both in concept and execution, except where otherwise indicated in the text.

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17.05.2000

Date

Approved for final submission

29/05/2000

Date

## DEDICATIONS

**This dissertation is dedicated to my brother Shaun Allan Thomson who  
would have reached the sky if he had been able.**

Firstly to my parents: “.....you would never have been given the ability to make a wish if you were not also given the ability to make that wish come true” A big thank you for the unconditional love and support over the years and for believing in me no matter what.

To Steve: ...”you’re the wind beneath my wings”. Thank you for the shoulder to cry on, especially when the going got tough.

To Jack: Thanks for the company during the long lonely times sitting at my desk.

To Shihan Chris and Sensei Julie: ...”the pain of losing is nothing compared to the pain of giving up.” Thank you for showing me that all things are possible, especially if they’re important.

To Dr Ray Rethman: Thank you for having faith in me even when I didn’t.

To Dr Worku for his patience

A big thank you to all the patients who were involved in this study and without whom this study would not have been possible.

Finally to all my friends who were there for me in the good times as well as the bad times. ".....a good-bye is necessary before you can meet again, and meeting again is certain for those who are friends". You guys are the best.

## **ABSTRACT**

Tension-type headache is generally accepted as the most common form of headache and has been shown to have a great impact on work and social activities (Shwartz et al. 1998). Tension-type headache occurs in 39% of people who suffer from headache symptoms with a higher incidence among females, and a peak in the 25-44 year old age group (Wong et al. 1995). The purpose of this study was to investigate the relative effectiveness of 1000mg acetaminophen (paracetamol) combined with 130mg caffeine as opposed to cervical manipulation as a treatment for tension-type headache.

It was hypothesized that manipulation would provide a significant long term benefit in comparison to the acetaminophen-caffeine combination. This study was performed as a clinical trial conducted at the Technikon Natal Chiropractic Day Clinic. Seventy patients presenting with tension-type headaches were selected and randomly allocated into two equal groups.

Patients in both groups were provided with one of two treatments at the first consultation (consultation 1) and returned twenty-four hours later for assessment (follow up 1). A second treatment (consultation 2) was supplied after a minimum "washout period" of forty-eight hours, if and when headache symptoms returned. A final assessment of each patient was again performed (follow up 2) twenty-four hours after this second treatment. Patients in Group 1 received 1000mg acetaminophen combined with 130mg caffeine in capsule form at both

consultations whilst Group 2 received cervical manipulation as an alternative to medication.

The subjective responses of each patient were recorded by means of the Short-form McGill Pain Questionnaire, the Numerical Pain Rating Scale, the CMCC Neck Disability Index and Pain Intensity and Pain Relief Ordinal Scales. The first three questionnaires were completed at both consultation and follow up sessions under the supervision of the researcher. The Pain Ordinal Scales were taken home by the patients and completed at hourly intervals for 4 hours after each consultation whilst the 24 hour column was completed at each follow up session. The objective data consisted of the six cervical ranges of motion obtained by the Cervical Range of Motion Instrument (CROM) and pressure pain sensitivity measurements obtained by the algometer. These objective measurements were taken and recorded at each consultation and each follow up. The subjective and objective data was analyzed using two-tailed parametric tests due to the large sample size ( $n = 70$ ) with the degree of significance set at the 95% confidence level ( $\alpha = 0.05$ ).

At follow up 1, Group 2, which received manipulation, reported statistically significant improvements ( $p < 0.05$ ) with regards to subjective measurements. Group 1, which had received medication, reported some initial subjective benefits immediately after treatment, but these improvements had disappeared within twenty-four hours. There were no significant differences between the two groups in respect of range of motion or algometer measurements. At follow up

2, statistically significant differences ( $p < 0.05$ ) were noted for both subjective and objective data in favour of Group 2.

The results obtained from this study indicate that although the acetaminophen-caffeine combination provided some initial benefits, this effect was short lived compared to manipulation which demonstrated slower but sustained benefits. It is evident from the results of this study that manipulation is the recommended treatment in the management of tension-type headache.

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## **DEFINITIONS**

Acetaminophen - Same as paracetamol

Adjustment - The chiropractic adjustment is a specific form of direct articular manipulation using either long or short leverage techniques with specific contacts and is characterized by a dynamic thrust of controlled velocity, amplitude and direction (Gatterman 1990:405).

Chiropractic - Chiropractic is a discipline of the scientific healing arts concerned with the pathogenesis, diagnosis, therapeutics and prophylaxis of functional disturbances, pathomechanical states, pain syndromes and neurophysiological effects related to the statics and dynamics of the locomotor system, especially of the spine and pelvis (Gatterman1990:406).

Fixation - The state whereby articulation has become temporarily immobilized in a position that it may normally occupy during any phase of physiological movement. The immobilization of an articulation in a position of movement when the joint is at rest, or in a position of rest when the joint is in movement (Gatterman 1990:408).

Joint dysfunction - Joint mechanics showing area disturbances of function without structural change; subtle joint dysfunctions affecting quality and

range of joint motion. They are diagnosed with the aid of motion palpation, and stress and motion radiography investigation (Gatterman1990:409)

Manipulation -Passive manoeuvre in which specifically directed manual forces are applied to vertebral and extravertebral articulations of the body with the object of restoring mobility to restricted areas (Gatterman 1990:410).

Motion palpation - Palpatory diagnosis of passive and active segmental joint range of motion (Gatterman 1990:412).

Objective findings - Findings obtained from the Cervical Range of Motion Instrument (CROM) and algometer.

Subjective findings - Findings obtained from the Short-form McGill Pain Questionnaire, Numerical Pain Rating Scale, CMCC Neck Disability Index and Pain Intensity and Pain Relief Ordinal Scales.



# **CHAPTER ONE**

## **INTRODUCTION**

Tension-type headache is the most common form of headache (Edwards et al. 1991: 851), with 80% of the people presenting at a physician's office diagnosed with muscle contraction (tension-type) headache (Diamond 1987:172). In the United States of America (USA), headaches have lead to more than 18 million visits to physicians a year (Sternbach 1986). The Nuprin Pain Report (Sternbach 1986) showed that 156 million workdays are lost each year as a result of headaches, at a cost of an estimated \$25 billion. A National Ambulatory Medical Care Survey (NAMCS) conducted in the USA during 1977 - 1978 reported that 4,32% of all Americans visited their general practitioner at least once per year complaining of unspecified headaches. This average annual visitation rate increased with advancing age, whilst visitation rates for female patients over 44 years of age were approximately twice as high as those for their male counterparts. Prescription and non-prescription medication was recommended by the physician as therapy in 73,8% of patients complaining of unspecified headache (Cypress 1981).

Raskin (1988:215) defines tension-type headache as a head pain which is bilateral, commonly occipitonuchal, with a tendency to wax and wane throughout the day. The pain is of a heavy, pressing and tight quality, and associated with contracted muscles of the neck and scalp.

Various treatments are advocated for patients suffering from tension-type headache. Medical practitioners often prescribe analgesics, anti-depressants, anti-inflammatories and ergotamine derivatives (Raskin 1988:223). Other treatments include massage of the neck muscles (Penter 1994), biofeedback and relaxation methods (Chesney et al. 1976, Cott et al. 1992) injection of active trigger points (Travell et al. 1983:202), and cervical traction (Donkin 1998). Manipulation in combination with other manual therapies is the preferred chiropractic treatment (Gatterman 1990:252-253). The use of chiropractic cervical manipulation has been shown in many studies to provide both an immediate and long term benefit to patients suffering from tension-type headache (Turk et al. 1987, Mootz et al. 1994, Vernon 1995, Boline et al. 1995).

The patient with a headache will often first seek relief with over-the-counter (OTC) analgesics before consulting their doctor for treatment and/or advice (Diamond 1987:173). A number of clinical trials have compared the effect of prescription and non-prescription medication to placebo in the relief of pain associated with tension-type headache. Nebe et al. (1995) conducted a double-blind, three fold crossover clinical trial and concluded that ibuprofen and acetylsalicylic acid were both more effective than placebo in providing relief (n=95). Schachtel et al. (1996) demonstrated in a randomized clinical trial that both ibuprofen and acetaminophen provided significant relief compared to

placebo (n=455), with 400mg ibuprofen more effective than 1000mg acetaminophen. Van Gerven et al. (1996) conducted a double-blind randomized clinical trial and reported that a single dose of 25mg or 50mg ketoprofen were both more effective in treating tension-type headaches (n=166) compared to either 200mg ibuprofen or placebo.

Sawynock et al. (1993) stated that caffeine exerts a pharmacological action on various organ systems that may alter subsequent absorption and metabolism of substances, including analgesics. Caffeine has been combined with various mild analgesics to enhance their efficacy and the combination of acetaminophen with caffeine may allow for increased analgesic effect without the risk of cumulative toxicity due to increased acetaminophen intake (Beaver 1984). Migliardi et al. (1994) conducted six separate, multicenter randomized, double-blind crossover studies and concluded that caffeine combined with 1000mg acetaminophen was more effective than 1000mg acetaminophen alone, and that both were significantly superior to placebo.

The purpose of this current study was to determine the relative efficacy of 1000mg acetaminophen combined with 130mg caffeine as opposed to cervical manipulation in the treatment of tension-type headaches, with reference to the patient's perception of the benefit derived from the treatment as well as objective findings. Group 1 was treated with 1000mg acetaminophen combined with 130mg caffeine in capsule form. Group 2 was treated with cervical manipulation

at all those levels, and directions in which restriction of normal motion was detected. The patient's perception of the benefit of the treatment was measured using the Short-form McGill Questionnaire (Melzack 1975), the Numerical Pain Rating Scale 101 (NRS 101) (Jensen et al. 1986), the Canadian Memorial Chiropractic College (CMCC) Neck Disability Index (Vernon et al. 1991), and Pain Intensity and Pain Relief Scales (Migliardi et al. 1994). The first three questionnaires were completed at each visit and the pain intensity and pain relief scales were completed at each follow up. The objective findings were obtained using a cervical range of motion (CROM) goniometer (Youdas et al. 1991) and a pressure threshold meter (algometer) (Fischer 1987). All objective measurements were repeated at each visit.

The Nuprin Pain Report (Sternbach 1986) and the NAMCS (Cyress 1981) demonstrated that the problem of tension-type headache is real and has an impact on the economy of a country as well on the individual in their personal lives. Research has covered many diverse areas of treatment including chemical and manual therapies, with no standard effective conclusion. The ideal treatment should be at low cost, decrease the necessary number of patient visits, and have a good result with as few side-effects as possible. Patient dependence on the treatment itself in order to prolong the symptom-free period should also be a factor in consideration of treatment selection. Chiropractic focuses on the vertebral motion segment and the maintenance of normal motion therein, using manipulation as a primary means. Medication is a popular choice among

members of the medical profession and public alike, with a wide range in efficacy, duration of effect, dependence and undesirable side effects. Caffeine has been demonstrated to enhance the efficacy of acetaminophen but studies using other analgesics combined with caffeine are scarce. Acetaminophen is a mild analgesic with few side effects that is available at most pharmacies at a reasonable price. No clinical study comparing the effects of acetaminophen combined with caffeine to cervical manipulation in the treatment of tension-type headaches could be located, and thus this study sets out to determine which of the two treatments is the more effective treatment option in the management of tension-type headache.

## **CHAPTER TWO**

### **REVIEW OF THE RELATED LITERATURE**

#### **2.1. INTRODUCTION**

The term headache is conventionally used to describe any discomfort (usually pain) in the upper half of the head, from the forehead to the back of the neck excluding the face below the eyebrows . This area is supplied by the second cervical sensory root and it's extension, the greater occipital nerve, and by the sensory divisions of the trigeminal nerves (Vernon 1988:141).

Headache is a common problem and the management of headache has varied greatly between medical professions, with varying success. It is thus important to review the relevant anatomy, physiology, biomechanics, differential diagnosis and other approaches in the management of this condition. Headache and head pain are, needless to say, symptoms and not a disease in and of themselves.

As a sole symptom, it is not diagnostic of any specific disorder. Headache may indicate the presence of psychic overload such as anxiety, personal or life style difficulties or it may reflect the presence of organic disease (Vernon 1988:141).

#### **2.2. INCIDENCE AND PREVALENCE**

Eighty percent of headache patients who consult a doctor are diagnosed as suffering from tension-type headaches (Dalessio 1987:172), thus making tension headache the most prevalent form of headache (Edwards et al. 1991:851).

Tension-type headache can occur at any age, but is more common in adulthood. Tension-type headache can manifest itself in relationship to stress, depression, anxiety, emotional conflicts, fatigue, repressed hostility, or the patient is overwhelmed by the environment (Dalessio 1987:172).

A door to door survey in Saudi Arabia in 1994-1995 by Abdul-Jabbar et al. (1996) of 5891 people, concluded that the crude lifetime prevalence rate of all headache types was 8%, of which 39% were classified as tension-type headache. The overall prevalence rate for tension-type headache in Hong Kong during July 1992 to March 1993 was 2%, with a female preponderance and a peak in the 25-44 year old age group (Wong et al. 1995). A recent large survey of 5000 persons selected from 30 000 households representative of the German population reveals (on extrapolation) that 54 million people suffer from unspecified headache at least occasionally during their lifetime. Approximately 38,3% of these people fit the tension-type headache profile, with no significant differences in prevalence between the various geographic regions of Germany (Gobel et al. 1994).

Srikiatkhachorn et al. (1997) examined 220 consecutive headache patients visiting the Chulalongkorn Headache Clinic and concluded that the prevalence of tension-type headache was 36,7%. He reported that 56,7% of the patients said their headaches were aggravated by stress and 58.3% ingested analgesics on a daily basis.

Schwartz et al. (1998) conducted a telephonic survey in Maryland in the USA and calculated the overall prevalence of tension-type headache during 1997 was 38.3%. Women had a higher prevalence rate than men and prevalence peaked in the 30 - 39 year old age group in both men and women. Tension headaches resulted in lost workdays for 8.3% of the subjects and 43,6% reported decreased effectiveness at work, home, or school. Micieli et al. (1996) interviewed 400 consecutive headache patients and found relatively low levels of handicap or disability in work and social activities which is in contrast to Schwartz et al. (1998), who concluded that tension-type headache is a highly prevalent condition with a significant functional impact at work, home or school. Micieli et al. (1996) attributed these low impact level findings to timely, and at times excessive, use of analgesics.

The prevalence and incidence of headache may not always be easy to determine by means of epidemiological surveys because some headaches are so mild they may not be reported, even on direct questioning. Published information on population studies may be difficult to interpret because of the varied co-operation and accurate response rates. Definitions of the various headache types have varied from study to study, and the studies have been conducted in different ways, making interstudy comparisons inappropriate (Dalessio 1987:51,52).



### **2.3. ANATOMY**

The cervical vertebrae consist of the first seven vertebrae in the spinal column and form the bony axis of the neck. The presence of a transverse foramen in each transverse process is the distinctive feature of the cervical vertebrae. The transverse foramina provide a pathway for the vertebral arteries, except in C7, which transmit only small accessory vertebral veins. The first, second and seventh cervical vertebrae are atypical. The first cervical vertebra is the atlas, and has kidney-shaped, concave superior articular facets which receive the occipital condyles. The atlas has no spinous process or vertebral body. The second cervical vertebra is known as the axis, with the odontoid as a distinguishing feature. The transverse ligament of the atlas holds the odontoid of the axis in place and allows rotation of the atlas on the axis, while preventing forward displacement. The seventh cervical vertebra is called the vertebra prominens as it has a prominent spinous process (Moore 1985:576). A typical lower cervical vertebra has a small vertebral body that is concave on its superior surface and lipped by a raised edge of bone on its margin. The inferior surface is correspondingly convex, although the anteroinferior portion of the vertebral body tends to project downward over the anterosuperior surface of the vertebra below it. (Sherk et al. 1989:11).

#### **2.3.1. Atlantooccipital Joints**

The atlantooccipital joints are between the superior articular facets on the lateral masses of the atlas and the occipital condyles. They are synovial joints with thin,

loose articular capsules (Moore 1985: 592). The occipital condyles face downward and outward, while the superior atlantal joint faces upwards and inward to support the occiput. The inferior atlantal facets are flatter and more circular than the superior facets and face downwards and inwards to transmit the weight of the skull onto the superior facets of the axis (Sherk et al. 1989:13-14). These joints allow flexion and extension of the head. The atlantooccipital membranes also connect the skull and the atlas. The transverse ligament holds the odontoid of the axis against the anterior arch of the atlas with a synovial joint between them. The cruciform ligament passes vertically from the transverse ligament to the occiput superiorly and the vertebral body inferiorly (Moore 1985: 592-593).

### **2.3.2. Atlantoaxial Joints**

The atlantoaxial joints allow rotation of the head and consist of two lateral joints and one medial joint (Moore 1985: 594). The superior articular facets of the axis are large, slightly convex, and face upwards and outwards to articulate with the inferior facets of the atlas vertebra. The odontoid of the axis extends upwards to reach the anterior lip of the foramen magnum and has a narrow waist where it is compressed by the transverse ligament of the atlas. The inferior surface of the axis vertebra resembles those of the lower cervical vertebrae (Sherk et al. 1989:13).

### **2.3.3. Intervertebral Disc**

The intervertebral discs are composed of annuli fibrosi enclosing nuclei pulposi. The annulus fibrosus is composed of concentric lamellae of fibrocartilage which run obliquely from one vertebra to another. The annuli fibrosi insert into the smooth, rounded rims on the articular surfaces of the vertebral bodies. Some of the fibers of one lamella may run at 90 degrees to the adjacent lamella thus allowing movement between the vertebra while maintaining a strong bond. The lamellae of the annulus fibrosus are thinner and less numerous posteriorly than they are anteriorly or laterally. Adjacent blood vessels supply the peripheral parts of the annulus fibrosus. The nucleus pulposus contacts the hyaline plates of the articular cartilage and acts as a shock absorber for axial compression and like a semifluid ball bearing during flexion, extension and lateral bending of the spine. The nucleus pulposus is avascular and derives its nourishment by diffusion from blood vessels at the periphery of the annulus fibrous and adjacent surfaces of the vertebral bodies (Moore 1985:589-590).

### **2.3.4. Posterior Spinal Articulations**

The posterior spinal articulations, known as zygapophyseal joints are often referred to as facet joints for brevity. Facet joints are formed by the opposing articular processes of the adjacent vertebral arches. The articular surfaces consist of smooth, shiny, compact bone covered with hyaline cartilage. A thin, loose articular capsule is attached to the articular margins of the articular processes and surrounds each facet joint. The facet joints help to control

flexion, extension, lateral flexion and rotation of adjacent vertebrae (Moore. 1985:591). These joints are freely movable (paired diarthroidal) and are located between the superior and inferior facets of adjacent vertebrae from C2-C3 to C7-T1 (Bland 1994: 51-61).

The superior facets face forwards and downwards at 45 degrees, while the inferior joints face backwards and upwards at the same angle. Complex movements such as rotation and lateral flexion are possible as the surfaces of the facets do not fit perfectly together. The fibrous capsule of the facet joints is lax to allow for complex movements and is also innervated with proprioceptive and pain receptors (Bland 1994:51-61).

### **2.3.5. Spinal Ligaments**

The spinal ligaments are divided into the long spinal ligaments and short intersegmental ligaments. The long spinal ligaments are the anterior and posterior longitudinal ligaments and the supraspinous ligaments. The intersegmental ligaments consist of the ligamentum flava, the interspinous intertransverse and capsular ligaments. Regional accessory ligaments such as the ligamentum nuchae, the accessory ligament between the axis and atlas, the transverse ligament of the atlas, the cruciform ligament of the atlas and the apical and alar ligaments of the dens of the axis are also present. These ligaments provide postural support between vertebrae, restrict motion within

physiological limits, and resist tensile forces applied to the spine (Gatterman 1990: 207-210).

#### **2.3.6. Intersegmental Muscles**

The intersegmental muscles include the deep transversospinal muscles of the multifidus, rotatores, interspinal and intertransversarii. These muscles extend only between adjacent vertebrae acting as dynamic ligaments and allow for adjustments of small movements of the vertebral column. These muscles are thought to be postural muscles and assist the long superficial muscles (Gatterman 1990:16-18).

#### **2.3.7. Intervertebral Foramina And Spinal Canal**

The intervertebral foramen is a canal which is bound superiorly and inferiorly by the pedicles of adjacent vertebrae, anteriorly by the intervertebral disc, and posteriorly by the posterior joints and ligamentum flavum. This short, elliptical canal allows for the exit of the segmental spinal nerves and the entrance of blood vessels and nerve branches that supply the contents of the spinal canal. The vertebral bodies and vertebral arches make up the spinal canal which protects the spinal cord, meninges and associated vessels (Gatterman 1990:18).

### **2.4. SUBLUXATION, SUBLUXATION COMPLEX AND SUBLUXATION SYNDROME**

Walker and Buchbinder (1997) conducted a postal survey and found that chiropractors use a variety of methods to examine the spine and to identify areas

of subluxations that require adjustments. Methods used included static palpation, pain description, orthopedic tests, motion palpation, visual posture analysis, neurological tests and plain static x-rays. The subluxation complex encompasses elements of the kinesiopathology of joints and muscles, neuropathophysiology and the biomechanical effects of histopathology (Gatterman 1990:40). Changes may occur in the nerves, muscles, ligaments, vascular components and connective tissues (Gatterman 1995:11).

Gatterman (1995:11) defines the term “subluxation” as “a motion segment, in which alignment, movement, integrity, and/or physiological function are altered although contact between joint surfaces remains intact”. Jull et al. (1988) concluded that the joint signs that are pathognomonic of symptomatic cervical zygapophyseal joints are: abnormal “end-feel”, abnormal quality of resistance to motion, and reproduction of pain.

Mennell (1990) states that joint dysfunction presupposes the presence of mechanical synovial joint play, which is a prerequisite for normal efficient motion. Bogduk (1992) continues that joint dysfunction affecting the upper cervical synovial joints may play a role in the source of headache. He states that the pathological nature of the joint dysfunction that causes headache is unknown, but the role of these joints in headache is strongly implicated by the presence of abnormal palpatory and motion findings as well as the relief of the headache upon anaesthetization of the responsible joint. He concludes that a large

proportion of patients diagnosed as suffering from tension-type headache may, in fact, be suffering from cervicogenic headache.

Vernon et al. (1992) found a high prevalence of neck pain during headache, cervical joint dysfunction, postural malalignment and myofascial tenderness in patients diagnosed with tension-type headache, thus suggesting that the cervical spine may play a much larger role in the etiology of headache. Kidd et al. (1993) demonstrated a link between cervical spine dysfunction and tension-type headache and proposed that cervical spine dysfunction does not in itself cause headache, but rather contributes to the conditions manifesting as a tension-type headache. Gatterman (1990 :40) states that the prognosis for the patient depends on the reversibility of the pathophysiological elements of the subluxation complex

## **2.5. MECHANISM AND PATHOPHYSIOLOGY OF TENSION-TYPE HEADACHE**

### **2.5.1. Pathomechanics Of The Upper Cervical Spine**

Excessive stress on musculoligamentous tissues can lead to pain, inflammation, proliferative reactions, protective spasms and altered neurological reflex patterns (Vernon. 1988:111). According to Vernon (1988: 107-112) fixation of the upper cervical spine occurs as follows:

Flexion fixation of C0 - C1, and C0 to C2 may be produced by spasm of the occipital extensor muscles while regional fixation of occiput flexion related to the

entire cervicothoracic spine may involve the long extensor muscles. Unilateral involvement of these muscles may result in a restriction of lateral flexion and rotation, in addition to forward flexion restriction. Anterior head carriage, muscle spasm and suboccipital tenderness often indicates bilateral involvement of the extensor muscles. Unilateral involvement of the occipital extensors produces excessive rotation of C2 spinous process during lateral flexion and can produce a static rotational misalignment of C2. Upper cervical complex fixation may result in hypomobility or hypermobility during lateral flexion at C1-C2. Rotational movement is structurally bound to lateral flexion, and thus will also be affected. Flexion and extension fixation at C2-C3 occurs in the same manner as discussed above with the additional involvement of the anterior musculature. Vernon (1988:110) suggests that pre- and post manipulation palpation be done to monitor the interrelated biomechanical effects.

### **2.5.2. Muscular Factors**

The mechanism of this type of headache is similar to that of chronic muscle contraction in any other part of the body (Diamond 1987:173), and involves 3 independent reflex arcs and 4 independent steps (Dalessio 1987:173-174).

These are as follows:

1. Muscle spasm is initiated by a multisynaptic reflex of withdrawal, and the impulse is transmitted to the spinal cord and then to the ventral roots. The



stimulus then passes via the efferent nerves to the neuromuscular junction, which results in a painful muscle spasm.

2. The initial impulse is conducted up the spinal cord to the thalamic and central levels via the polysynaptic spinal pathways and the lemniscal system. At these areas, the stimulus is perceived as painful.
3. Impulses are transmitted through the reticulospinal system to activate the gamma-efferent neurons that contract the muscle spindle.
4. A monosynaptic stimulus is evoked during the muscle contraction, which travels to the ventral horn. The efferent peripheral nerve discharge is augmented and the muscle contraction increased.

Dalessio (1987:174) states that the contraction of the muscle spindle itself (the 3rd reflex arc) is a monosynaptic pathway and is related to simple tendon stretch reflexes. The contracting muscle would normally inhibit the firing of the muscle spindle, thereby terminating the 3rd arc stretch reflex, causing the muscle to relax. The activity level of the gamma motor system determines the degree of muscle tone. If the gamma-efferent system continues to fire, the muscle spindle will remain tight, and the muscle will continue to contract until the contraction itself becomes painful.

Lacroix et al. (1990) found no relation between sustained contraction of the frontalis muscle and headache pain, and thus their published data provides strong evidence against the classic etiological account of tension-type headache.

### **2.5.3. Psychological Factors**

#### **2.5.3.1 Anxiety And Stress**

Stress or anxiety are common precipitants to tension-type headache (Reid 1992:857; Scharff et al. (1995) and there is sometimes an underlying depressive illness. Ukestad et al. (1996) reported that tension headache sufferers cope differently and presumably less effectively with stressful events. Anxiety about the headache itself may lead to continued propagation of symptoms, and patients often become convinced of a serious underlying condition (Edwards et al. 1991:851).

#### **2.5.3.2 Depression**

A headache secondary to depression is usually considered a muscle contraction (tension-type) headache. The duration of this headache is the distinguishing feature. A depressed person will describe the headache as lasting for years, or throughout their lifetime. A depressive headache is usually dull and generalized, worse in the morning and evening. These headaches usually appear at regular intervals, with the greatest incidence occurring between 16h00 to 20h00 and 04h00 to 08h00. The headache often coincides with interpersonal situations in which the sufferer feels compelled to maintain an exterior of calm or affection although they are struggling to repress resentment or dissatisfaction.

Statistically, it has been noted that 84% of depressed patients complained of headache (Dalessio 1987: 176,177). Sternbach et al. (1980) reported that patients suffering from vascular headache, muscle contraction (tension-type) headache and mixed headache all had mild masked depressions with somatization and anxious features.

#### **2.5.3.3. Coping**

Ukestad et al. (1996) found that individuals with tension-type headache have a lower threshold for defining a stimulus as painful. They suggested that this lower threshold may then exacerbate the patient's experience of pain. They further suggest that recurrent headache sufferers are more likely to report physical symptoms, not just those producing physical discomfort.

#### **2.5.4. Cervical Spine**

Lewit (1971) states that one of the mechanisms causing vertebrogenic symptoms is ligament pain. He found frequent signs of cervical hypermobility, but no specific radiological picture. Schultz (1977) found that patients suffering from tension-type headache which increased in frequency or intensity, also suffered from occipital neuralgia as a complicating feature. He postulated that irritation of the occipital nerve where it pierces the musculotendinous attachments of the trapezius muscle was the cause of the neuralgia. Vernon et al. (1992) placed emphasis on the role of cervical joint dysfunction in tension-type and migraine headaches as noted in decreased segmental mobility on

radiographs and in motion palpation. Nagasawa et al. (1993) found on radiological evaluation that a large number of patients with tension-type headache had a loss of cervical lordosis as measured by the Cervical Spine Curvature Index (CSCI) and/or low-set shoulder as measured by the observation of the first or second thoracic vertebra on intermediate lateral projections. He suggests that low-set shoulder may be involved in traction of the brachial plexus which may refer pain to the neck and shoulders and in combination with a straightened cervical spine, may play an important role in the pathogenesis of tension-type headache.

Bogduk (1992) relates the anatomical basis for headache originating from the cervical spine to convergence within the trigeminocervical nucleus. Both the trigeminal and cervical areas transmit impulses to the nociceptive neurons in this nucleus. The central connections of these neurons are poorly organised and thus information that is received may be interpreted as originating from the trigeminal region, cervical region, or both. Thus, nociceptive input from C1-3 may be interpreted by the brain as a headache.

#### **2.5.5. Central Nervous System Involvement**

Brendtsen et al. (1996) found a relationship between central hypersensitivity and increased myofascial tenderness. They concluded that a general hypersensitivity to mechanical and electrical stimuli in patients with chronic tension headache is an important factor, thereby providing evidence that central

factors are a part of the pathogenesis of the disorder. Jensen (1996) found that in the headache state, thermal pain detection and tolerance thresholds decreased selectively in the temporal region, indicating a relationship with a segmental central sensitization and / or a decreased antinociception. He postulates that the central changes are reversibly linked to headache in the episodic form of tension-type headache, whereas a more frequent activation may induce a permanent pain condition such as chronic tension-type headache.

#### **2.5.6. Myofascial Model**

##### **2.5.6.1. Definition**

A myofascial trigger point is a hyperirritable locus within a taut band of skeletal muscle, and may be located either in the muscle tissue or the associated fascia. The spot is tender on palpation and autonomic phenomena and referred pain may be evoked on compression of the area. An active trigger point causes the patient pain, compared to a latent trigger point that is clinically silent, but may cause a limitation of movement with an associated weakness of the involved muscle(s). Both active and latent trigger points will cause dysfunction, but only active trigger points cause pain (Travel et al. 1983 :13). Myofascial trigger points located in the trapezius muscle, posterior cervical muscles, temporalis muscles and sternocleidomastoid muscles refer pain to the head and neck and this pain referral may be confused with the onset of a tension-type headache (Appendix 6). It is thus important to examine these muscles for trigger points, as the myofasciitis may be part of the initial problem.

#### **2.5.6.2. Prevalence**

Individuals of either sex and age, regardless of activity levels may develop myofascial trigger points. Middle-aged women with sedentary lifestyles are apparently especially vulnerable to developing trigger points (Travel et al. 1983:13).

#### **2.5.6.3. Symptoms**

The referred pain of myofascial trigger points is dull and aching, often deep, ranging from low-grade discomfort to severe and incapacitating. The more hypersensitive a trigger points is, the more intense and constant the referred pain, and the wider the pain distribution. The severity and extent of the referred pain pattern depends on the degree of irritability of the trigger point and not on the size of the muscle. Trigger points are activated directly by acute overload, overwork fatigue, direct trauma and chilling of the muscle(s). Trigger points may be activated indirectly by other trigger points, visceral disease, arthritic joints and by emotional distress. Active myofascial trigger points vary in irritability from hour to hour and from day to day, with irritability increased from a latent to active level by many factors (Travell et al. 1983:13-14.)

#### **2.5.6.4. Trapezius Muscle**

The trapezius muscle originates from the medial third of the superior nuchal line, external occipital protuberance, ligamentum nuchae and spinous processes of C7 to T12. The superior fibers insert into the lateral third of the clavicle, the

middle fibers insert into the acromion and spine of the scapula, and the lower fibers insert into the base of the scapular spine (Moore 1985: 662). The trapezius muscle is innervated by the spinal root of the accessory nerve (CN XI) and the ventral rami of the third and fourth cervical nerves (C3 and C4) (Moore 1985: 662). The trapezius muscle elevates, retracts and rotates the scapula so that the glenoid fossa faces superiorly and anteriorly (Moore 1985 : 662). TP1 causes severe posterolateral neck pain, often associated with a headache on the same side, with pain occasionally referred to the angle of the jaw. TP2 causes similar neck pain, but without the headache. TP3 and TP4 cause suprascapular, interscapular, acromial and or neck pain. TP5 causes burning interscapular pain and TP6 refers pain over the acromion. TP7 may produce pilomotor activity on the anterolateral surfaces of the homolateral arm and sometimes thigh (Travell et al. 1983 :189).

#### **2.5.6.5. Posterior Cervical Muscles**

The posterior cervical muscles include the semispinalis capitis, semispinalis cervicis and multifidi muscles. The splenius capitis and splenius cervicis muscle originate from the inferior half of the ligamentum nuchae and spinous processes of C7 to T6 vertebrae. The splenius capitis inserts into the mastoid process of the temporal bone and into the adjacent occipital bone, whereas the splenius cervicis inserts into the transverse processes or the superior two to four vertebrae (Moore 1985:598). The semispinalis capitis is supplied by lateral branches of the dorsal rami of the middle cervical nerves and the semispinalis

cervicis is supplied by lateral branches of the dorsal rami of the inferior cervical nerves (Moore 1985:598). The semispinalis cervicis extends the cervical region and rotates it towards the opposite side. The semispinalis capitis extends the head and turns the face to the opposite side (Moore 1985:599). TP1 is located at the C4, C5 level and travels upward to the suboccipital region, and downward over the neck and upper part of the shoulder girdle. TP2 is located a few centimeters below the occiput and refers pain to the posterior occiput and towards the vertex. TP3 lies at the insertion of the semispinal capitis and refers pain forward like a band that half encircles the head and reaches it's maximum intensity in the temple and forehead over the eye (Travell et al. 1983 :305-307).

#### **2.5.6.6. Temporalis Muscle**

The temporalis muscle originates from the floor of the temporal fossa and the temporal fascia. It inserts into the coronoid process and the anterior border of the ramus of the mandible. The temporalis muscle is supplied by the deep branches of the mandibular nerve (CN V3). The temporalis closes the mouth by elevating the mandible and retracts the mandible after protraction (Moore 1985:920). The temporal area is tender and painful, often with associated hypersensitivity and aching of the upper teeth (Travell et al. 1983 :236).

#### **2.5.6.7. Sternocleidomastoid Muscle**

The sternal head originates from the anterior surface of the manubrium sterni and the clavicular head originates from the superior surface of the medial third of



the clavicle. The sternocleidomastoid muscle inserts onto the lateral surface of the mastoid process of the temporal bone and the lateral half of the superior nuchal line of the occipital bone. The sternocleidomastoid muscle is supplied by the accessory nerve (CN XI) and the ventral ramus of the second cervical nerve (C2). Occasionally the ventral ramus of the third cervical nerve (C3) may also be involved. Acting alone, the sternocleidomastoid muscle tilts the head to it's own side, and rotates the head so the face is turned superiorly to the opposite side. Acting together, the sternocleidomastoids flex the neck (Moore 1985: 989). An active TP in the lower end of the sternal division refers pain down over the upper portion of the sternum. TPs in the middle portion of the sternal division refer pain homolaterally across the cheek, into the maxilla, over the supraorbital ridge and deep within the orbit. TPs in the upper portion of the sternal division refer pain to the occipital ridge and to the vertex of the head with scalp tenderness in the pain reference zone. At the mid level of the clavicular division, TPs refer pain to the frontal area. Upper level TPs of this division may refer pain to the homolateral ear and the posterior auricular region (Travel et al. 1983 :203-204).

## **2.6. CLINICAL CONSIDERATIONS AND DIFFERENTIAL DIAGNOSIS**

### **2.6.1. Definition Of Tension-Type Headache**

The Headache Classification Committee of the International Headache Society (1988) describes tension-type headache as recurrent episodes of headache lasting from minutes to days. The pain is typically pressing or tightening in quality, of mild or moderate intensity, bilateral in location and does not worsen

with routine physical activity. Nausea is absent, but photophobia or phonophobia may be present. Dalessio (1987:174) states that tension-type headache is due to anxiety, stress, tension or psychogenic determinants.

#### **2.6.1.1. Signs And Symptoms Of Tension-Type Headache**

Tension-type headache usually occurs at the forehead and temples or at the occiput and neck. The pain may be unilateral or bilateral over the frontal, temporal, occipital or parietal regions, or any combination of these areas.

Brushing the hair or putting a hat on the head may be painful. Severity and site of the headache may vary, the pain may continue for weeks, months, or even years. Duration of the pain may be short, and may be relieved by a change in postural position. Limitation of movement of the head, neck and jaws may reduce the headache severity. Relief may be obtained by resting or supporting the head in the hands. Palpation of tender areas of the head, neck and upper back may reveal sharply localized "nodules". Pressure on tender areas during examination may cause referred pain to other parts of the head and increase the intensity of the headache. Tinnitus, vertigo and lacrimation may also be described. (Dalessio 1987:172,173).

The pain is usually constant and may be generalized or predominately nuchal.

The patient can usually continue normal activities and the pain may be less noticeable when the patient is occupied. Local tenderness may be present over the skull vault or in the occiput, but this should be distinguished from the acute

pain precipitated by skin contact in trigeminal neuralgia. (Edwards et al. 1991:851).

## **2.6.2. Differential Diagnosis Of Headache**

### **2.6.2.1. Cervicogenic Headache**

The International Headache Society (1988) criteria for cervicogenic headache are as follows:

- A. Pain localized to the neck and occipital region. May project to the forehead, orbital region, temples, vertex or ears
- B. Pain is precipitated or aggravated by special neck movements or sustained neck posture
- C. At least one of the following:
  - 1. resistance to or limitation of passive neck movements
  - 2. changes in neck muscle contour, texture, tone, or response to active and passive stretching and contraction
  - 3. abnormal tenderness of neck muscles
- D. Radiological examination reveals at least one of the following:
  - 1. movement abnormalities in flexion or extension
  - 2. abnormal posture

3. fractures, congenital abnormalities, bone tumours, rheumatoid arthritis or other distinct pathology (excluding spondylosis or osteochondrosis)

#### **2.6.2.2. Migraine Headache**

The terms “common migraine” and “classic migraine” have been widely confused and have thus been replaced with “migraine without aura” and “migraine with aura”. The aura is the complex of focal neurological symptoms which initiates or accompanies an attack. Premonitory symptoms occur hours to a day or two before an attack and may consist of hyperactivity, hypoactivity, depression, craving for special foods, repetitive yawning and similar atypical symptoms.

Migraine without aura is described as an idiopathic, recurring headache disorder manifesting in attacks lasting 4 to 72 hours. Typical characteristics of the headache are unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity and association with nausea, photophobia and phonophobia. Migraine with aura has been described as an idiopathic, recurring disorder manifesting with attacks of neurological symptoms unequivocally localizable to the cerebral cortex or brain stem. This disorder gradually develops over 5 to 20 minutes and usually lasts less than 60 minutes. Headache, nausea, and/or photophobia usually follow the neurological symptoms directly or after an interval of less than an hour. The headache usually lasts 4 to 72 hours, but may be completely absent (International Headache Society 1988).

#### **2.6.2.3. Similarity Of Tension-Type And Migraine Headache**

Raskin (1988:224) states that the similarities between tension-type headache and migraine headache appear to be more striking than the differences. He cites the following similarities: neck muscle contraction, nuchal muscle contraction and pain, cephalic hyperemia, increased prevalence of epilepsy, low platelet serotonin, psychological data similarities, and the responsiveness of both disorders to amitriptyline, ergonovine and propranolol. He concludes that a biologic mechanism of tension-type headache may be similar to that of migraine. Iverson et al. (1990) suggest that recording frequency and graded severity of characteristics using a headache diary may improve the distinction between the different types of headache.

Rasmussen et al. (1994) in comparison, supports the theory that migraine and tension-type headache are separate clinical entities and not part of a continuum although they may coexist and interrelate. Rasmussen (1995) supports this theory by means of the specific symptom clustering in both migraine and tension-type headache, the difference in the relationship between frequency and severity, the difference in sex distribution and age of onset, and finally, in the difference in endogenous and exogenous risk factors.

#### **2.6.2.4. Mixed Headache**

Coexisting migraine and tension-type headache was previously known as mixed headache, tension-vascular headache or combination headache.

Dalessio (1987:9) identifies these types of mixed headache:

1. A headache of migraine quality and has minor muscular involvement and which occurs over many years.
2. A headache which is mainly tension-type in character and has accompanying intermittent throbbing pain, nausea and photophobia.
3. An episodic migraine headache that progresses to a daily tension-type headache.

The International Headache Society (1988) comments that patients in the mixed headache category represent a continuum and thus the concept of a mixed headache is arbitrary. They recommend that patients be coded for migraine and tension-type headache separately with the number of attacks per year for each headache type in brackets after each diagnosis, thereby making the evaluation of the relative importance of the two conditions easy.

### **2.6.3. Warning Signs**

Dodick (1997) published an outline of the warning signs of headache as an ominous disease. He indicated that these “red flags” were important to identify early on in the case history and physical exam as the presence of a serious neurological manifestation may be underestimated. Signs to take note of include:

1. A headache which is subacute and progressive.
2. New onset of headache in adult life, especially over 40 years of age.

3. Onset of headache with exercise or intercourse.
4. Significant change in established headache pattern.
5. Nocturnal occurrence of headache or morning awakening.
6. Associated nausea and vomiting not explained by migraine or systemic illness.
7. Precipitation or worsening of headache with changing posture.
8. Confusion and change in cognitive abilities.
9. Seizures.
10. Weakness.
11. Any abnormal neurological sign.
12. Personality changes.
13. Signs of raised intracranial pressure: transient visual obscurations, diplopia, intracranial noises, papilloedema.
14. Resistance of headaches to analgesics.
15. Decreased level of consciousness, lethargy or excessive sleepiness.
16. Fever associated with headache.
17. Meningeal signs such as resistance to passive flexion of the neck.

## **2.7. TREATMENTS AND THEIR EFFECTIVENESS FOR TENSION-TYPE HEADACHE**

### **2.7.1. Medication**

The most frequently used drug treatments include analgesics, anxiolytics and antidepressants. Treatment with analgesics is one of the most common

practices, often on the basis of self prescription by the patient's themselves (Biondi et al. 1994). They suggest that treatment with anxiolytics such as benzodiazepines may be a valid solution in cases where specific stressful factors can be identified as precipitants, the onset of the tension-type headache is associated with anxiety and tension states, and the scheduled treatment is to be of a short duration. The choice of a tricyclic antidepressant treatment requires long-term treatment under medical control. Valid alternatives to classic tricyclics are new serotonergic antidepressants such as fluoxetine and fluvoxamine (Biondi et al. 1994).

A number of clinical trials have compared the effect of prescription and non-prescription medication to the relief of pain associated with tension-type headache. Nebe et al. (1995) conducted a double-blind, threefold crossover, double-dummy trial, investigating the efficacy of 200mg ibuprofen compared with 500mg acetylsalicylic acid and placebo in mild to moderate migraine or episodic tension-type headache (n=95). The study showed ibuprofen to be significantly superior to acetylsalicylic acid in decreasing headache intensity by 50% within 1 hour, but the difference in pain reduction of ibuprofen and acetylsalicylic acid diminished with observation past 1 hour. He concluded that 200mg ibuprofen was at least equivalent to 500mg acetylsalicylic acid and both were more effective than placebo in providing relief. It was suggested in the discussion of this study that the greater initial difference in results may have been due to the faster reabsorption of ibuprofen. The verbal rating scale was used in this study,



and although it is the appropriate scale for typical migraine attacks, it may not have been sufficiently sensitive for this study which included tension-type headache. Both migraine and tension-type headache were included in this study as it is difficult to distinguish between them in the early stages, and this may have lead to a bias in the results as the two headaches are the result of different mechanisms.

Schachtel et al. (1996) conducted a single center, double blind, randomized, placebo-controlled trial comparing the efficacy of 400mg ibuprofen and 1000mg acetaminophen in the treatment of tension-type headache (n=455). He demonstrated that single doses of both ibuprofen and acetaminophen are safe and effective analgesic agents that provide significant relief compared to placebo, with 400mg ibuprofen more effective than 1000mg acetaminophen. He used the guidelines established by the Ad Hoc Committee on Classification of Headache (1962) as his diagnostic criteria, which is now out of date. He did however, review the case histories of the patients included in the study in an attempt to reconcile the criteria for tension-headache diagnosis with the new criteria as published by the Headache Classification Committee of the International Headache Society (1988), and found the patient characteristics to be consistent with the new criteria..

Van Gerven et al. (1996) conducted a single dose, double-blind, randomized, parallel group, placebo-controlled efficacy study of 25mg ketoprofen, 50mg

ketoprofen and 200mg ibuprofen in the treatment of a single headache episode. He reported that a single dose of 25mg or 50mg ketoprofen were both more effective in treating tension-type headaches (n=166), compared to either 200mg ibuprofen or placebo. This study attempted to mimic the situation where an over the counter medication is taken for an "ordinary" headache. There was strict exclusion of refractory headache types, and there was good instruction in the use of the electronic diary. The electronic diary did not allow for the alteration of previously entered information, and in addition, did not display the previously entered data. This study demonstrated the practicality of electronic diaries in studies of this design.

Dahlof et al. (1996) compared the efficacy and tolerability of a single oral dose of 25mg ketoprofen, with 2 x 25mg ketoprofen, 500mg and 1000mg paracetamol and placebo in the treatment of tension-type headache (n=40). The results of this study showed that a single dose of 50mg ketoprofen was significantly better than paracetamol and placebo. Patients experiencing tension-type headache in association with or without migraine were included in the study. Patients used in this study were recruited from the Gothenburg Migraine Clinic and this may have resulted in a positive selection of severe headache sufferers, which may have accounted for the severity of the headache attacks. It is also conceivable that some of the reported headaches were either intricate migraine-episodic tension-type headaches, or episodic tension-type headache preceding a migraine attack. In some cases, a migraine attack was reported in close

association to the treated headache episode. Neither dose of paracetamol could be differentiated from placebo, which may be explained by the severity of the baseline headache, or the low number of evaluable patients in the study. These circumstances may not have been truly representative of typical tension-type headache.

Lange et al. (1995) conducted a prospective, randomized, double-blind parallel group study (n=345) to compare the safety and efficacy of a single dose 12,5mg (n=86) or 25mg (n=87) ketoprofen, 200mg ibuprofen (n=87) and 275mg naproxen sodium (n=85) in the treatment of tension-type headache. The change in headache intensity scores compared with the baseline values was almost identical in all treatment groups during the 4 hour observation period. No placebo group was used as he considered the ibuprofen to be a standard over the counter analgesic.. No major differences were thus noted between the treatment groups ( $p=0,539$ ) at any point during the study.

Mitsikostas et al. (1997) explored the efficacy of buspirone in comparison with amitriptyline in the treatment of chronic tension-type headache. Twenty-six patients were treated with 30mg buspirone daily for 12 weeks and a parallel group of thirty-two patients was treated with 50mg amitriptyline daily for the same time period. Both buspirone and amitriptyline treatment significantly reduced the headache index as well as the mean use of drugs as compared to the observation stage, indicating that both therapies were effective. Undoubtedly,

buspirone showed a better safety profile than the amitriptyline, although the participants had a better opinion of the amitriptyline. This was an exploratory, open label study and a double-blind, placebo controlled study is necessary to draw more concrete conclusions.

Schneider et al. (1993) questioned 80 patients suffering from tension-type headache and discovered patients consumed an average of 2.5 different drugs, primary as compound preparations and the cumulative doses of derivatives in some cases reached a maximum of several kilograms. He concluded that patients with tension-type headache are at considerable risk of becoming drug-dependent and of acquiring analgesics-induced-headache.

Allison et al. (1992) examined the stomach, duodenum and small intestine of 713 patients post mortem. He concluded that patients who take nonsteroidal anti-inflammatory drugs (NSAIDs) have an increased risk of nonspecific ulceration of the small intestinal mucosa. These ulcers are less common than gastric or duodenal ulcers, but can lead to life-threatening complications. Wilcox et al. (1994) concluded that over the counter nonsteroidal anti-inflammatory drug (NSAIDs) use is frequent and exceeds prescription use. He found that ulcer-related bleeding as well as nonulcer-related upper gastrointestinal haemorrhage was significantly associated with the use of NSAIDs.

#### **2.7.1.1. Acetaminophen**

The chemical name of acetaminophen (paracetamol) is N-(4-hydroxyphenyl)acetamide and is prepared from p-nitrophenol by reduction with tin in glacial acetic acid (Windholz et al. 1976:6).

##### **2.7.1.1.1. Dosage And Mode Of Action**

The usual dose is 0,5g to 1,0g every 4 to 6 hours for no longer than 10 days (Trounce 1997:122). Acetaminophen is well absorbed orally and does not cause gastric irritation but has no significant anti-inflammatory action. Acetaminophen produces analgesia by increasing pain threshold and antipyresis through action on the thalamic heat regulating center (Arky 1997:1570). It also acts partially by reducing cytoplasmic peroxide levels (Neal 1992: 66-67).

##### **2.7.1.1.2. Indications**

Acetaminophen is indicated for the temporary relief of simple pain such as headache, but is not recommended for continuous use for longer than 10 days (Snyman 1998: 37-38). It's use is also indicated for minor aches such as common cold, toothache, backache and menstrual cramps (Arcky 1997:1570). Acetaminophen is a proven analgesic antipyretic (Trounce 1997:122).

##### **2.7.1.1.3. Special Precautions**

Special precautions are recommended in liver and kidney disorders. Dosage of acetaminophen must be reduced and monitored if other prescription medication

is being ingested. Acetaminophen should not be taken for longer than 10 days as this may result in toxic accumulation, especially in patients who are already compromised (Snyman 1998: 37-38).

#### **2.7.1.1.4. Side Effects**

Adverse effects are uncommon at normal dosage, but as little as 7,5g (15 of the usual tablets) can be dangerous (Trounce 1997:338). Known side effects of acetaminophen are reversible skin rashes and blood dyscrasias (Snyman 1998:37-38). Acute hepatic damage is the best recognized form of drug-induced liver injury. Such damage may be dose-related and predictable, or it may be unrelated to dose and unpredictable. Predictable drug hepatotoxicity is mediated biochemically, though its occurrence and severity can be modified by factors affecting the drug metabolizing enzymes such as alcohol or nutritional status. Paracetamol in therapeutic doses is mainly conjugated to produce glucuronide and sulphate, but a small amount is metabolized to potentially toxic intermediates which are conjugated with glutathione to form mercapturic acid which is not toxic. Paracetamol in large doses produces toxic intermediates in amounts sufficient to deplete glutathione stores and damage the liver (Edwards et al. 1991:515). Early symptoms may include minimal nausea and vomiting, and it is only after 2 to 3 days that jaundice with liver failure, or more rarely kidney failure develop (Trounce 1997:338).

#### **2.7.1.1.5. Contraindications**

Acetaminophen is contra-indicated in cases of severe liver function impairment or acetaminophen sensitivity (Snyman 1998:37-38).

#### **2.7.1.1.6. Clinical Features Of Acute Acetaminophen Poisoning**

Nausea and vomiting initially, but at first, symptoms are often non-specific. After about 36 hours in severe poisoning, more serious toxic effects may develop including hypotension, hypothermia, metabolic acidosis, hypoglycemia, hypoprothrombinemia, renal failure and delirium. The main danger, however, is acute liver failure which tends to develop a few days after ingestion, and carries a high mortality.

Oral adsorbents , of which activated charcoal is the safest, may be given with water if a large dose of acetaminophen has been taken within the previous hour. Specific drug treatment can alter the metabolism of acetaminophen and prevent liver damage. The drug protocol is methionine, 2.5g every 4 hours orally for 4 doses or N-acetylcysteine 150mg/kg in 200ml of 5% dextrose over 15 minutes followed by 50mg/kg infused over 4 hours and finally, 100mg/kg infused over the next 16 hours. This treatment is effective if given within 10 hours of ingestion of acetaminophen (Trounce 1997:338).

Gastric aspiration and lavage are other treatment options for cases of oral poisoning. Additional supportive therapy may include administration of oxygen, control of hypothermia and treatment of convulsions with diazepam.

Single plasma paracetamol levels taken after 4 hours following ingestion of paracetamol provide good diagnostic indicators for the development of liver toxicity, and it is on these that the decision to give specific antidote therapy is made. Emergency measurement of blood levels is thus essential (Edwards et al. 1991:973-979).

#### **2.7.1.2. Caffeine**

Caffeine is a methylated xanthine and the chemical name of caffeine is 1,3,7-trimethylxanthine (Gilman et al. 1990). Caffeine occurs in tea, coffee, maté leaves, guarana paste and cola nuts, and is obtained as a by-product of the production of caffeine-free coffee. Caffeine is categorized as a central nervous system stimulant ((Windholz et al. 1976:207).

##### **2.7.1.2.1. Dosage And Mode Of Action**

Caffeine exerts a pharmacological action on various organ systems that may alter subsequent absorption and metabolism of substances, including analgesics (Sawynock et al. 1993). Caffeine has for many years been combined with various mild analgesics to enhance their efficacy (Beaver 1984). Laurence et al. (1987:307) state that 30mg to 60mg caffeine enhances the analgesic effect of



analgesics and accelerates the onset of effect. Beaver (1984) estimated that when caffeine is added to analgesics, the required administered dose may be reduced by as much as 40% with no loss of therapeutic benefit. Acetaminophen has a relatively low dose-response curve which indicates that increased dosage will result in a relatively small increment in analgesic effect. The combination of acetaminophen with caffeine may allow for increased analgesic effect, without the associated risk of cumulative toxicity due to increased acetaminophen intake. Beaver (1984) concludes that the addition of caffeine seems to be a safe and useful way to extend the efficacy of analgesics, including acetaminophen.

Caffeine has effects on intracellular calcium, adenosine receptors, and noradrenergic function. Caffeine also acts as an inhibitor of phosphodiesterase, the enzyme which breaks down cyclic-AMP, so that bronchodilation is enhanced, although this requires dosages outside the therapeutic spectrum (Laurence et al. 1987:365).

Caffeine may induce feelings of alertness, well-being, euphoria or exhilaration and habitual tea and coffee drinkers are seldom willing to recognize that they have an emotional drug dependence. Overdose can cause anxiety, tension and tremors, although ill-effects are rare and seldom serious when they do occur. Respiration is stimulated, onset of sleep may be delayed and there may be increased awakenings, metabolism of skeletal muscle is increased, cardiac

output is increased and there may be ectopic beats and palpations (Laurence et al. 1987:367).

#### **2.7.1.2.2. Dependence**

Tolerance to the effects of caffeine is slight. Psychological and mild physical dependence may result in withdrawal symptoms in habitual coffee drinkers who drink 5 or more cups a day. Withdrawal symptoms occur 12 to 16 hours after the last cup of coffee and include headache, irritability and jitteriness (Laurence et al. 1987:367).

#### **2.7.1.2.3. Overdose**

There is great individual variation in the effect of caffeine both between individuals and also in the same individual at different times of life. Excessive prolonged consumption of caffeine may cause anxiety, restlessness, tremors insomnia, headache, cardiac extrasystoles and confusion. Diarrhoea may occur with coffee overdose and constipation with tea overdose (Laurence et al. 1987:367).

#### **2.7.1.2.4. Caffeine Poisoning**

Fatal poisoning in man by the ingestion of caffeine is rare (Gillman et al. 1990:625) with death only being reported in a few cases following intravenous injection or oral administration (Feldmann et al. 1986:367). The short term lethal dose of caffeine in adults appears to be 5g to 10g, but side effects such as

insomnia, restlessness, and excitement may be observed following the ingestion of as little as 1g.

#### **2.7.1.3. Caffeine As An Acetaminophen Adjuvant**

Ward et al. (1990) conducted a double-blind clinical trial of the analgesic effects of caffeine in headache and reported that caffeine appeared to have independent analgesic effects that were equivalent to acetaminophen. In contrast, Zhang et al. (1996) concluded that acetaminophen was an effective analgesic but its combination with caffeine added little to the analgesic effect. Six, separate, multicentre randomised, double-blind, two period crossover studies comparing the effectiveness of a single dose of a combination of 1000mg acetaminophen and caffeine with that of 1000mg acetaminophen alone and placebo in patients with tension-type headache were conducted by Migliardi et al. (1994). In all six studies containing a total of 1900 patients, the caffeine containing analgesics were superior to both placebo and 1000mg acetaminophen alone ( $p < 0,01$ ), with the acetaminophen alone significantly superior to placebo ( $p < 0,05$ ). A meaningful subgroup analysis was conducted on the effect of usual and immediate previous caffeine consumption. It was found that the adjuvant effect of caffeine was independent of patients' usual caffeine consumption. This effect was also significant both for patients with the highest caffeine consumption and for those who usually consumed little or no caffeine.

## **2.7.2 CHIROPRACTIC**

### **2.7.2.1. Joint Manipulation**

Spinal manipulation according to Curl (1994:293) is an assisted passive motion applied to the spinal apophyseal joints during which the motion segment is suddenly carried beyond its normal physiological range of motion without exceeding the anatomical barrier. The usual characteristic is a high velocity, short-amplitude thrust that is given at the end of the normal passive range of motion and is usually accompanied by a cracking noise.

### **2.7.2.2. Manipulation Versus Mobilization**

Mobilization is when a joint is passively assisted into the small buffer zone of passive mobility at the end of active range of motion. Manipulation occurs if the articulation surfaces are forced beyond the end of passive range of motion into the paraphysiological space. The anatomical barrier is at the end of the limit of the paraphysiological space and forced movement beyond this point would result in ligamentous and joint capsule damage (Curl 1994:293).

There are 4 grades of mobilization. Grades 1 and 4 are small amplitude movements at the beginning and end respectively of the possible range of motion. Grades 2 and 3 are larger amplitude movements occupying the middle parts of the possible range of motion, although oscillatory movements are also effective. Grade 5 mobilization is when the passive range of motion is exceeded, so it can also be termed as manipulation (Nook et al. 1990)

Cassidy et al. (1992a) demonstrated that both manipulation and mobilization resulted in an increased range of motion, but manipulation had a greater effect on the relief of pain intensity. They concluded that a single manipulation is more effective than mobilization in decreasing pain.

#### **2.7.2.3. Effects Of Manipulation**

The therapeutic effects of manipulation can be explained on the grounds of mechanical and reflex mechanisms (Curl 1994:297-8). Mechanical mechanisms include: 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. Cassidy et al. (1992b) demonstrated that cervical manipulation results in an immediate increase in range of motion in all directions and a decrease in pain. They demonstrated that the biggest effect was on rotation and that an improvement in rotation is associated with the greatest reduction in pain. Vernon (1988) demonstrated an average increase in pressure pain threshold by 45,7% after spinal manipulation. He suggested that manipulation exerted an inhibitory influence on the pain-transmitting spinal cord centers, thus resulting in increased pressure pain tolerance. Vernon et al. (1990) found an improvement in pressure pain threshold ranging from 40-56% in subjects receiving manipulation, and thus his proposed hypothesis (Vernon 1988) is lent further support.

#### **2.7.2.4. Chiropractic Intervention**

In 1979, Hoyt et al. conducted a randomised clinical trial involving 22 subjects with tension-type headache. The subjects were randomly allocated into one of 3 groups consisting of cervical palpation and manipulation, cervical palpation only and placebo. Intervention consisted of a single 10 minute session, after which pain intensity was assessed. He reported that the group receiving manipulation of the cervical spine demonstrated, on average, a 50% reduction of headache severity. This was statistically significant when compared to the other groups. Unfortunately, duration of this effect was not measured in any follow up.

Vernon (1982) conducted a prospective study of chiropractic treatment for tension-type headache on 18 patients, who received an average of 9 treatments consisting of cervical spine manipulation. He reported statistically significant reductions in headache activity as measured by frequency, duration and intensity. The average frequency was reduced from 13 to 3 headaches per month, average duration was reduced from 12 to 2 hours, and average intensity was reduced from 3,5 to 1,5 out of a maximum score of 5.

Turk et al. (1987) reported on 100 cases of chronic nonvascular headaches that were treated with cervical manipulation. Analysis of the results of the study show that in 75% of all the cases headaches were alleviated by the end of the three week treatment period and at the 6 month follow up examination, 25% were headache free, 40% showed improvement but still took analgesics and 35% had

a transient improvement for approximately 1 month, but the headaches had returned.

Bove et al. (1998) conducted a randomized clinical trial (n = 75) comparing soft tissue treatment combined with cervical spinal manipulation to soft tissue treatment combined with placebo laser and demonstrated significant reductions in mean daily headache hours as well as reductions in daily analgesic intake for the manipulation group. These changes were maintained throughout the observation period, although headache pain intensity was unchanged for the duration of the trial.

#### **2.7.2.5. Indications For Manipulation**

Gatterman (1990:50-51) states that the primary indication for manipulation is joint fixation or blockage, which is described as a reversible mechanical derangement of the facet joint, causing a limitation in normal movement.

#### **2.7.2.6. Contraindications To Manipulation**

Contraindications to manipulation as stated by Gatterman (1990: 67-68) are listed as follows:

1. Vertebral-basilar artery insufficiency (VBAI)
2. Atherosclerosis of major blood vessels
3. Aneurysm
4. Tumours (lung, thyroid, breast, bone)

5. Bone infections (tuberculosis, osteomyelitis)
6. Traumatic injuries (fracture, instability or hypermobility, severe sprains or strains, unstable spondylolisthesis)
7. Arthritis (rheumatoid, ankylosing spondylosis, psoriatic arthritis, unstable stage and late stage osteoarthritis, uncoarthritis)
8. Metabolic disorders (clotting disorders, osteoporosis, osteomalacia)
9. Neurologic complications (disc lesions with advancing neurological deficits, space occupying lesions)

#### **2.7.2.7. Side Effects Of Manipulation**

Leboeuf-Yde et al. (1997) state that reactions to spinal manipulation are common, benign, and typically arise and disappear shortly after treatment. They list the reactions as follows: local discomfort, fatigue, headache, nausea or dizziness. Senstad et al. (1997) studied the type, frequency and characteristics of unpleasant side effects to spinal manipulative therapy. They reported that 55% of the patients experienced at least one reaction during the course of 6 treatments, but 85% of these were of mild or moderate nature. Seventy-four of the patients reported that the reactions had disappeared within 24 hours, and there were no reports of serious complications. Dabbs et al. (1995) state that the estimated incidence for stroke from cervical manipulation is 1-3 incidents per million treatments and concluded that cervical manipulation is much safer than the use of NSAIDs by as much as a factor of several hundred times.



#### **2.7.2.8. Chiropractic Compared To Medication**

Amitriptyline is the prescribed treatment of choice for chronic tension-type headaches (Mitsikostas et al. 1997). Boline et al. (1995) conducted a randomised clinical trial of chiropractic manipulation versus amitriptyline involving 150 patients suffering from tension-type headaches. The study consisted of a 2 week baseline period, a 6 week treatment period and a 4 week post-treatment follow-up period. Patients in the manipulation group were treated twice weekly for 6 weeks and the patients in the amitriptyline group were managed by a medical physician. During the treatment period, both groups improved at similar rates in all primary measures with reductions in headache intensity, headache frequency, reduction in over the counter medication usage, and improved functional health status. However, four weeks after cessation of treatment, the manipulation group showed sustained therapeutic benefit whilst the amitriptyline group showed no improvement from baseline values in the same four major outcome measures. Of the patients that completed the study, 82,1% in the amitriptyline group experienced side effects, including dry mouth, drowsiness or weight gain. In the manipulation group, 4,3% of the patients reported neck stiffness after the first treatment that disappeared in all cases after the first 2 weeks of treatment. The results of this study show that spinal manipulative therapy is an effective treatment for tension-type headache with sustained therapeutic benefit.

Dabbs et al. (1995) evaluated the risk of serious injury or death from cervical manipulation as opposed to nonsteroidal anti-inflammatories. They concluded that cervical manipulation is one of the safest forms of treatment and it should not be considered dangerous, compared to NSAIDs which carries a hundred-times-greater chance of serious injury or death.

### **2.7.3. Miscellaneous Treatments**

#### **2.7.3.1. Traction**

Donkin (1998) concluded that manual traction did not enhance the effect of the cervical adjustment and appears to have limited value in the treatment of tension-type headache.

#### **2.7.3.2. Massage**

Gatterman (1990:250) included massage as one of the treatment options for tension-type headaches. Penter (1994) demonstrated that massage could be an effective short-term therapy for tension-type headache. He conducted a clinical trial (n=30) comparing the effects of massage combined with manipulation to massage only in patients suffering from tension-type headache. Both groups fared equally well, although at the one month follow up, the group that had received manipulation in conjunction with the massage therapy fared slightly better than the massage group with respect to headache frequency. Both groups demonstrated a decrease in pain intensity, duration, frequency and disability of the tension-type headaches.

#### **2.7.3.3. Biofeedback**

Biofeedback is associated with a more formal setting than general relaxation techniques and allows for more objective control of the patient's condition. Biofeedback training is more specifically and "scientifically" orientated towards headache disorders as it is the only treatment that implies control of actual muscle tension (Biondi et al. 1994). Chesney et al. (1976) concluded that muscle relaxation and muscle relaxation combined with biofeedback were significantly effective in reducing headache frequency. Bogaards et al. (1994) found that irrespective of the type of measurement used, cognitive therapy and EMG biofeedback alone or in combination, were found to be superior to no treatment and pseudo/placebo treatment. Treatment in the acute stage may be directed specifically at the muscle in the form of electrical stimulation and relaxation techniques (Curl 1994:332.)

#### **2.7.3.4. Relaxation Methods**

Relaxation techniques are based on learning techniques to reach a psycho-physical state of complete muscular and mental relaxation. This state is characterized by important autonomic modifications such as local vasodilation, decrease in heart rate, blood pressure and respiratory rate, and other physiological responses (Biondi et al. 1994).

Simple measures such as massage, manual stretching of the muscles of the neck and shoulder girdle, hot tub baths, and the application of local heat must

not be overlooked. Some patients prefer other relaxation techniques such as meditation, hypnosis or yoga (Raskin 1988:221). Raskin (1988) stated that in his experience, the benefits of biofeedback methods were short-lived and overall disappointing. He concluded that relaxation training was preferable in that patients could continue to practice at home without expensive instrumentation, with occasional reinforcement from the physician.

#### **2.7.3.5. Myofascial Trigger Points**

Travell et al. (1983: 86-93) listed and discussed treatment possibilities that were specific to myofascial complaints. She discussed TP injection and stretch and spray. Alternative treatment techniques listed were ischaemic compression, massage, stretch without spray and ultrasound. Moist heat, drug therapy and biofeedback were listed as useful adjuncts.

### **2.8. CONCLUSION**

The treatment of tension-type headache has varied greatly, with no universally supreme treatment identified. This would indicate that more extensive research is needed with more attention to the area of tension-type headache specifically. Further research will increase our understanding and management of this condition. This current study sought to identify the effects of acetaminophen combined with caffeine as opposed to cervical manipulation in order to determine the more effective approach in the management of this condition.

## **CHAPTER THREE**

### **MATERIALS AND METHODS**

#### **3.1. INTRODUCTION**

The object of this study was to compare the relative effectiveness of acetaminophen combined with caffeine as opposed to cervical manipulation in the treatment of tension-type headaches in order to determine the most effective approach in the management of tension-type headaches. This chapter describes the methods used for collection of both the objective and subjective data, as well as the methods used for statistical interpretation and presentation.

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

This study was a randomised clinical trial involving 70 patients with the purpose of determining the possible effect of each treatment protocol. Patients in group 1 received 1000mg acetaminophen combined with caffeine and patients in group 2 received cervical manipulation. Firstly, intra-group changes were considered for the two groups, and secondly, inter-group differences were analyzed to determine which of the two treatment protocols were, if at all, more effective

#### **3.3. THE DATA**

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

### **3.3.1 The Primary Data**

The primary data consisted of the following:

Patients' pain sensitivity, as measured with an algometer.

Patients' cervical range of motion, as determined by a cervical range of motion (CROM) goniometer.

Patients' pain perception, as determined by a short form McGill Pain Questionnaire (Appendix 7) and a Numerical Pain Rating Scale-101 (Appendix 8).

Patients' disability, as determined by a Canadian Memorial Chiropractic College (CMCC) Disability Index (Appendix 9).

Patients' pain intensity and pain relief, as determined by an Ordinal Scale (Appendix 10) (Migliardi et al. 1994).

### **3.3.2. The Secondary Data**

The secondary data consisted of recognized diagnostic and evaluatory criteria relevant to the patients' presenting pressure pain threshold, perception of pain and disability, as well as cervical range of motion.

## **3.4. RESEARCH METHODOLOGY AND MATERIALS USED**

Experimental and questionnaire design were the same as outlined in the data collection process.

Volunteers who suffer from tension-type headache were recruited by advertisements in the local newspaper, The Natal Mercury and The Daily News, and the local radio station, East Coast Radio. It was advertised that free treatment was available for people suffering from tension-type headache who were willing to participate in the pilot study and who also agreed to abide by the treatment restrictions defined by the experimental design. All patients who responded to the advertisements were screened by telephonic interview using the following questions:

- a. Have you injured your head, neck or shoulders in the past two years?
- b. Are you pregnant or breastfeeding?
- c. Do you suffer from a stomach, intestine, liver or kidney disease?
- d. Are you allergic to paracetamol (South African equivalent of acetaminophen) or caffeine?

If the volunteer answered “no” to all of the above questions, they were then invited to attend an initial consultation in order to determine whether they fitted the desired patient profile.

#### **3.4.1. Inclusion And Exclusion Criteria**

Male or female volunteers in good general health were required to be between the ages of 10 and 65 years, experience a minimum of 7 headaches per month which respond to over the counter medications (OTC), and must fit the specific

diagnostic criteria outlined by the International Headache Society (1988). These criteria are as follows:

- A At least 10 previous headache episodes fulfilling criteria B to D listed below. Number of days with such headache: less than 180 per year (less than 15 per month).
- B Headache lasting from 30 minutes to days.
- C At least 2 of the following characteristics:
  - 1. Pressing / tightening (non-pulsating) quality.
  - 2. Mild or moderate intensity (may inhibit, but does not prohibit activities).
  - 3. Bilateral location.
  - 4. No aggravation by walking stairs or similar routine physical activity.
- D Both of the following:
  - 1. No nausea or vomiting (anorexia may occur)
  - 2. Photophobia and phonophobia are absent, or one but not the other is present.



E At least one of the following:

1. History, physical and neurological examinations do not suggest one of the following:
  - a. trauma
  - b. vascular disorders
  - c. non-vascular intracranial disorders
  - d. substances or their withdrawal
  - e. non-cephalic infection
  - f. metabolic disorders
  - g. disorders of the cranium, neck, eyes, ears, nose, sinuses, teeth, mouth, or other facial or cranial structures.
2. History and/or physical and/or/ neurological examinations do suggest such a disorder, but it is ruled out by appropriate investigation.
3. Such a disorder is present, but tension-type headache does not occur for the first time in close temporal relation to the disorder.

Subjects suffering from other types of headaches, or had clinical findings that contraindicated manipulation were excluded from the study. Pregnancy, breastfeeding, known hypersensitivity to acetaminophen, caffeine or both, and history of gastrointestinal, hepatic or renal disease were also grounds for exclusion.

### **3.4.2. Procedure**

At the initial consultation, volunteers underwent a full case history (Appendix 3), physical examination (Appendix 4) and regional cervical examination (Appendix 5). During this consultation, subjects were screened for cervical facet syndrome or myofasciitis, or a combination of these two syndromes. If deemed clinically necessary, the patients underwent radiological examination of the cervical spine (cervical spine series including stress views) to rule out any pathology that would exclude them from the study.

Eligible subjects were assigned to either group 1 or group 2 by using a simple random allocation method as follows:

The number 1 was written on 35 cards and the number 2 was written on 35 cards, and all the cards were then placed in a hat. The cards were then drawn one at a time, and the sequence in which they were drawn was recorded. This procedure continued until a minimum number of 35 subjects had been randomly

allocated to group 1 and a minimum number of 35 subjects randomly allocated to group 2.

Group 1 was the medication group (MED) and group 2 was the cervical manipulation group (SMT). There was no blinding of either the patients or the researcher in this study. Once the eligible subject had given their written consent (Appendix 1), the initial part of the study began.

Subjects were asked to refrain from taking any analgesics in the 6 hours prior to the visit, or any alcoholic beverages in the 8 hours prior to the visit (Migliardi et al. 1994). Any caffeine-containing foods or beverages that were consumed within the 4 hours prior to the visit were recorded, but the subjects were asked to abstain from caffeine-containing products for 4 hours following the treatment. (Caffeine abstinence before treatment is unrealistic as the onset of a tension-type headache is unpredictable.) Caffeine intake was calculated as done by Migliardi et al. (1994):

- a. 150mg per cup of coffee
- b. 64mg per cup of tea
- c. 30mg per can caffeine containing soft drink (e.g. cola drinks)
- d. 6 mg per cup of hot chocolate
- e. 6mg per chocolate bar

All questionnaires and measurements were taken while the patients were experiencing a tension-type headache. Patients were asked to complete the Short-form McGill Pain Questionnaire (Melzack 1975; Turk et al. 1985) (Appendix 7), the Numerical Rating Scale-101 Questionnaire (Jensen et al. 1986) (Appendix 8) and the Canadian Memorial Chiropractic College (CMCC) Neck Disability Index (Vernon et al. 1991) (Appendix 9).

Cervical ranges of motion were measured using the cervical range of motion (CROM) goniometer (Performance Attainment Associates. 1988. St. Paul, MN). A single reading for each direction was taken at all consultations, using the apparatus as indicated in the handbook instructions (Appendix 11). Cervical range of motion was measured in flexion, extension, right and left lateral flexion and right and left rotation.

The trapezius muscle, posterior cervical muscles, temporalis muscles, and sternocleidomastoid muscles were examined bilaterally by palpation for trigger points (Travell et al. 1983). The muscles were re-examined for new trigger points at the consultation for headache number 2. A pressure threshold reading was obtained by means of an algometer supplied by Wagner Instruments (P.O. Box 1217, Greenwich, CT 06836, USA). Readings were taken over the most tender areas located in each of the specified muscles. If no tender area could be located in a particular muscle, no reading was taken for that muscle on that side.

A single reading was obtained for each trigger point at each visit prior to the start of the treatment and at the 24 hour follow-up (Appendix 12).

The most fixated cervical articulation(s) were identified using motion palpation. At each visit, including the follow-up, motion palpation was repeated and the fixation listing was noted in the Subjective, Objective, Analysis, Procedure (SOAP) notes.

### **3.4.3. Interventions**

Group 1 (MED) received no physical or manual therapy. Subjects were given 1000mg acetaminophen with 130mg caffeine in capsule form, and were asked to ingest the medication with 200ml water. Group 2 (SMT) also did not receive any other form of manual or physical therapy, and were adjusted according to principles of diversified technique (Nansel et al. 1989; Szaraz 1990; Nansel et al. 1992) at the fixated level and direction indicated by motion palpation. The manipulation was administered by the examiner in the form of either a diversified rotatory or lateral break adjustment (Szaraz 1990). The rotatory or lateral break adjustment was performed in the supine position with the point of contact being on the ipsilateral side to the diagnosed facet joint syndrome. If more than one joint was symptomatic then all were manipulated. Rotation of the cervical spine beyond 45 degrees was not used in these adjustments.

Selection of the technique(s) used was based on the level to be treated, direction of the fixation, patient build and comfort. No stretching or strengthening exercises were prescribed and no advice on pain management was given to either of the groups.

During the 4 hours following consultation 1, each patient was asked to record hourly evaluations of pain intensity and pain relief (Appendix 10) (Migliardi et al. 1994). Pain intensity was rated on a 4-point ordinal scale, and pain relief on a 5-point ordinal scale.

Patients were asked to return in 24 hours for follow-up 1 for reassessment. No treatment was given on Fridays or the day before a public holiday as this would not allow for the 24 hour follow-up. A minimum of 48 hours as a “washout” period was allowed to pass before the patient could be treated for the next headache. Headache number 2 (consultation 2 ) was treated in the same manner as headache number 1 to reduce variability and enable a more powerful analysis for possible carryover effects (Migliardi et al. 1994).

The patient was discharged from the study at the end of the follow-up 2.

#### **3.4.4 Special Circumstances**

If a patient sustained a shoulder, neck or head injury, they were immediately excluded from the study. If a patient became ill and required medication that

contained an analgesic agent, they were also immediately excluded from the study. They were allowed to re-enter the study as a new patient if their headache reoccurred, provided a minimum of seven days had passed since the completion of the course of medication. If a patient fell pregnant they were immediately excluded from the study. If a patient sought other treatment for the headache, such as massage, aromatherapy or physiotherapy, they were excluded from the study, and only allowed to re-enter as a new patient provided a minimum of 7 days had passed.

Self medication between treatment and follow-up due to an excessively painful headache did not exclude the patient from the study. It was noted that the patient did self medicate, as well as the medication type and dosage. If the patient ingested any form of analgesic medication 6 hours prior to the treatment, or alcoholic beverages 8 hours prior to the treatment, they were asked to return when 6 or 8 hours respectively had passed, provided the headache was still present.

All patients accepted into the study were used for demographics.

### **3.5. MEASUREMENTS AND OBSERVATIONS**

#### **3.5.1. Subjective Measurement**

##### **3.5.1.1. Short-Form McGill Questionnaire**

The Short-Form McGill Questionnaire (Melzack 1987) was used to provide subjective information on the sensory, affective and overall intensity of pain. The Short-Form McGill Pain Questionnaire has a high correlation with other recognized questionnaires and is sensitive for traditional therapies (Melzack 1987). Questions 1 to 11 assesses the sensory perception of pain and questions 12 to 15 assess the affective dimension of pain. A minimum score of zero is allocated for no pain, and a maximum score of three for the most severe pain for each question. Each question must be answered by the patient. The sum of the completed questions is divided by the highest possible score to arrive at a percentage.

##### **3.5.1.2. CMCC Neck Disability Index**

The CMCC Neck Disability Index (Vernon et al. 1991) was used to assess the disability experienced by the patient. This questionnaire assesses disability in relation to pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. Vernon et al. (1991) demonstrated a high degree of test-retest reliability and internal consistency, an acceptable level of validity, and sensitivity to severity variation. The patient was instructed to mark one block in each section which most appropriately described their disability. A score of zero was allocated to no disability ranging to a score



of five for the maximum disability. The total of the whole questionnaire was divided by the highest possible total of fifty to arrive at a percentage disability.

#### **3.5.1.3. Numerical Rating Scale**

The Numerical Rating Scale 101 (NRS 101) (Jensen et al. 1986) was used to determine the pain intensity the patient experienced during the course of the study. This questionnaire is easy to administer and to score, has a high relative rate of correct scoring, and has a large choice of response categories (101) (Jensen et al. 1986). The questionnaire has two lines which each indicate a scale of 0 -100 depicting pain intensity. On the top line, the patient is asked to indicate a number between 0 and 100 which best describes the pain when it is at it's worst. On the bottom line, the patient is asked to indicate a number between 0 and 100 it indicate the pain intensity when it is at it's least. The average pain intensity was calculated by adding the values representing the patient's worst and least intensity of pain and dividing the total by two.

#### **3.5.1.4. Pain Intensity And Pain Relief Ordinal Scales**

Pain Intensity and Pain Relief Ordinal Scales (Migliardi et al. 1994) were used to assess pain intensity and pain relief in the 4 hours immediately after the treatment and again at the 24 hour follow up visit. The patient took the questionnaire home and completed it without supervision. Pain intensity was rated on a 4-point ordinal scale with 4 being severe pain and 0 being pain free.

Pain relief was rated on a 5-point ordinal scale with 0 being no relief at all and 5 being pain free.

### **3.5.2. Objective Measurements**

#### **3.5.2.1. Cervical Range Of Motion Instrument**

A cervical range of motion (CROM) goniometer was used to assess the cervical range of motion of each patient. The CROM manufactured by Performance Attainment Associates (3600 Labore Road, Suite 6, St. Paul, Minnesota 55110-4144, USA) was used to assess six ranges of motion of the cervical spine. The six ranges of motion were forward flexion, extension, left and right lateral flexion, and left and right rotation. The CROM has been found to have a good to high intra-examiner reliability by Youdas et al. (1991)

The CROM measurements were obtained at the start of each of the two treatments and were repeated at the start of each follow up visit. The patient was instructed to sit erect in a straight-back chair. The patient's sacrum was placed against the back of the chair, with the thoracic spine away from the back of the chair, arms hanging at sides and feet flat on the floor. The patient was then instructed to place the CROM instrument on the head as if putting on a pair of glasses. The examiner then fastened the velcro firmly around the patient's head to prevent slippage.

The patient was instructed to place their chin on their chest and a reading was obtained from the sagittal plane meter. A second reading was taken from the

sagittal plane meter with the head of the patient in full extension. The subject was instructed to keep the head in a neutral position and then to focus on a point in front of them to eliminate rotation while measuring lateral flexion. The patient was instructed to laterally flex the head to the left while keeping the shoulders level. Shoulder elevation was monitored by the researcher and was checked by the researcher placing a hand on the right shoulder. Any head deviation from the coronal plane was corrected by the researcher. A reading was taken from the lateral flexion meter. From the neutral position, the patient was instructed to laterally flex the head to the right in the same manner as for left lateral flexion. The magnetic yoke was placed around the patient's neck with the arrow pointing north. The lateral flexion and sagittal plane meter read zero to ensure the rotation meter was level. With the patient looking straight ahead and the head in the neutral position, the rotation meter was turned so that one of the pointers pointed to zero. The patient was instructed to visualize a horizontal line on the wall to ensure that the head was not tipped during rotation. The patient was instructed to rotate the head to the left. The right shoulder was stabilized by the hand of the researcher to prevent rotation of the shoulders. A reading was then obtained from the rotation meter. From the neutral position, the subject was instructed to rotate the head to the right with the same procedure as used for left rotation, with the left shoulder lightly stabilized by the researcher.

#### **3.5.2.2. Algometer**

The pressure threshold meter (algometer), manufactured by Wagner Instruments (P.O. Box 1217, Greenwich, CT 06836, USA) was used to measure pressure pain sensitivity. The posterior cervical muscles, trapezius muscle, temporalis muscle and sternocleidomastoid muscle were examined bilaterally by palpation for trigger points. The flat pad of the algometer was placed over the trigger point and a gradual increasing pressure was applied by the examiner. The patient was instructed to indicate when the pressure became uncomfortable by clearly saying "now". The reading was then recorded and the algometer was reset. If no trigger point was located in a particular muscle, no reading was done for that muscle on the same side. This procedure was repeated for each of the specified muscles bilaterally. Algometer measurements have been proven to be reliable by Fischer (1987).

### **3.6. STATISTICAL METHODS AND ANALYSIS**

#### **3.6.1. INTRODUCTION**

The sample size per group is large ( $n_1 = 35$ ,  $n_2 = 35$ ). Hence, parametric tests methods were used for statistical data analyses (Fischer et al. 1993). There were a pair of 2 consultations (beginning and follow-up) for each of the clinical experiments: range of motion and algometer. Subjective information was also collected from the patients using questionnaires.

### **3.6.2. Procedure 1: Comparison between group 1 and group 2**

The two-sample unpaired t-test was used to compare groups 1 and 2 with respect to each variable of interest. In each test, the null hypothesis states that there is no significant difference between groups 1 and 2 with respect to the variable in charge, at the  $\alpha = 0,05$  level of significance. The alternative hypothesis states that there is a significant difference.

Decision rule: The null hypothesis is rejected at the  $\alpha = 0.05$  level of significance if the p-value is less than the level of significance of the test. Otherwise, the null hypothesis is accepted at the same level.

### **3.6.3. Procedure 2: Comparison between related samples within group 1**

The two-sample paired t-tests will be used to compare results from related samples within group 1. In each test, the null hypothesis states that there is no significant improvement between the two related samples being compared, at the alpha level of significance. The alternative hypothesis states that there is significant improvement.

Decision rule: The null hypothesis is rejected at the  $\alpha = 0.05$  level of significance if  $p < \alpha$  where p is the observed significance level or p-value. Otherwise, the null hypothesis is accepted at the same level.

#### **3.6.4. Procedure 3: Comparison between related samples within group 2**

Procedure 2 is repeated within group 2 with the same decision rule.

#### **3.6.5. Procedure 4: Frequencies and percentages**

Frequencies and percentages for all variables of study in the 4 questionnaires will be obtained. Bar charts will also be constructed for a few interesting variables.

#### **3.6.6. Procedure 5: Comparison using barcharts**

Selected visual summaries of analytical findings will be given by use of barcharts to compare groups 1 and 2 with respect to range of motion and algometer readings. Average readings will be used to make barcharts. The average readings will be obtained from the summary statistics procedure.

#### **3.6.7. Procedure 6: Power analysis**

The power of each two-sample unpaired t-test will be determined using power analysis. Power analysis will be done at a UCLA web site using summary statistics results obtained in procedure 4.

#### **3.6.8. Statistical packages:**

The statistical package SPSS and Statgraphics was used for entry and analysis.

### **3.7. THE SPECIFIC TREATMENT OF EACH OBJECTIVE**

#### **3.7.1. Objective One**

The first objective of this study was to investigate the relative effectiveness of acetaminophen with caffeine as opposed to cervical manipulation in terms of objective clinical findings, in order to determine the more effective treatment in the management of tension-type headache.

##### **3.7.1.1. The Data Required**

The data required testing the hypothesis of objective 1, was the readings obtained of cervical spine range of motion (Appendix 13) and pressure pain sensitivity (Appendix 14).

##### **3.7.1.2. How The Data Was Secured**

All data was collected from the participating patients at the Technikon Natal Chiropractic Day Clinic. This data was recorded in each of the patient's files at the time of the visit. All data collection was done by the researcher.

#### **3.7.2. Objective Two**

The second objective of this study was to investigate the relative effectiveness of acetaminophen with caffeine as opposed to cervical manipulation in terms of subjective findings, in order to determine the more effective treatment in the management of tension-type headache.

#### **3.7.2.1. The Data Required**

The data required for testing the hypothesis of objective 2 was the response of the patients to the Short-Form McGill Pain Questionnaire (Appendix 7), the Numerical Rating Scale (Appendix 8), the CMCC Neck Disability Index (Appendix 9), and the Ordinal Scales (Appendix 10).

#### **3.7.2.2. How The Data Was Secured**

The data required was obtained in the same manner as for objective 1. All questionnaires were completed under the supervision of the researcher.

#### **3.7.3. Objective Three**

The third objective of this study was to integrate the results of objective 1 and objective 2 to investigate the relative effectiveness of acetaminophen with caffeine as opposed to cervical manipulation in terms of objective and subjective clinical findings, in order to determine the more effective treatment in the management of tension-type headache.

##### **3.7.3.1. The Data Required**

The data required for the testing of the hypothesis of objective 3, was the response of the patients in both groups to the Short-form McGill Pain Questionnaire, the Numerical Rating, the CMCC Neck Disability Index, the Ordinal Scales, the readings obtained of cervical range of motion (Appendix 13) and pressure pain sensitivity (Appendix 14).



#### **3.7.3.2. How The Data Was Secured**

The data required was recorded in the files of all participating patients during the process of securing data for objectives 1 and 2.

### **3.8 CONCLUSION**

Seventy patients suffering from tension-type headache were selected and received either medication or cervical manipulation as treatment. Each patient was assessed in terms of subjective and objective clinical findings and the data was recorded for further statistical analysis.

## **CHAPTER 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 data and then the inter-group data. Each table of the intra-group data will contain the mean, standard deviation and standard error of the paired samples t-test. The p-value and correlation from the paired samples is also displayed, as well as the confidence interval and p-value of the paired samples t-test. Each table of the inter-group data will contain the mean, standard deviation and standard error of the group statistics, as well as the p-value for Levene's test for equality of variance. The p-value and confidence intervals for the equality of means concludes the presentation of the independent samples tests. The discussion of this data will be covered in chapter 5.

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

Information obtained from the case history, physical examination, regional examination, questionnaires, CROM and algometer was used as the data for this study. The McGill Pain Questionnaire, NRS 101 and CMCC neck disability Index were completed under the supervision of the researcher. The Pain Intensity and

Pain Relief Ordinal Scales were completed independently by each patient and returned to the researcher at the follow up examination. All CROM and algometer measurements were taken by the researcher.

For the following data, the level of significance ( $\alpha$ ) was set at 0.05, thus the null hypothesis is rejected when  $p < 0.05$  and the null hypothesis is accepted when  $p \geq 0.05$ .

**ABBREVIATIONS USED IN THE TABLES**

- 1. n - number
- 2. S.D. - standard deviation
- 3. S.E. - standard error
- 4. Corr - correlation
- 5. Flex - flexion
- 6. Ext - extension
- 7. R.Rot - right rotation
- 8. L.Rot - left rotation
- 9. R.LF - right lateral flexion
- 10. L.LF - left lateral flexion
- 11. Alg - algometer
- 12. C.I. - 95% confidence interval

### 4.3 DEMOGRAPHIC DATA TABLE

		<u>GROUP 1</u>		<u>GROUP 2</u>	
Size		n = 37		n = 35	
Age range		19 - 47 years		20 - 62 years	
Mean Age		31.5 years		31.8 years	
Male : Female		17 : 20		13 : 22	
Pain description					
	dull ache	9		11	
	pressure	7		7	
	tight band	14		7	
	throb	2		2	
	cramp	5		7	
	other	0		1	
Headache duration		<u>minimum</u>	<u>maximum</u>	<u>minimum</u>	<u>maximum</u>
	< 1 hour	5	0	9	0
	1 hour	8	0	2	1
	2 hours	5	1	7	0
	3 hours	11	3	9	2
	4 hours	3	10	2	11
	5 hours	1	0	0	1
	6 hours	3	14	4	9
	> 6 hours	0	8	1	10
	> 24 hours	1	1	0	1
Headache frequency					
	1-2 / week	19		17	
	1-3 / week	15		14	
	1-4 / week	3		4	
	> 4 / week	0		0	
Headache location					
	temporal	29		22	
	occipital	21		27	
	frontal	11		11	
	parietal	2		4	
Level of fixation					
	C0	4		4	
	C1	17		18	
	C2	30		27	
	C3	14		10	
	C4	3		4	
	C5	1		0	
	C6	1		0	
	C7	1		2	

#### 4.4 . INTRA-GROUP DATA

##### 4.4.1. SUBJECTIVE DATA

**TABLE 1 :**     Statistical results of the subjective findings comparing consultation 1 and follow up 1 in Group 1.

	Consult 1			Follow up 1					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
McGill (0-45)	16.40	6.41	1.08	14.89	6.23	1.05	0	0.862	0.37	2.65	0.011
McGill (%)	36.44			33.08							
NRS 101	40.29	9.88	1.67	39.13	10.11	1.71	0	0.798	-1.03	3.34	0.289
CMCC (0-50)	15.4	5.17	0.88	15.09	4.33	0.73	0	0.906	-0.45	1.08	0.408
CMCC (%)	30.80			30.18							

\*note:- % values calculated as  $\frac{\text{raw score}}{\text{total}} \times 100$

**TABLE 2 :**     Statistical results of the subjective findings comparing consultation 1 and follow up 1 in Group 2.

	Consult 1			Follow up 1					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
McGill (0-45)	16.31	6.52	1.10	6.34	5.11	0.86	0.01	0.442	7.82	12.12	0
McGill (%)	36.24			14.08							
NRS 101	40.23	13.39	2.26	25.36	13.01	2.20	0.03	0.492	10.30	19.44	0
CMCC (0-50)	18.23	7.23	1.22	11.86	6.17	1.04	0	0.594	4.27	8.47	0
CMCC (%)	36.46			23.72							

**TABLE 3 :**     Statistical analysis of the subjective findings comparing consultation 1 and consultation 2 in Group 1.

	Consult 1			Consult 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
<b>McGill (0-45)</b>	16.40	6.41	1.08	15.77	6.29	1.06	0	0.911	-0.29	1.55	0.174
<b>McGill (%)</b>	36.44			35.04							
<b>NRS 101</b>	40.29	9.88	1.67	39.57	10.08	1.70	0	0.861	-1.10	2.52	0.428
<b>CMCC (0-50)</b>	15.40	5.17	0.87	15.20	4.48	0.76	0	0.941	-0.42	0.82	0.514
<b>CMCC (%)</b>	30.80			30.40							

**TABLE 4 :**     Statistical analysis of the subjective findings comparing consultation 1 and consultation 2 in Group 2.

	Consult 1			Consult 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
<b>McGill (0-45)</b>	16.31	6.52	1.10	11.71	5.20	0.88	0	0.766	3.16	6.04	0
<b>McGill (%)</b>	36.24			26.02							
<b>NRS 101</b>	40.23	13.39	2.26	31.50	10.58	1.79	0	0.601	4.95	12.51	0
<b>CMCC (0-50)</b>	18.09	7.29	1.25	15.41	6.30	1.08	0	0.832	1.26	4.09	0
<b>CMCC (%)</b>	36.18			30.82							

**TABLE 5 :** Statistical analysis of the subjective findings comparing consultation 1 and follow up 2 in Group 1.

	Consult 1			Follow up 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
<b>McGill (0-45)</b>	16.40	6.41	1.08	14.20	7.34	1.24	0	0.755	0.52	3.88	0.012
<b>McGill (%)</b>	36.44			31.55							
<b>NRS 101</b>	40.29	9.88	1.67	37.64	10.93	1.85	0	0.719	-0.06	5.34	0.055
<b>CMCC (0-50)</b>	15.40	5.17	0.87	14.83	4.59	0.77	0	0.739	-0.65	1.80	0.350
<b>CMCC (%)</b>	30.80			29.66							

**TABLE 6 :** Statistical analysis of the subjective findings comparing consultation 1 and follow up 2 in Group 2.

	Consult 1			Follow up 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
<b>McGill (0-45)</b>	16.31	6.52	1.10	1.91	2.34	0.40	0.629	0.085	12.08	16.72	0
<b>McGill (%)</b>	36.24			4.24							
<b>NRS 101</b>	40.23	13.39	2.26	11.43	10.54	1.78	0.018	0.399	24.22	33.38	0
<b>CMCC (0-50)</b>	18.23	7.23	1.22	7.11	5.05	0.85	0.006	0.453	8.82	13.41	0
<b>CMCC (%)</b>	36.46			14.22							

**TABLE 7 :**     Statistical analysis of the subjective findings comparing follow up 1 and consultation 2 in Group 1.

	Follow up 1			Consult 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
<b>McGill (0-45)</b>	14.89	6.23	1.05	15.77	6.29	1.06	0	0.938	-1.64	-0.13	0.023
<b>McGill (%)</b>	33.09			35.04							
<b>NRS 101</b>	39.13	10.11	1.71	39.57	10.08	1.70	0	0.844	-2.38	1.49	0.645
<b>CMCC (0-50)</b>	15.09	4.33	0.73	15.20	4.48	0.76	0	0.980	-0.42	0.19	0.458
<b>CMCC (%)</b>	30.18			30.40							

**TABLE 8 :**     Statistical analysis of the subjective findings comparing follow up 1 and consultation 2 in Group 2.

	Follow up 1			Consult 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
<b>McGill (0-45)</b>	6.34	5.10	0.86	11.71	5.20	0.88	0	0.702	-6.74	-4.00	0
<b>McGill (%)</b>	14.08			26.02							
<b>NRS 101</b>	25.36	13.01	2.20	31.50	10.58	1.79	0	0.712	-9.31	-2.97	0
<b>CMCC (0-50)</b>	11.71	6.20	10.7	15.41	6.30	1.08	0	0.647	-5.54	-1.87	0
<b>CMCC (%)</b>	23.42			30.82							



**TABLE 9 :**     Statistical analysis of the subjective findings comparing follow up 1 and follow up 2 in Group 1.

	Follow up 1			Follow up 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
<b>McGill (0-45)</b>	14.89	6.23	1.05	14.20	7.34	1.24	0	0.910	-0.37	1.75	0.197
<b>McGill (%)</b>	33.08			31.55							
<b>NRS 101</b>	39.13	10.11	1.71	37.64	10.93	1.85	0	0.906	-0.11	3.08	0.066
<b>CMCC (0-50)</b>	15.09	4.33	0.73	14.83	4.58	0.77	0	0.915	-0.38	0.89	0.417
<b>CMCC (%)</b>	30.18			29.66							

**TABLE 10 :**     Statistical analysis of the subjective findings comparing follow up 1 and follow up 2 in Group 2.

	Follow up 1			Follow up 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
<b>McGill (0-45)</b>	6.34	5.10	0.86	1.91	2034	0.40	0	0.605	3.01	5.85	0
<b>McGill (%)</b>	14.08			4.24							
<b>NRS 101</b>	25.36	13.01	2.20	11.43	10.54	1.78	0	0.723	10.82	17.04	0
<b>CMCC (0-50)</b>	11.59	6.17	1.04	7.11	5.05	0.85	0	0.833	3.57	5.92	0
<b>CMCC (%)</b>	23.18			14.22							

**TABLE 11 :**     Statistical analysis of the subjective findings comparing consultation 2 and follow up 2 in Group 1.

	Consult 1			Follow up 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
McGill (0-45)	15.77	6.29	1.06	14.20	7.34	1.24	0	0.904	0.49	2.66	0.006
McGill (%)	35.04			31.55							
NRS 101	39.57	10.08	1.70	37.64	10.93	1.85	0	0.863	0.02	3.84	0.048
CMCC (0-50)	15.20	4.48	0.76	14.83	4.58	0.77	0	0.917	-0.26	1.01	0.243
CMCC (%)	30.40			29.66							

**TABLE 12 :**     Statistical analysis of the subjective findings comparing consultation 2 and follow up 2 in Group 2.

	Consult 2			Follow up 2					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	Corr	Lower	Upper	P-value
McGill (0-45)	11.71	5.20	0.88	1.91	2.34	0.40	0.64	0.317	8.09	11.51	0
McGill (%)	26.02			4.24							
NRS 101	31.50	10.58	1.79	11.43	10.52	1.78	0	0.584	16.76	23.38	0
CMCC (0-50)	15.41	6.30	1.08	7.06	5.12	0.88	0	0.630	6.60	10.10	0
CMCC (%)	30.82			14.12							

**TABLE 13 :** Statistical analysis of pain intensity and pain relief comparing the 1st hour post treatment to the 2nd hour post treatment in group 1.

	1 hour post treatment			2 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity(0-4)	1.39	0.91	0.15	0.26	0.44	0.07	0.16	0.404	0.84	1.42	0
Pain Intensity (%)	34.75			6.50							
Pain Relief (0-5)	2.36	1.21	0.20	3.60	0.69	0.12	0.001	0.525	-0.60	-0.89	0
Pain Relief (%)	47.20			72.00							

\*note:- % values calculated as  $\frac{\text{raw score}}{\text{total}} \times 100$

**TABLE 14 :** Statistical analysis of pain intensity and pain relief comparing the 1st hour post treatment to the 2nd hour post treatment in group 2.

	1 hour post treatment			2 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	1.33	0.65	0.11	0.63	0.57	0.01	0	0.690	0.53	0.87	0
Pain Intensity (%)	33.25			15.75							
Pain Relief (0-5)	2.54	0.85	0.14	3.19	0.88	0.15	0	0.839	-0.81	-0.47	0
Pain Relief (%)	50.80			63.80							

**TABLE 15 :** Statistical analysis of pain intensity and pain relief comparing the 1st hour post treatment to the 3rd hour post treatment in group 1.

	1 hour post treatment			3 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	1.39	0.91	0.15	0.17	0.38	0.06	0.413	0.143	0.89	1.54	0
Pain Intensity (%)	34.75			4.25							
Pain Relief (0-5)	2.36	1.21	0.20	3.69	0.76	0.13	0.096	0.286	-1.75	-0.91	0
Pain Relief (%)	47.20			73.80							

**TABLE 16 :** Statistical analysis of pain intensity and pain relief comparing the 1st hour post treatment to the 3rd hour post treatment in group 2.

	1 hour post treatment			3 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	1.33	0.65	0.11	0.49	0.59	0.01	0.001	0.530	0.64	1.05	0
Pain Intensity (%)	33.25			12.25							
Pain Relief (0-5)	2.54	0.85	0.14	3.49	0.64	0.11	0.001	0.517	-1.20	-0.68	0
Pain Relief (%)	50.80			69.80							

**TABLE 17 :**     Statistical analysis of pain intensity and pain relief comparing the 1st hour post treatment to the 4th hour post treatment in group 1.

	1 hour post treatment			4 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	1.39	0.91	0.15	0.34	0.54	0.09	0.209	-0.218	0.65	1.44	0
Pain Intensity (%)	34.75			8.50							
Pain Relief (0-5)	2.36	1.21	0.20	3.46	0.95	0.16	0.975	-0.005	-1.63	-0.57	0
Pain Relief (%)	47.20			69.20							

**TABLE 18 :**     Statistical analysis of pain intensity and pain relief comparing the 1st hour post treatment to the 4th hour post treatment in group 2.

	1 hour post treatment			4 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	1.33	0.65	0.11	0.37	0.51	0.09	0.001	0.534	0.76	1.15	0
Pain Intensity (%)	33.25			9.25							
Pain Relief (0-5)	2.54	0.85	0.14	3.46	0.95	0.16	0.160	-0.243	-1.40	-0.43	0
Pain Relief (%)	50.80			69.20							

**TABLE 19 :** Statistical analysis of pain intensity and pain relief comparing the 1st hour post treatment to the 24th hour post treatment in group 1.

	1 hour post treatment			24 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	1.39	0.91	0.15	1.63	0.60	0.10	0.436	0.136	-0.59	0.11	0.167
Pain Intensity (%)	34.75			40.75							
Pain Relief (0-5)	2.36	1.21	0.20	1.64	1.00	0.17	0.082	0.298	0.26	1.17	0.003
Pain Relief (%)	47.20			32.80							

**TABLE 20 :** Statistical analysis of pain intensity and pain relief comparing the 1st hour post treatment to the 24th hour post treatment in group 2.

	1 hour post treatment			24 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	1.33	0.65	0.11	0.36	0.39	0.07	0.450	0.798	0.71	1.23	0
Pain Intensity (%)	33.25			9.00							
Pain Relief (0-5)	2.54	0.85	0.14	3.64	0.41	0.07	0.250	0.380	-1.37	-0.83	0
Pain Relief (%)	50.80			72.80							

**TABLE 21 :** Statistical analysis of pain intensity and pain relief comparing the 2nd hour post treatment to the 3rd hour post treatment in group 1.

	2 hours post treatment			3 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.25	0.44	0.07	0.17	0.38	0.06	0	0.600	-0.04	0.21	0.183
Pain Intensity (%)	6.25			4.25							
Pain Relief (0-5)	3.60	0.69	0.12	3.67	0.76	0.13	0	0.704	-0.28	0.11	0.373
Pain Relief (%)	72.00			73.40							

**TABLE 22 :** Statistical analysis of pain intensity and pain relief comparing the 2nd hour post treatment to the 3rd hour post treatment in group 2.

	2 hours post treatment			3 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.63	0.57	0.10	0.49	0.59	0.10	0	0.770	0.01	0.28	0.039
Pain Intensity (%)	15.75			12.25							
Pain Relief (0-5)	3.19	0.88	0.15	3.49	0.64	0.11	0	0.568	-0.55	-0.05	0.022
Pain Relief (%)	63.80			69.80							

**TABLE 23 :** Statistical analysis of pain intensity and pain relief comparing the 2nd hour post treatment to the 4th hour post treatment in group 1.

	2 hours post treatment			4 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.26	0.44	0.07	0.34	0.54	0.09	0.173	0.235	-0.30	0.12	0.413
Pain Intensity (%)	6.50			8.50							
Pain Relief (0-5)	3.60	0.69	0.12	3.46	0.95	0.16	0.027	0.374	-0.18	0.47	0.377
Pain Relief (%)	72.00			69.20							

**TABLE 24 :** Statistical analysis of pain intensity and pain relief comparing the 2nd hour post treatment to the 4th hour post treatment in group 2.

	2 hours post treatment			4 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.63	0.57	0.1.	0.37	0.51	0.09	0	0.694	0.11	0.40	0.001
Pain Intensity (%)	15.75			9.52							
Pain Relief (0-5)	3.19	0.88	0.15	3.60	0.55	0.09	0	0.503	-0.38	-0.15	0.003
Pain Relief (%)	63.80			72.00							



**TABLE 25 :**     Statistical analysis of pain intensity and pain relief comparing the 2nd hour post treatment to the 24th hour post treatment in group 1.

	2 hours post treatment			24 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.26	0.44	0.07	1.63	0.60	0.10	0.828	0.038	-1.62	-1.12	0
Pain Intensity (%)	6.50			40.75							
Pain Relief (0-5)	3.60	0.69	0.12	1.64	1.00	0.17	0.221	0.212	1.58	2.33	0
Pain Relief (%)	72.00			32.80							

**TABLE 26 :**     Statistical analysis of pain intensity and pain relief comparing the 2nd hour post treatment to the 24th hour post treatment in group 2.

	2 hours post treatment			24 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.63	0.57	0.10	0.36	0.39	0.07	0.394	0.149	0.05	0.49	0.018
Pain Intensity (%)	15.75			9.00							
Pain Relief (0-5)	3.19	0.88	0.15	3.64	0.41	0.07	0.003	0.490	-0.72	-0.19	0.001
Pain Relief (%)	63.80			72.80							



**TABLE 27 :** Statistical analysis of pain intensity and pain relief comparing the 3rd hour post treatment to the 4th hour post treatment in group 1.

	3 hours post treatment			4 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.17	0.38	0.06	0.34	0.54	0.09	0	0.705	-0.30	-0.04	0.012
Pain Intensity (%)	4.25			8.50							
Pain Relief (0-5)	3.69	0.76	0.13	3.46	0.95	0.16	0	0.736	0.01	0.45	0.044
Pain Relief (%)	73.80			69.20							

**TABLE 28 :** Statistical analysis of pain intensity and pain relief comparing the 3rd hour post treatment to the 4th hour post treatment in group 2.

	3 hours post treatment			4 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.49	0.59	0.10	0.37	0.51	0.09	0	0.762	-0.02	0.25	0.088
Pain Intensity (%)	12.25			9.25							
Pain Relief (0-5)	3.49	0.64	0.11	3.60	0.55	0.09	0	0.882	-0.22	-0.01	0.030
Pain Relief (%)	69.80			72.00							

**TABLE 29 :** Statistical analysis of pain intensity and pain relief comparing the 3rd hour post treatment to the 24th hour post treatment in group 1.

	3 hours post treatment			24 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.17	0.38	0.06	1.63	0.60	0.10	0.095	0.286	-1.67	-1.25	0
Pain Intensity (%)	4.25			40.75							
Pain Relief (0-5)	3.69	0.76	0.13	1.64	1.00	0.17	0.038	0.353	1.69	2.39	0
Pain Relief (%)	73.80			32.80							

**TABLE 30 :** Statistical analysis of pain intensity and pain relief comparing the 3rd hour post treatment to the 24th hour post treatment in group 2.

	3 hours post treatment			24 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.49	0.59	0.10	0.36	0.39	0.07	0.219	0.213	-0.09	0.35	0.239
Pain Intensity (%)	12.25			9.00							
Pain Relief (0-5)	3.49	0.64	0.18	3.64	0.41	0.07	0.239	0.204	-0.39	0.08	0.183
Pain Relief (%)	69.20			72.80							

**TABLE 31 :** Statistical analysis of pain intensity and pain relief comparing the 4th hour post treatment to the 24th hour post treatment in group 1.

	4 hours post treatment			24 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.34	0.54	0.09	1.63	0.60	0.10	0.015	0.406	-1.50	-1.07	0
Pain Intensity (%)	8.50			40.75							
Pain Relief (0-5)	3.46	0.95	0.16	1.64	1.00	0.17	0.004	0.473	1.47	2.16	0
Pain Relief (%)	69.20			32.80							

**TABLE 32 :** Statistical analysis of pain intensity and pain relief comparing the 4th hour post treatment to the 24th hour post treatment in group 2.

	4 hours post treatment			24 hours post treatment					Confidence Interval		
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	P-value	Corr.	Low	Up	P-value
Pain Intensity (0-4)	0.37	0.51	0.09	0.36	0.39	0.07	0.022	0.385	-0.16	0.19	0.869
Pain Intensity (%)	9.25			9.00							
Pain Relief (0-5)	3.60	0.55	0.09	3.64	0.41	0.07	0.910	0.290	-0.24	0.16	0.668
Pain Relief (%)	72.00			72.80							

#### 4.4.2. OBJECTIVE DATA

**TABLE 33 :** Statistical analysis of objective findings comparing consultation 1 and follow up 1 in Group 1.

	Consult 1			Follow up 1					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	P-value
Flex	36.00	6.79	1.15	35.77	6.76	1.14	0	0.962	-0.41	0.87	0.473
Ext	55.74	10.36	1.75	55.20	10.83	1.83	0	0.980	-0.21	1.29	0.151
R.Rot	63.60	8.11	1.37	62.77	7.90	1.34	0	0.979	0.25	1.40	0.006
L.Rot	64.54	8.45	1.43	63.83	7.55	1.28	0	0.956	-0.15	1.58	0.104
R. LF	38.29	6.90	1.17	37.97	6.49	1.10	0	0.944	-0.47	1.09	0.419
L. LF	37.89	6.69	1.13	37.54	6.34	1.07	0	0.958	-0.31	1.00	0.295
Alg	1.94	0.56	0.10	1.78	0.51	0.09	0	0.927	0.09	0.24	0

**TABLE 34 :** Statistical analysis of objective findings comparing consultation 1 and follow up 1 in Group 2.

	Consult 1			Follow up 1					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	P-value
Flex	34.49	9.33	1.58	39.09	8.33	1.41	0	0.902	-5.98	-3.22	0
Ext	50.37	11.09	1.87	56.77	10.10	1.71	0	0.814	-8.64	-4.16	0
R.Rot	59.23	11.35	1.92	66.06	9.82	1.66	0	0.929	-8.29	-5.37	0
L.Rot	58.40	11.50	1.94	66.49	10.65	1.80	0	0.891	-9.88	-6.29	0
R. LF	35.23	6.75	1.14	40.83	5.81	0.98	0	0.690	-7.32	-3.88	0
L. LF	35.31	5.94	1.00	41.89	5.29	0.89	0	0.620	-8.26	-4.88	0
Alg	1.55	0.62	0.10	2.16	0.71	0.12	0	0.912	-0.71	-0.51	0

**TABLE 35 :** Statistical analysis of objective findings comparing consultation 1 and consultation 2 in Group 1.

	Consult 1			Consult 2					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	P-value
<b>Flex</b>	36.00	6.79	1.15	36.57	5.67	0.96	0	0.924	-1.49	0.34	0.212
<b>Ext</b>	55.74	10.36	1.75	55.34	10.32	1.74	0	0.980	-0.32	1.12	0.265
<b>R.Rot</b>	63.60	8.11	1.37	62.26	7.60	1.28	0	0.948	0.45	0.03	0.004
<b>L.Rot</b>	64.54	8.45	1.43	63.00	7.31	1.24	0	0.963	0.71	0.37	0.001
<b>R. LF</b>	38.89	6.90	1.17	38.66	6.37	1.08	0	0.907	-1.37	0.63	0.454
<b>L. LF</b>	37.89	6.69	1.13	37.51	6.71	1.13	0	0.960	-0.28	1.02	0.254

**TABLE 36 :** Statistical analysis of objective findings comparing consultation 1 and consultation 2 in Group 2.

	Consult 1			Consult 2					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	P-value
<b>Flex</b>	34.49	9.33	1.58	37.23	8.35	1.41	0	0.924	-3.97	-1.51	0
<b>Ext</b>	50.37	11.09	1.87	54.91	9.42	1.59	0	0.864	-6.46	-2.62	0
<b>R.Rot</b>	59.23	11.35	1.92	62.77	8.77	1.48	0	0.944	-5.00	-2.09	0
<b>L.Rot</b>	58.40	11.50	1.94	63.77	11.10	1.88	0	0.833	-7.62	-3.12	0
<b>R. LF</b>	35.23	6.75	1.14	39.60	5.77	0.98	0	0.683	-6.11	-2.63	0
<b>L. LF</b>	35.31	5.94	1.00	40.00	5.75	0.98	0	0.766	-6.06	-3.31	0
<b>Alg</b>	1.55	0.62	0.10	1.90	0.52	0.09	0	0.852	-0.46	-0.24	0

**TABLE 37 :** Statistical analysis of objective findings comparing consultation 1 and follow up 2 in Group 1.

	Consult 1			Follow up 2					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	P-value
Flex	36.00	6.79	1.15	36.11	6.13	1.04	0	0.906	-1.10	0.87	0.815
Ext	55.74	10.36	1.75	55.06	10.60	1.79	0	0.970	-0.20	1.57	0.126
R.Rot	63.60	8.11	1.37	61.31	8.12	1.37	0	0.931	1.25	3.32	0
L.Rot	64.54	8.45	1.43	62.63	7.46	1.26	0	0.939	0.91	2.92	0
R. LF	38.29	6.90	1.17	38.11	6.25	1.06	0	0.910	-0.81	1.15	0.725
L. LF	37.89	6.69	1.13	37.17	6.55	1.11	0	0.929	-0.14	1.57	0.099
Alg	1.94	0.56	0.10	1.70	0.48	0.08	0	0.919	0.16	0.31	0

**TABLE 38 :** Statistical analysis of objective findings comparing consultation 1 and follow up 2 in Group 2.

	Consult 1			Follow up 2					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	P-value
Flex	34.49	9.33	1.58	41.26	7.71	1.30	0	0.822	-8.60	-4.94	0
Ext	50.37	11.09	1.87	59.80	8.75	1.48	0	0.799	-7.14	-8.37	0
R.Rot	59.23	11.35	1.92	70.40	6.74	1.14	0	0.854	-13.44	-8.90	0
L.Rot	58.40	11.50	1.94	71.09	8.37	1.41	0	0.779	-15.17	-10.20	0
R. LF	35.23	6.75	1.14	45.57	4.56	0.77	0	0.490	-12.41	-8.28	0
L. LF	35.31	5.93	1.00	46.20	4.65	0.79	0	0.489	-12.76	-9.01	0
Alg	1.55	0.62	0.04	2.42	0.61	0.10	0	0.788	-1.01	-0.74	0



**TABLE 39 :** Statistical analysis of objective findings comparing follow up 1 and consultation 2 in Group 1.

	Follow up 1			Consult 2					Confidence Interval		P-value
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	
<b>Flex</b>	35.77	6.76	1.14	36.57	5.67	0.96	0	0.943	-1.61	0.01	0.053
<b>Ext</b>	55.20	10.83	1.83	55.34	10.32	1.74	0	0.973	-1.00	0.72	0.737
<b>R.Rot</b>	62.77	7.90	1.34	62.26	7.60	1.28	0	0.963	-0.21	1.24	0.160
<b>L.Rot</b>	63.83	7.55	1.28	63.00	7.31	1.24	0	0.944	0.03	1.68	0.057
<b>R. LF</b>	37.97	6.49	1.10	38.66	6.37	1.08	0	0.921	-1.56	0.19	0.121
<b>L. LF</b>	37.54	6.34	1.07	37.51	6.71	1.13	0	0.968	-0.55	0.61	0.921
<b>Alg</b>	1.78	0.51	0.09	1.78	0.49	0.08	0	0.964	-0.05	0.04	0.803

**TABLE 40 :** Statistical analysis of objective findings comparing follow up 1 and consultation 2 in Group 2.

	Follow up 1			Consult 2					Confidence Interval		P-value
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	
<b>Flex</b>	39.09	8.33	1.41	37.23	8.35	1.41	0	0.969	1.14	2.57	0
<b>Ext</b>	56.77	10.10	1.71	54.91	9.42	1.59	0	0.920	0.50	3.22	0.009
<b>R.Rot</b>	66.06	9.82	1.66	62.77	8.77	1.48	0	0.928	2.02	4.55	0
<b>L.Rot</b>	66.49	10.65	1.80	63.77	11.01	1.88	0	0.901	1.04	4.38	0.002
<b>R. LF</b>	40.83	5.81	0.98	39.60	5.77	0.98	0	0.704	-0.30	2.76	0.112
<b>L. LF</b>	41.89	5.29	0.89	40.00	5.75	0.97	0	0.697	0.40	3.37	0.014
<b>Alg</b>	2.16	0.71	0.12	1.90	0.52	0.09	0	0.870	0.14	0.38	0



**TABLE 41 :** Statistical analysis of objective findings comparing follow up 1 and follow up 2 in Group 1.

	Follow up 1			Follow up 2					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	P-value
<b>Flex</b>	35.77	6.76	1.14	36.11	6.13	1.31	0	0.950	-1.07	0.39	0.347
<b>Ext</b>	55.20	10.83	1.83	55.06	10.60	1.79	0	0.981	-0.58	0.87	0.690
<b>R.Rot</b>	62.77	7.90	1.34	61.31	8.17	1.37	0	0.953	0.61	2.30	0.001
<b>L.Rot</b>	63.83	7.55	1.28	62.63	7.46	1.26	0	0.927	0.21	2.19	0.018
<b>R. LF</b>	37.97	6.49	1.10	38.11	6.25	1.06	0	0.932	-0.95	0.67	0.722
<b>L. LF</b>	37.54	6.34	1.07	37.17	6.56	1.11	0	0.957	-0.28	1.02	0.254
<b>Alg</b>	1.78	0.51	0.09	1.70	0.48	0.08	0	0.967	0.03	0.12	0.002

**TABLE 42 :** Statistical analysis of objective findings comparing follow up 1 and follow up 2 in Group 2.

	Follow up 1			Follow up 2					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Low	Up	P-value
<b>Flex</b>	39.09	8.33	1.41	41.26	7.71	1.30	0	0.925	-3.26	-1.08	0
<b>Ext</b>	56.77	10.10	1.71	59.80	8.75	1.48	0	0.882	-4.66	-1.39	0.001
<b>R.Rot</b>	66.06	9.82	1.66	70.40	6.74	1.14	0	0.865	-6.14	-2.55	0
<b>L.Rot</b>	66.49	10.65	1.80	71.09	8.37	1.41	0	0.819	-6.70	-2.50	0
<b>R. LF</b>	40.83	5.81	0.98	45.57	4.56	0.77	0	0.643	-6.30	-3.19	0
<b>L. LF</b>	41.89	5.29	0.89	46.2	4.65	0.79	0	0.598	-5.86	-2.77	0
<b>Alg</b>	2.16	0.70	0.12	2.42	0.61	0.10	0	0.858	-0.39	-0.14	0

**TABLE 43 :** Statistical analysis of objective findings comparing consultation 2 and follow up 2 in Group 1.

	Consult 2			Follow up 2					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Lower	Upper	P-value
Flex	36.57	5.67	0.96	36.11	6.13	1.04	0	0.976	-0.02	0.93	0.058
Ext	55.34	10.32	1.74	55.06	10.60	1.79	0	0.992	-0.18	0.75	0.223
R.Rot	62.26	7.60	1.28	61.31	8.12	1.37	0	0.965	0.21	1.67	0.013
L.Rot	63.00	7.31	1.24	62.63	7.65	1.26	0	0.975	-0.19	0.94	0.191
R. LF	38.66	6.37	1.08	38.11	6.25	1.06	0	0.976	0.06	1.02	0.028
L. LF	37.51	6.71	1.13	37.17	6.56	1.11	0	0.984	-0.07	0.76	0.103
Alg	1.78	0.49	0.08	1.70	0.48	0.08	0	0.984	0.05	0.11	0

**TABLE 44 :** Statistical analysis of objective findings comparing consultation 2 and follow up 2 in Group 2.

	Consult 2			Follow up 2					Confidence Interval		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	Corr	Lower	Upper	P-value
Flex	37.23	8.35	1.41	41.26	7.71	1.30	0	0.923	-5.14	-2.92	0
Ext	54.91	9.42	1.59	59.80	8.75	1.48	0	0.913	-3.57	-7.53	0
R.Rot	62.77	8.77	1.48	70.40	6.74	1.14	0	0.858	-9.20	-6.06	0
L.Rot	63.77	11.10	1.88	71.09	8.37	1.41	0	0.841	-9.40	-5.23	0
R. LF	39.60	5.77	0.98	45.57	4.56	0.77	0	0.654	-7.50	-4.45	0
L. LF	40.00	5.75	0.97	46.02	4.65	0.79	0	0.666	-7.70	-4.70	0
Alg	1.90	0.52	0.09	2.42	0.67	0.10	0	0.946	-0.59	-0.45	0

#### 4.5. INTER-GROUP DATA

##### 4.5.1. SUBJECTIVE DATA

**TABLE 45 :** Statistical results of the subjective findings comparing consultation 1 of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
McGill (0-45)	16.40	6.41	1.08	16.31	6.52	1.10	0.549	0.956	-3.00	3.32
McGill (%)	36.44			36.24						
NRS 101	40.29	9.89	1.67	40.23	13.39	2.26	0.221	0.984	-5.56	5.67
CMCC (0-50)	15.40	5.18	0.88	18.23	7.23	1.22	0.035	0.065	-5.83	0.17
CMCC (%)	30.80			36.46						

\*note:- % values calculated as  $\frac{\text{raw score}}{\text{total}} \times 100$

**TABLE 46 :** Statistical results of the subjective findings comparing follow up 1 of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
McGill (0-45)	14.89	6.23	1.05	6.34	5.11	0.86	0.368	0	5.83	11.26
McGill (%)	33.09			14.09						
NRS 101	39.13	10.11	2.20	25.36	13.01	2.20	0.189	0	8.21	19.33
CMCC (0-50)	15.09	4.33	0.73	11.86	6.18	1.04	0.014	0.014	0.68	5.78
CMCC (%)	30.18			23.72						

**TABLE 47 :**     Statistical results of the subjective findings comparing consultation 2 of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
McGill (0-45)	15.77	6.29	1.06	11.71	5.20	0.88	0.82	0.004	1.31	6.81
McGill (%)	35.04			26.02						
NRS 101	39.57	10.08	1.70	31.50	10.58	1.79	1.00	0.002	3.14	13.00
CMCC (0-50)	15.20	4.48	0.76	15.41	6.30	1.08	0.048	0.873	-2.85	2.43
CMCC (%)	30.40			30.82						

**TABLE 48 :**     Statistical results of the subjective findings comparing follow up 2 of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
McGill (0-45)	14.20	7.34	1.24	1.91	2.34	0.40	0	0	9.65	14.91
McGill (%)	31.56			4.24						
NRS 101	37.64	10.93	1.85	11.43	10.54	1.78	0.319	0	21.09	31.34
CMCC (0-50)	14.83	4.58	0.77	7.11	5.05	0.85	0.439	0	5.41	10.01
CMCC (%)	29.66			14.22						

**TABLE 49 :** Statistical results of the subjective findings 1 hour post treatment of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
Pain intensity (0-4)	1.39	0.91	0.15	1.33	0.65	0.11	0.016	0.763	-0.32	0.44
Pain Intensity (%)	34.75			33.25						
Pain relief (0-5)	2.54	0.85	0.14	2.54	0.85	0.14	0.012	0.461	-0.69	0.31
Pain Relief (%)	50.80			50.80						

\*note:- % values calculated as  $\frac{\text{raw score}}{\text{total}} \times 100$

**TABLE 50 :** Statistical results of the subjective findings 2 hours post treatment of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
Pain intensity (0-4)	0.26	0.44	0.08	0.63	0.58	0.10	0.079	0.003	-0.62	-0.13
Pain Intensity (%)	6.50			15.75						
Pain relief (0-5)	3.60	0.70	0.12	3.19	0.89	0.15	0.477	0.033	0.04	0.79
Pain Relief (%)	72.00			63.80						

**TABLE 51 :** Statistical results of the subjective findings 3 hours post treatment of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
Pain intensity (0-4)	0.17	0.38	0.07	0.49	0.59	0.10	0.011	0.01	-0.55	-0.08
Pain Intensity (%)	4.25			12.25						
Pain relief (0-5)	3.69	0.76	0.13	3.49	0.64	0.11	0.884	0.236	-0.13	0.53
Pain Relief (%)	73.80			69.80						

**TABLE 52 :** Statistical results of the subjective findings 4 hour post treatment of both Group 1 and Group 2.

	Group 1			Group 2			Levene s Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
Pain intensity (0-4)	0.34	0.54	0.09	0.37	0.50	0.09	0.311	0.820	-0.28	0.22
Pain Intensity (%)	8.50			9.25						
Pain relief (0-5)	3.46	0.95	0.16	3.60	0.55	0.09	0.008	0.445	-0.51	0.22
Pain Relief (%)	69.20			72.00						

**TABLE 53 :** Statistical results of the subjective findings 24 hours post treatment of both Group 1 and Group 2.

	Group 1			Group 2			Levene's Test	Equality of means		
	Mean	S.D	S.E	Mean	S.D	S.E	P-value	P-value	Lower C.I	Upper C.I
Pain intensity (0-4)	1.63	0.60	0.10	0.36	0.39	0.07	0.002	0	1.03	1.51
Pain Intensity (%)	40.75			9.00						
Pain relief (0-5)	1.64	1.00	0.17	3.64	0.41	0.07	0	0	-2.37	-1.63
Pain Relief (%)	32.80			72.80						

#### 4.5.2. OBJECTIVE DATA

**TABLE 54 :** Statistical results of objective findings comparing consultation 1 of both Group 1 and Group 2.

	Group 1			Group 2			Levene Test	Equality of means		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	P-value	Lower C.I.	Upper C.I.
Flex	36.00	6.97	1.15	34.45	9.34	1.58	0.424	0.440	-2.38	5.41
Ext	55.74	10.36	1.75	50.37	11.09	1.87	0.680	0.040	0.25	10.49
R.Rot	63.60	8.11	1.37	59.23	11.35	1.92	0.138	0.068	-0.33	9.08
L.Rot	64.54	8.45	1.43	58.40	11.50	1.94	0.077	0.013	1.33	10.86
R. LF	38.29	6.90	1.17	35.23	6.75	1.14	0.398	0.065	-0.20	6.31
L. LF	37.89	6.69	1.13	35.31	5.94	1.00	0.737	0.093	-0.44	5.59
Alg	1.94	0.56	0.10	1.55	0.62	0.10	0.672	0.008	0.11	0.67

**TABLE 55 :** Statistical results of objective findings comparing follow up 1 of both Group 1 and Group 2.

Group 1				Group 2			Levene Test	Equality of means		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	P-value	Lower C.I.	Upper C.I.
<b>Flex</b>	35.77	6.76	1.14	39.09	8.33	1.41	0.916	0.072	-6.93	0.30
<b>Ext</b>	55.20	10.83	1.83	56.77	10.10	1.71	0.829	0.532	-6.57	3.42
<b>R.Rot</b>	62.77	7.09	1.34	66.06	9.83	1.66	0.330	0.128	-7.54	0.97
<b>L.Rot</b>	63.83	7.55	1.28	66.49	10.65	1.80	0.058	0.233	-7.06	1.75
<b>R. LF</b>	37.97	6.49	1.10	40.83	5.81	0.98	0.399	0.057	-5.80	0.08
<b>L. LF</b>	37.54	6.34	1.07	41.89	5.29	0.89	0.242	0.003	-7.13	-1.56
<b>Alg</b>	1.78	0.51	0.09	2.16	0.71	0.12	0.307	0.012	-0.67	-0.09

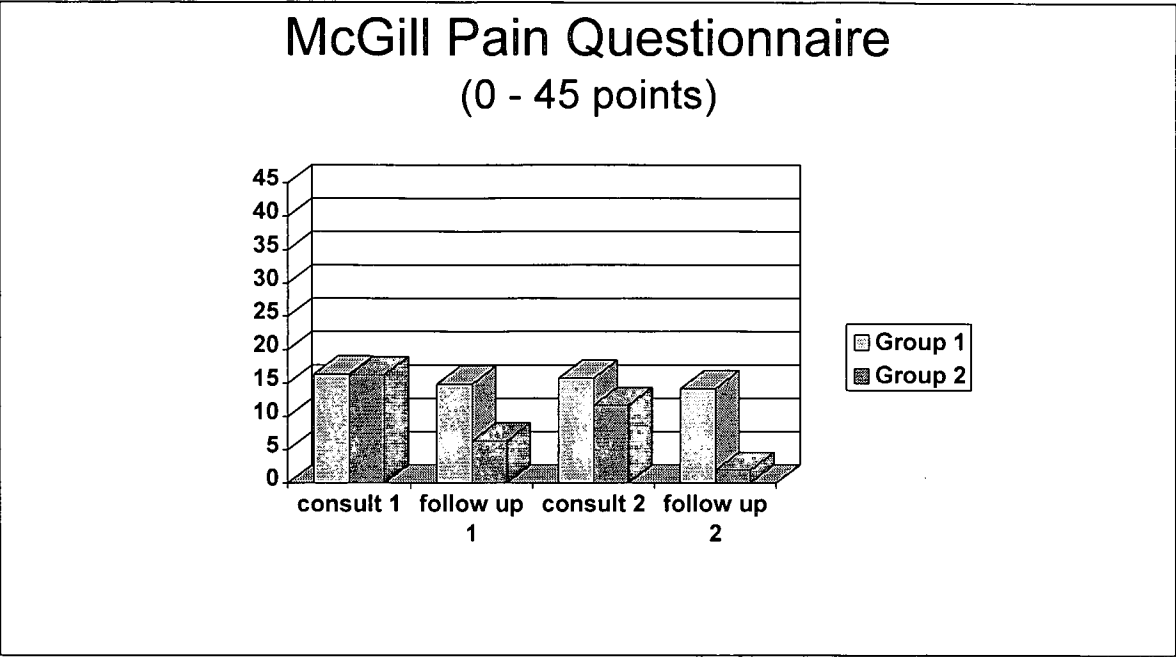
**TABLE 56 :** Statistical results of objective findings comparing consultation 2 of both Group 1 and Group 2.

Group 1				Group 2			Levene Test	Equality of means		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	P-value	Lower C.I.	Upper C.I.
<b>Flex</b>	36.57	5.67	0.96	37.23	8.35	1.41	0.485	0.701	-4.06	2.75
<b>Ext</b>	55.34	10.32	1.74	54.91	9.42	1.59	0.665	0.857	-4.28	5.14
<b>R.Rot</b>	62.26	7.60	1.28	62.77	8.77	1.48	0.580	0.794	-4.28	3.40
<b>L.Rot</b>	63.00	7.31	1.24	63.77	11.1	1.88	0.038	0.733	-5.27	3.73
<b>R. LF</b>	38.66	6.37	1.08	39.60	5.77	0.98	0.622	0.518	-3.84	1.96
<b>L. LF</b>	37.51	6.71	1.13	40.00	5.76	0.97	0.392	0.110	-5.47	0.50
<b>Alg</b>	1.78	0.49	0.08	1.90	0.52	0.09	0.774	0.338	-0.36	0.12

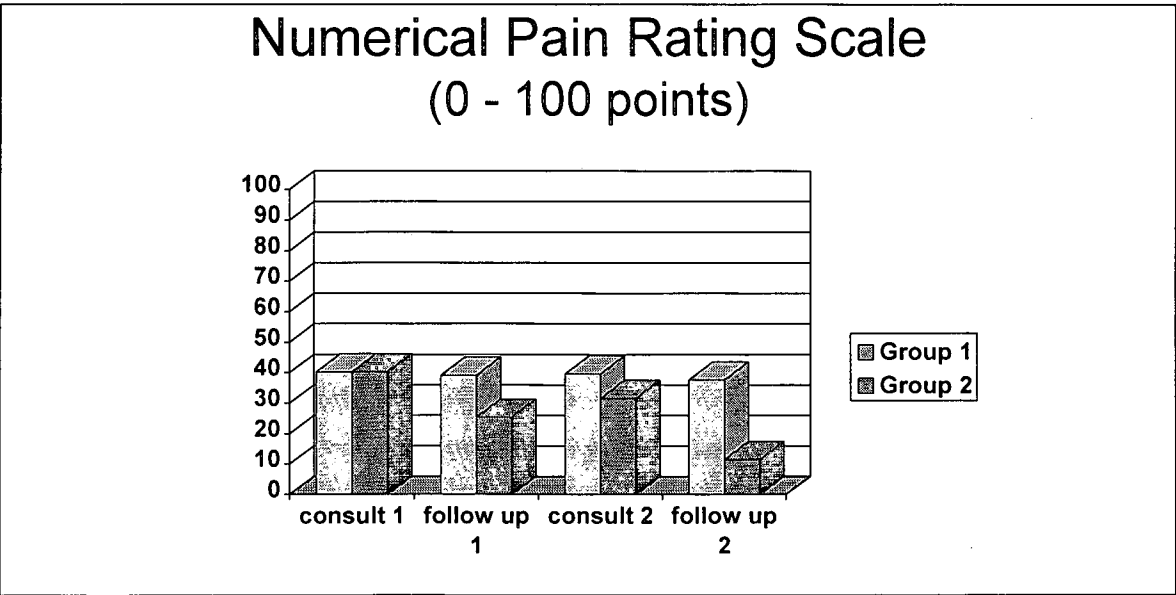


**TABLE 57 :** Statistical results of objective findings comparing follow up 2 of both Group 1 and Group 2.

Group 1				Group 2			Levene Test	Equality of means		
	Mean	S.D.	S.E.	Mean	S.D	S.E.	P-value	P-value	Lower C.I.	Upper C.I.
<b>Flex</b>	36.11	6.13	1.04	41.26	7.71	1.30	0.945	0.003	-8.46	-1.82
<b>Ext</b>	55.06	10.60	1.79	59.80	8.75	1.48	0.508	0.045	-9.38	-0.11
<b>R.Rot</b>	61.31	8.12	1.37	70.40	6.74	1.14	0.076	0	-12.64	-5.53
<b>L.Rot</b>	62.63	7.46	1.26	71.09	8.37	1.41	0.835	0	-12.24	-4.68
<b>R. LF</b>	38.11	6.25	1.06	45.57	4.56	0.77	0.022	0	-10.07	-4.85
<b>L. LF</b>	37.17	6.56	1.11	46.20	4.65	0.79	0.032	0	-11.74	-6.31
<b>Alg</b>	1.70	0.48	0.08	2.42	0.61	0.10	0.348	0	-0.98	-0.46

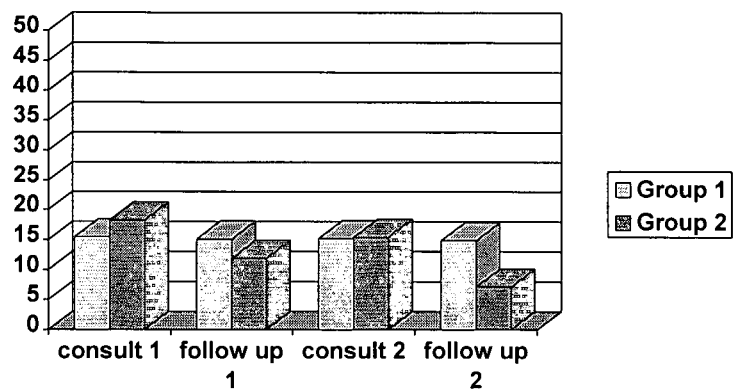


GRAPH 1



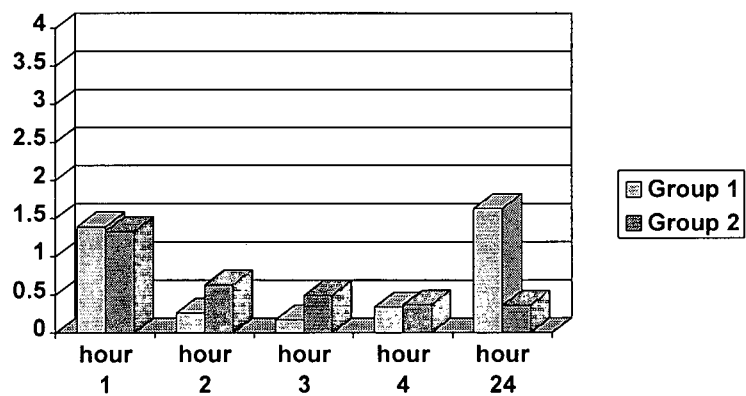
GRAPH 2

## CMCC Neck Disability Index ( 0 - 50 points)

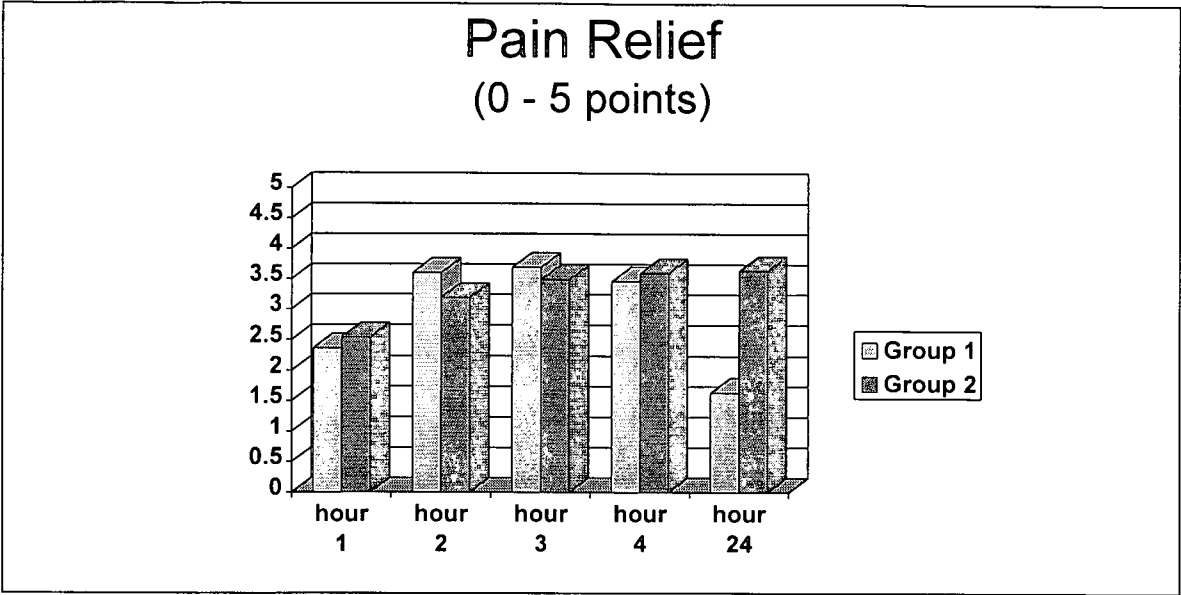


GRAPH 3

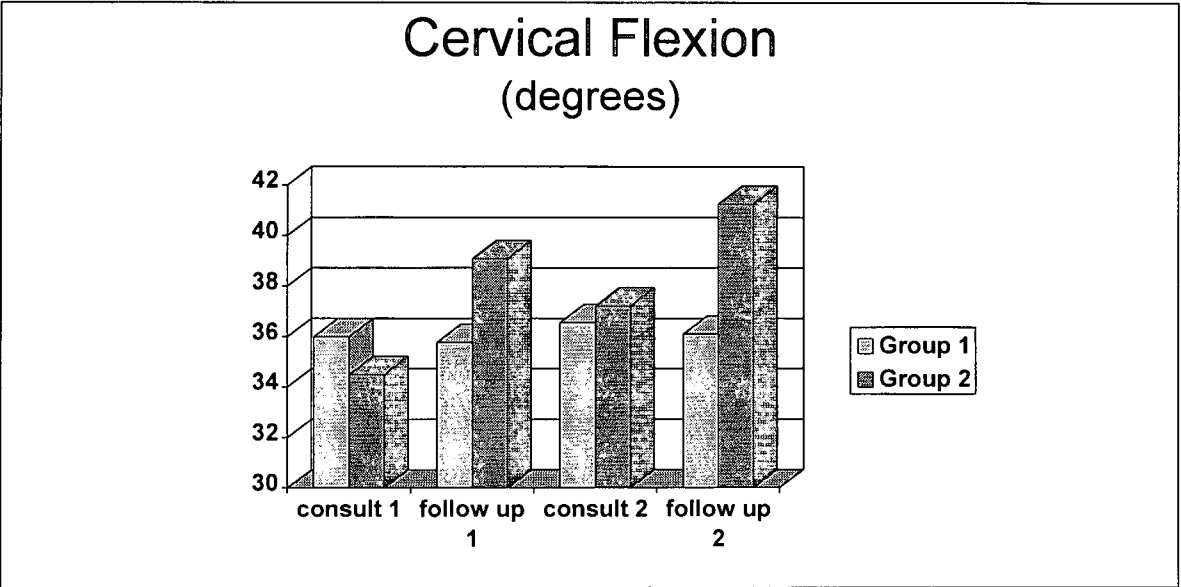
## Pain Intensity ( 0 - 4 points)



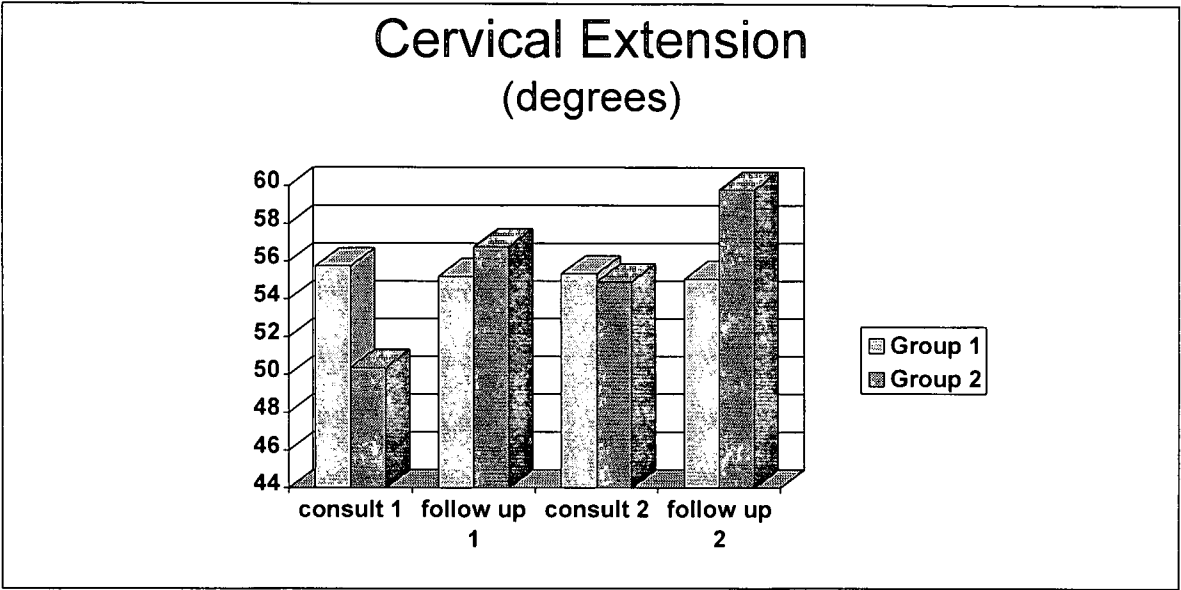
GRAPH 4



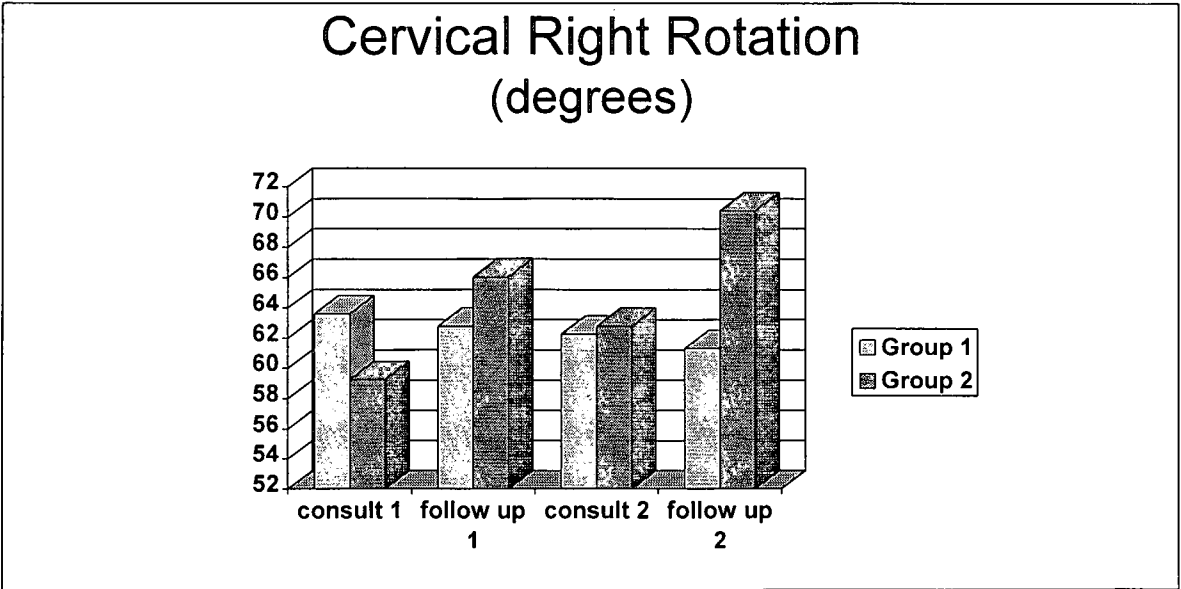
GRAPH 5



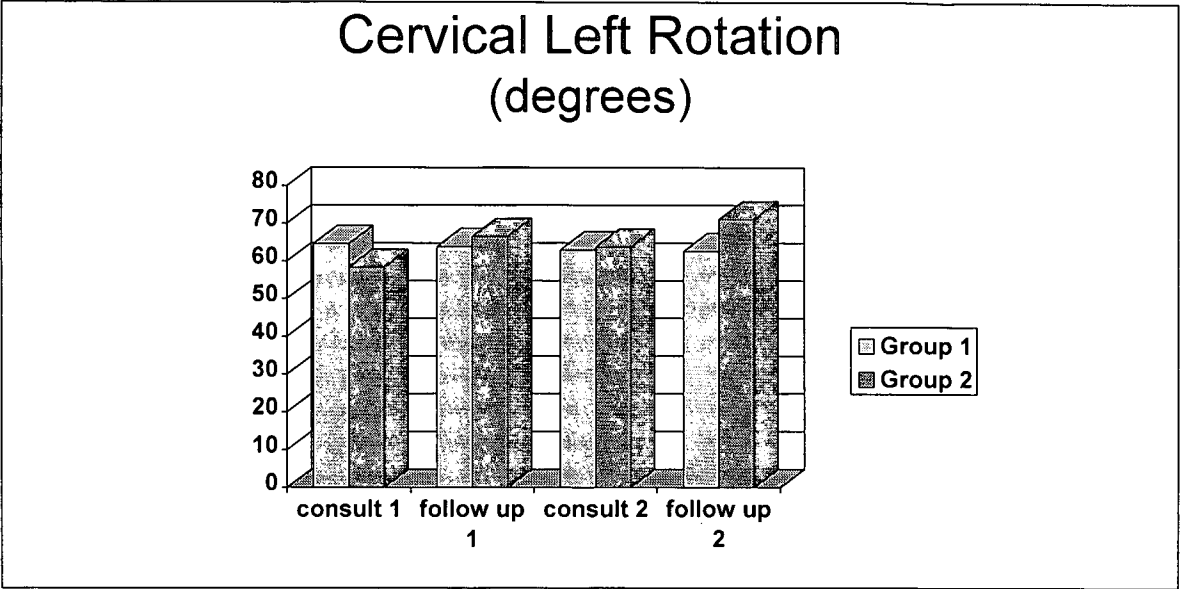
GRAPH 6



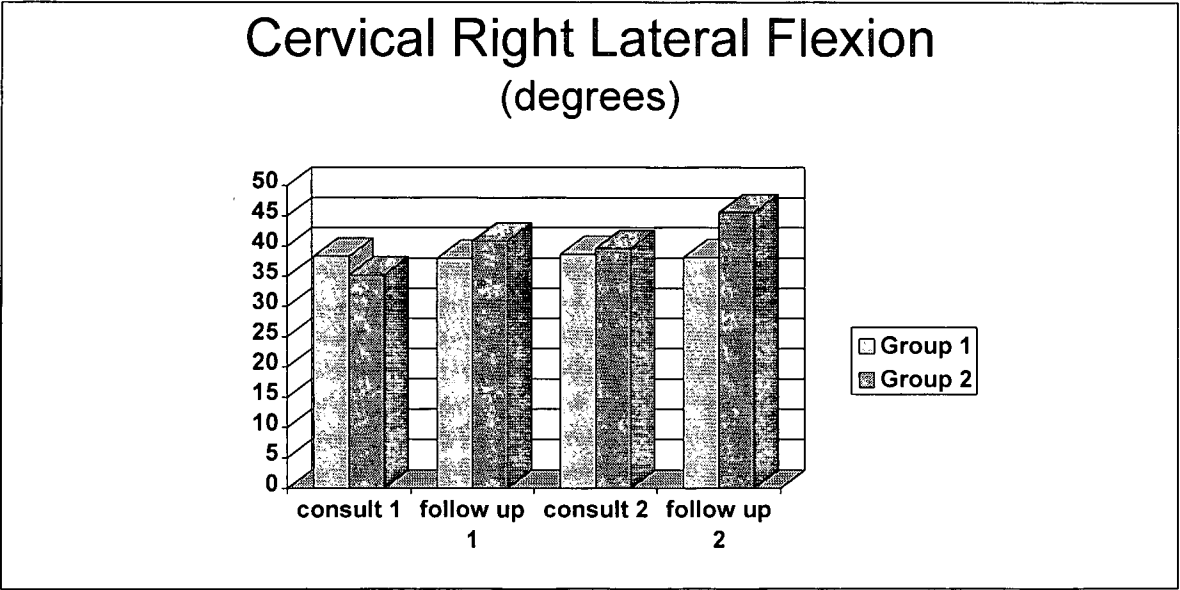
GRAPH 7



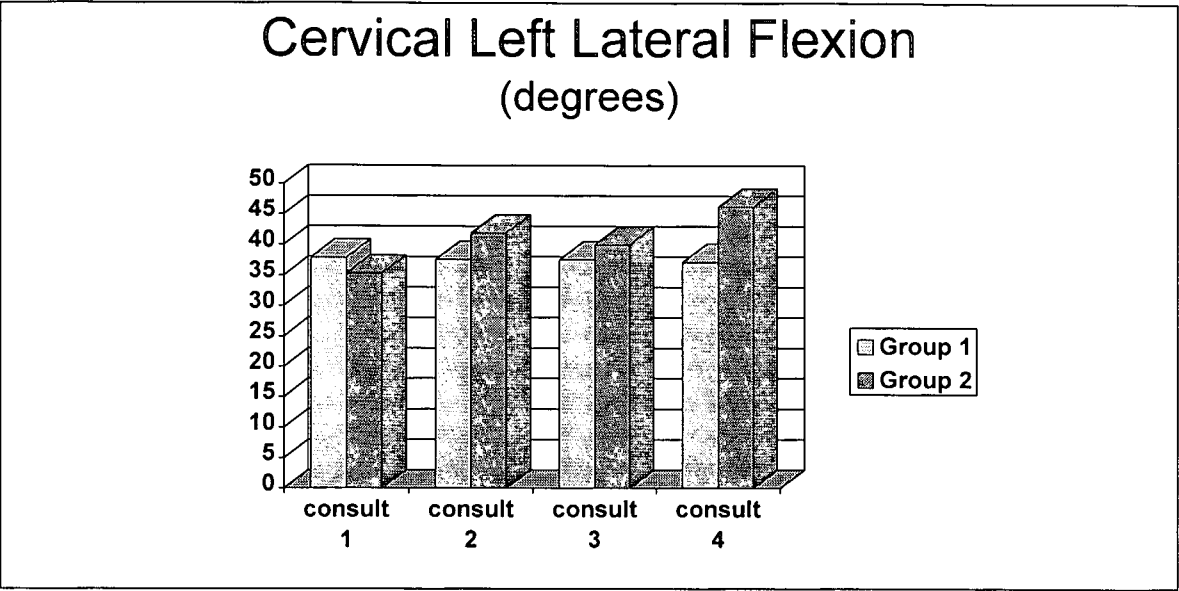
GRAPH 8



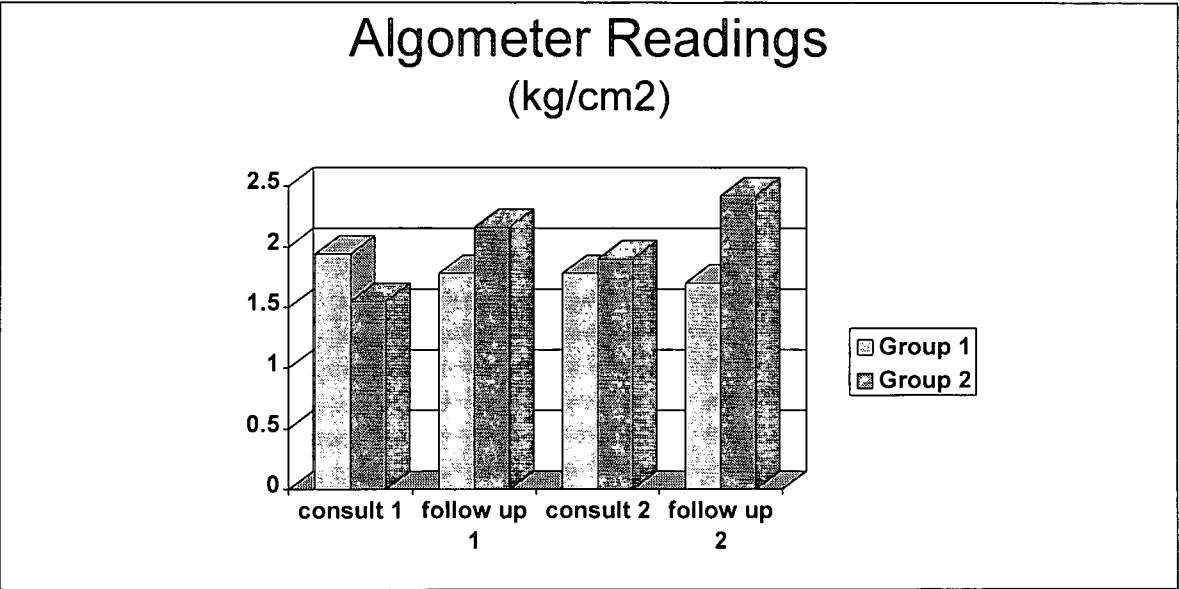
GRAPH 9



GRAPH 10



GRAPH 11



GRAPH 12

#### 4.6. CONCLUSION

The data included in this chapter was collected during the course of the study and represents the subjective and objective measurements for both intra-group and inter-group comparisons. The data has been statistically analyzed by parametric methods using SPSS and Statgraphics software packages.



## **CHAPTER 5**

### **DISCUSSION**

#### **5.1 INTRODUCTION**

This chapter focuses on three main areas of analysis, namely demographic data analysis, subjective data analysis, and objective data analysis. Analysis of both the subjective and objective data includes intra-group comparisons as well as inter-group comparisons. The results of this study are then compared to published research in this area to determine if this study compares favourably or not with the documented trends in tension-type headache research.

The subjective data consisted of McGill, Numerical Rating Scale 101 (NRS) Canadian Memorial Chiropractic College (CMCC) Neck Disability Index and Pain Ordinal Scales (pain intensity and pain relief). The data was analyzed at the alpha ( $\alpha$ ) = 0.05 level of significance with  $H_0$  as the null hypothesis and  $H_1$  as the alternative hypothesis.

#### **5.2 Demographic data**

Ninety-seven people applied to be part of the study, of whom only 72 were accepted. Patients were excluded for the following reasons:- 11 subjects had sustained trauma to the cervical spine, 2 women were pregnant, 8 subjects did not fit within the stipulated age bracket, 1 woman was breastfeeding, and 3 subjects never arrived for their initial consultation. Group 1 was allocated 37 subjects and Group 2 was allocated 35 subjects. During the study only 2 people were excluded for non-compliance.

The age range of Group 1 was 19 - 47 years with a mean of 31.5 years whilst the range for Group 2 was 20 - 62 years with a mean of 31.8 years. The groups are considered similar and comparable with regards to age, and this strengthens the statistical results obtained from the study.

The male to female ratio revealed that 54.05% of Group 1 were female whereas 62.86% of Group 2 were female. The small male to female ratio in Group 1 as compared to Group 2 may affect the inter-group analysis to some degree. Both these ratios, however, confirm the hypothesis that tension-type headaches are more prevalent in females (Cypress 1981 : Wong et al. 1995).

The most common headache pain description in Group 1 was that of a "tight band", followed by "dull ache" and "pressure". Group 2 differed slightly, with the most common pain description of "dull ache" followed equally by "tight band" and "pressure". Pain descriptions of this nature were listed by Raskin (1988:215) as almost diagnostic of a tension-type headache. The International Headache Society Classification (1988) also mentions similar descriptive terms in it's definition of tension-type headache.

Headache duration in both groups ranged from 1 hour up to 24 hours. The majority of patients in Group 1 experienced their headaches for a minimum of 3 hours and a maximum of 6 hours. Patients in Group 2 indicated that their headaches generally lasted for a minimum of 1 to 3 hours, and a maximum of 4

to 6 hours. The duration of the headaches in Group 1 showed definite maximums and minimums, whereas the data from Group 2 was more evenly spread. This may also have an influence on the inter-group analysis.

Headache frequency between the groups was comparable with the majority of patients in both Group 1 and Group 2 experiencing a tension-type headache at least once to twice a week. Headache location differed slightly between the groups with the majority of patients in Group 1 complaining more of a temporal headache and the majority of Group 2 complaining more of an occipital headache. Most of these locations were in combination, often with the patient stating they had pain both over the temporal and occipital regions.

The most common level of fixation in both Group 1 and Group 2 was C2, followed by C1 and C3. Fixations at C0 and C3 were also noted, with very few fixations at C5, C6 and C7. The thoracic spine was not examined in this study. Dysfunction of the upper cervical spine was noted by Bogduk (1992) and Vernon (1992), and the results of this study confirm the role of the upper cervical spine in the mechanism of tension-type headache. The researcher was aware of this postulated relationship and may have been biased during the palpation and examination of the cervical spine. It is not known whether the results of the most common levels of fixation would have been different if the researcher had been blinded, either to the presenting complaint or to the possible relationship with the mechanism of tension-type headache. A study with a suitably blinded examiner would prove useful in examining the possible role of the upper cervical spine in

the mechanism of tension-type headache.

### **5.3. SUBJECTIVE DATA**

#### **5.3.1. Intra-group analysis**

##### **5.3.1.1. Subproblem 1**

Subproblem 1 is to determine the effectiveness of 1 000mg acetaminophen combined with 130mg caffeine in the treatment of tension-type headache in terms of subjective findings.

#### **McGill, NRS and CMCC**

Analysis of the paired sample correlation's indicated a positive correlation ( $p < \alpha$  and  $r > 0$ ) for all comparisons. Comparison of consultation 1 to follow up 1 (table 1) indicated no statistically significant difference for NRS and CMCC scores ( $p > \alpha$ ) thus  $H_0$  is accepted. However, a statistically significant improvement of 3.36% was noted for McGill ( $p < \alpha$ ) thus  $H_0$  is rejected and  $H_1$  is accepted. The initial consultation was thus able to reduce the headache symptoms, but had no effect on pain perception or neck disability.

Comparison of consultation 1 to consultation 2 (table 3) revealed no statistically significant difference ( $p > \alpha$ ) for all three questionnaires, indicating that there was no lasting or carryover effect between consultations thus  $H_0$  is accepted.

Comparison of consultation 1 to follow up 2 (table 5) indicated a statistically

significant difference in the McGill data ( $p < \alpha$ ), thus  $H_0$  is rejected and  $H_1$  is accepted. This 4.89% improvement was possibly due to the compound effect of two consultations or the extended time interval from consultation 1 to follow up 2. There was no significant difference in the score for NRS or CMCC ( $p > \alpha$ ) thus  $H_0$  is accepted

Comparison of follow up 1 to consultation 2 (table 7) indicated no statistically significant difference for NRS or CMCC ( $p > \alpha$ ) thus  $H_0$  is accepted. However, the McGill scores showed a 1.96% decrease ( $p < \alpha$ ) indicating an increase in headache symptoms, thus  $H_0$  is rejected and  $H_1$  is accepted. This was expected as the patients were instructed to return for a second consultation at the onset of renewed tension-type headache discomfort. These changes however, were not reflected in the NRS or CMCC data.

Comparison of follow up 1 to follow up 2 (table 9) revealed no statistically significant difference for the scores of all three questionnaires ( $p > \alpha$ ) thus  $H_0$  is accepted. This indicates that the status of the patient for these three subjective measures was similar following either consultation 1 or consultation 2.

Comparison of consultation 2 to follow up 2 (table 11) revealed no statistically significant difference for CMCC scores ( $p > \alpha$ ) thus  $H_0$  is accepted. However, the data for both McGill and NRS demonstrated significant differences ( $p < \alpha$ ), with McGill improving by 3.49% and NRS improving by 1.93%.  $H_0$  is thus rejected

and H1 is accepted for both questionnaires. This indicates that the second consultation produced benefits similar to the first consultation.

### Summary

There was no statistically significant differences recorded for CMCC scores for Group 1, indicating that the acetaminophen-caffeine combination offered no benefit in respect of neck disability. The only benefit noted for NRS scores was an improvement of 1.93% following two consultations. However, the McGill scores showed an improvement in headache symptoms of 3.36% after consultation 1 and 3.49% after consultation 2. No carryover or lasting effect was noted between follow up 1 and consultation 2.

### Pain Ordinal Scales

A statistically significant reduction in pain intensity was recorded for 1 hour post treatment compared to hours 2, 3 and 4 ( $p < \alpha$ ) (tables 13, 15, 17) thus  $H_0$  is rejected and H1 is accepted. At hour 24 (table 19), the recorded pain intensity value was higher than at hour 1, but this difference was not statistically significant ( $p > \alpha$ ). A similar significant increase in pain relief was noted from hour 1 compared to hours 2, 3, and 4 (tables 13, 15, 17) thus  $H_0$  is rejected, but by hour 24 (table 19) a significant loss of pain relief ( $p < \alpha$ ) was noted to levels worse than those recorded at hour 1. Hour 2 through hour 4 (tables 21 and 23) revealed no statistically significant difference for both pain intensity and pain relief ( $p > \alpha$ ) thus  $H_0$  is accepted although a slight loss of benefit was noted

between hour 2 and hour 4. Comparison of hour 2 to hour 24, revealed a statistically significant increase in pain intensity and a statistically significant decrease in pain relief ( $p < \alpha$ ). Comparison of hour 3 to hour 4 (table 27) and hour 3 to hour 24 (table 29) showed a statistically significant loss of benefit ( $p < \alpha$ ), thus  $H_0$  is rejected and  $H_1$  is accepted. Comparison of hour 4 to hour 24 ( table 31) yielded similar results (  $p < \alpha$ ).

### Summary

The degree of pain intensity at hour 1 was recorded as 34.75%, which reduced significantly by 28.25% at hour 2 to 6.50% and remained at this level with minor variations until hour 4 when the pain intensity increased by 2.00% to 8.50%.

However, by hour 24, pain intensity had returned to and even exceeded levels recorded at hour 1. The pain relief data followed similar trends with the 24 hour recordings indicating no lasting benefit. It would appear therefore, that a single treatment as offered to Group 1 provided a temporary, short term benefit in pain management which was lost 24 hours post treatment. The increased pain recorded between hour 1 and hour 24 could be due to benefits realized, but not recorded between hour 0 and hour 1 thereby artificially lowering the "baseline level" of hour 1.

#### **5.3.1.2. Subproblem 2**

Subproblem 2 is to determine the effectiveness of cervical manipulation in the treatment of tension-type headache in terms of subjective findings.

Analysis of the paired sample correlation's indicated a positive correlation ( $p < \alpha$  and  $r > 0$ ) for comparisons of consultation 1 to follow up 1 and follow up 2, follow up 1 to consultation 2 and follow up 2, but not to comparisons of consultation 1 to follow up 2 and consultation 2 to follow up 2 ( $p > \alpha$  and  $r > 0$ ).

### McGill, NRS and CMCC

Comparison of consultation 1 to follow up 1 (table 2) indicated a statistically significant improvement for all three questionnaire scores therefore  $H_0$  is rejected and  $H_1$  is accepted. McGill improved by 22.16%, NRS by 14.87% and CMCC by 12.74%. This data confirms that manipulation provided considerable benefits over 24 hours for all these criteria.

Comparison of consultation 1 to consultation 2 (table 4) again showed statistically significant improvements ( $p < \alpha$ ) in respect of all three questionnaires.  $H_0$  is thus rejected and  $H_1$  is accepted. McGill recorded an improvement of 10.22%, NRS of 8.73%, and CMCC of 5.72%. These benefits were less than recorded for comparison of consultation 1 and follow up 1, but nevertheless indicate a carryover effect of this treatment.

Comparison of consultation 1 to follow up 2 (table 6) revealed statistically significant improvements for all three questionnaires ( $p < \alpha$ ) thus  $H_0$  is rejected and  $H_1$  is accepted. McGill improved by 32.00%, NRS by 28.8% and CMCC by 22.24%, reinforcing the concept of extended carryover and lasting effects.

Comparison of follow up 1 to consultation 2 (table 8) showed a significant



regression ( $p < \alpha$ ) in values for McGill of 11.93%, NRS 6.41% and CMCC 7.40%.  $H_0$  is thus rejected and  $H_1$  is accepted. This data indicates that some loss of benefit did occur between follow up 1 and consultation 2, but some residual benefit remained when compared to the initial consultation.

Comparison of follow up 1 to follow up 2 (table 10) reflected a statistically significant improvement ( $p < \alpha$ ) for all questionnaire scores, with McGill improving by 9.84%, NRS by 13.93% and CMCC by 8.96%.  $H_0$  is thus rejected and  $H_1$  is accepted. This result would indicate a compound benefit of two manipulations in the treatment of tension-type headache symptoms.

Comparison of consultation 2 to follow up 2 (table 12) again, reflected a significant improvement for all three questionnaire scores ( $p < \alpha$ ) with McGill improving by 21.78%, NRS by 20.07%, and CMCC by 18.56%.  $H_0$  is thus rejected and  $H_1$  is accepted.

### Summary

The initial treatment provided a marked improvement with respect to McGill, NRS and CMCC scores. This improvement extended through to the second consultation, indicating a carryover effect even though there was a small degree of reversion of symptoms. The second consultation induced further improvements compared to the initial consultation. It is possible that multiple manipulations may result in further improvements in the control of tension-type headache and associated symptoms.

### Pain Ordinal Scales

A statistically significant reduction in pain intensity ( $p < \alpha$ ) and an increase in pain relief ( $p < \alpha$ ) was recorded for hour 1 compared to hours 2,3,4 and 24 (tables 14, 16, 18 and 20).  $H_0$  is thus rejected and  $H_1$  is accepted. This data indicates a measurable and sustained relief from headache symptoms following cervical manipulation. Comparison of hour 2 to hour 3, 4 and 24 (tables 22, 24 and 26), revealed a statistically significant reduction in pain intensity ( $p < \alpha$ ) and increase in pain relief ( $p < \alpha$ ) for this time period, thus  $H_0$  is again rejected. Comparison of hour 3 to hours 4 and 24 ( tables 28 and 30) revealed further small reductions in pain intensity, but these were not statistically significant ( $p > \alpha$ ). The pain relief scale showed similar small improvements with the hour 3 to hour 4 comparison being statistically different ( $p < \alpha$ ), thus  $H_0$  is rejected. Comparison of hour 4 to 24 (table 32) revealed minor improvements in both pain intensity and pain relief although these were not statistically significant ( $p > \alpha$ ).

### Summary

The pain intensity as recorded at hour 1 was 33.25% which reduced significantly by 17.50% to 15.75% at hour 2 and continued to show significant reductions up to and including hour 4 to 9.25% and then stabilized at 9.00% by hour 24. The pain relief data followed similar trends, with the most significant improvement occurring between hours 1 and 2 where the pain relief scores improved by 13.00% from 50.80% to 63.80%. By hour 24 the pain relief had further improved by 9.00% to 72.80%. These sustained improvements indicate considerable

benefit for tension-type headache and associated symptoms following manipulative treatment.

### **5.3.2. Inter-group analysis**

#### **5.3.2.1. Subproblem 3**

Subproblem 3 is to determine the effectiveness of 1 000mg acetaminophen combined with 130mg caffeine as opposed to cervical manipulation in the treatment of tension-type headache in terms of subjective findings.

#### **McGill, NRS and CMCC**

Comparison of Group 1 and Group 2 for consultation 1 (table 45) indicated no statistically significant difference between groups ( $p > \alpha$ ), thus  $H_0$  is accepted. This indicates that both groups are comparable in respect of McGill (power = 0.05), NRS (power = 0.05) and CMCC (power = 0.46) questionnaires, thereby providing a suitable baseline for future comparisons.

Comparison of the groups for follow up 1 (table 46) indicated a statistically significant difference between groups ( $p < \alpha$ ), thus  $H_0$  is rejected and  $H_1$  is accepted. Manipulation provided superior improvements for McGill of 19.00% (power = 1.00), NRS 13.77% (power = 1.00) and CMCC 6.46% (power = 0.70). This data strongly suggests that manipulation provided significant relief with regards to tension-type headache and associated symptoms within a twenty-four hour period, compared to the acetaminophen-caffeine combination.

Comparison of Group 1 and Group 2 for consultation 2 (table 47) revealed statistically significant improvements ( $p < \alpha$ ) in favour of Group 2 with McGill scores differing by 9.02% (power = 0.83) and NRS by 8.07% (power = 0.90). CMCC values were not statistically significantly different ( $p > \alpha$ ) (power = 0.05). This further substantiates the benefits of manipulation over medication.

Comparison of the groups for follow up 2 (table 48) indicated statistically significant improvements for Group 2 over Group 1 for all measurements ( $p < \alpha$ ), thus  $H_0$  is rejected and  $H_1$  is accepted. McGill scores differed by 27.31% (power = 1.00), NRS by 26.21% (power = 1.00) and CMCC by 15.44% (power = 1.00). This data strongly reinforces the extended subjective benefits of manipulation over medication.

#### Pain Ordinal Scales

Comparison of the groups at 1 hour post consultation (table 49) showed no statistically significant difference ( $p > \alpha$ ) in respect of pain intensity (power = 0.06) or pain relief (power = 0.11), thus  $H_0$  is accepted.

Comparison of the groups at 2 hours post consultation (table 50) revealed a statistically significant difference in benefit ( $p < \alpha$ ) in favor of Group 1 in terms of pain intensity and pain relief, thus  $H_0$  is rejected and  $H_1$  is accepted. Group 1 showed a decreased pain intensity of 9.25% (power = 0.85) with an increased pain relief of 8.20% (power = 0.57) when compared to Group 2. This data

indicates an early benefit of acetaminophen combined with caffeine compared to manipulation.

Three hours post consultation, the positive trend in favour of Group 1 continued with a further significant difference ( $p < \alpha$ ) of 8.00% for pain intensity (power = 0.74) and 4.00% for pain relief (power = 0.21), thus  $H_0$  is rejected. However, the differential between groups at this stage was rapidly diminishing.

Four hours post consultation, no statistically significant difference could be established ( $p > \alpha$ ) between the groups in respect of pain intensity (power 0.56) or pain relief (power 0.11). This indicates that the initial benefits of medication seen in the first two hours was negated within 4 hours post treatment.

Twenty-four hour post consultation comparisons of Group 1 and Group 2 revealed statistically significant differences in favour of Group 2 ( $p < \alpha$ ), thus  $H_0$  is rejected and  $H_1$  is accepted. The difference in pain intensity was 31.75% (power 1.00) and the difference in pain relief was 40.00% (power 1.00) in favour of manipulation. This final comparison confirms the extended benefits in tension-type headache management by means of manipulation compared to the acetaminophen-caffeine combination.

## **5.4. OBJECTIVE DATA**

### **5.4.1. Intra-group analysis**

#### **5.4.1.1. Subproblem 1**

Subproblem 1 is to determine the effectiveness of 1 000mg acetaminophen combined with 130mg caffeine in the treatment of tension-type headache in terms of objective findings.

Consultation 1 compared to follow up 1 (table 33) showed a statistically significant reduction of  $0.83^{\circ}$  for right rotation ( $p < \alpha$ ), thus  $H_0$  is rejected and  $H_1$  is accepted. There was no statistically significant difference for all other range of motion measurements ( $p > \alpha$ ). In addition, a statistically significant reduction in algometer measurements was recorded with an average decrease of  $0.16 \text{ kg/cm}^2$ , thus  $H_0$  is rejected.

Consultation 1 compared to consultation 2 (table 35) showed no statistically significant difference for flexion, extension, or lateral flexion ( $p > \alpha$ ) thus  $H_0$  is accepted. A statistically significant reduction in rotation was noticed ( $p < \alpha$ ) with a decrease of  $1.34^{\circ}$  to the right and  $1.54^{\circ}$  to the left.  $H_0$  is thus rejected and  $H_1$  is accepted. However, minor reductions ( $p > \alpha$ ) of  $0.40^{\circ}$  for extension,  $0.23^{\circ}$  for right lateral flexion and  $0.38^{\circ}$  for left lateral flexion were also recorded.

Algometer readings revealed a statistically significant decrease ( $p > \alpha$ ) of  $0.16 \text{ kg/cm}^2$ , thus  $H_0$  is rejected and  $H_1$  is accepted.

Comparison of consultation 1 to follow up 2 (table 37) indicated no statistically

significant differences for flexion or extension ( $p > \alpha$ ), thus  $H_0$  is accepted. Right rotation showed a significant decrease of  $2.29^\circ$  ( $p < \alpha$ ) with left rotation revealing ( $p < \alpha$ ) a 95% confidence interval that contains 0 as an element of the set, indicating a degree of variance within the results. This anomaly also occurred within the lateral flexion results with left lateral flexion indicating no significant difference ( $p > \alpha$ ) and right lateral flexion a statistically indeterminate improvement of  $0.18^\circ$ . Algometer readings again reduced significantly ( $p < \alpha$ ) by  $0.24 \text{ kg/cm}^2$ , thus  $H_0$  is rejected and  $H_1$  is accepted.

Comparison of follow up 1 to consultation 2 (table 39) indicated no statistically significant differences for flexion, extension, right rotation and lateral flexion ( $p > \alpha$ ). However, a conflicting response was noted for left rotation. A minor increase ( $p > \alpha$ ) in range of motion for flexion, extension and right lateral flexion was recorded with a similar minor decrease in values for right rotation and left lateral flexion. Similar algometer readings were recorded between follow up 1 and consultation 2 ( $p > \alpha$ ), thus  $H_0$  is accepted.

Comparison of follow up 1 to follow up 2 (table 41) indicated no statistically significant differences for flexion, extension and lateral flexion ( $p > \alpha$ ) thus  $H_0$  is accepted. Both right and left rotation values revealed significant differences ( $p < \alpha$ ) of  $1.46^\circ$  and  $1.20^\circ$  respectively, thus  $H_0$  is rejected and  $H_1$  is accepted. Algometer readings also indicated a significant decrease of  $0.08 \text{ kg/cm}^2$  ( $p < \alpha$ ) thus  $H_0$  is rejected and  $H_1$  is accepted.

Comparison of consultation 2 to follow up 2 (table 43) indicated no significant difference ( $p > \alpha$ ) for flexion and extension readings. However, for both right rotation and right lateral flexion there was a significant loss of movement ( $p < \alpha$ ) of  $0.95^\circ$  and  $0.55^\circ$  respectively, whereas loss of movement for left rotation and left lateral flexion was noted, but this was not statistically significant ( $p > \alpha$ ). The algometer readings were significantly reduced ( $p < \alpha$ ) by  $0.08 \text{ kg/cm}^2$ , thus  $H_0$  is rejected and  $H_1$  is accepted.

### Summary

Overall, application of the medication failed to achieve significant improvement in the range of motion measurements, with significant decreases in rotational ability. Flexion, extension and lateral flexion revealed minor reductions in range of motion, but none of these changes were statistically significant. Algometer readings indicated continued increased sensitivity for all comparisons except between follow up 1 and consultation 2. It would appear therefore, that this treatment failed to achieve a lasting measurable benefit to the patient.

#### **5.4.1.2. Subproblem 2**

Subproblem 2 is to determine the effectiveness of cervical manipulation in the treatment of tension-type headache in terms of objective findings.

Comparison of consultation 1 to follow up 1 (table 34) indicated a statistically significant improvement ( $p < \alpha$ ) for all range of motion and algometer



measurements, thus  $H_0$  is rejected and  $H_1$  is accepted. The improvements ranged from  $4.6^\circ$  for flexion up to  $8.09^\circ$  for left rotation. Algometer readings improved by  $0.61 \text{ kg/cm}^2$ .

Comparison of consultation 1 to consultation 2 (table 36) again revealed significant improvements for all recorded measurements ( $p < \alpha$ ), thus  $H_0$  is rejected. These improvements ranged from  $2.74^\circ$  for flexion to  $5.37^\circ$  for left rotation. Algometer readings improved by  $0.35 \text{ kg/cm}^2$ .

Comparison of consultation 1 to follow up 2 (table 38) again confirmed the benefit of this treatment as all measurements revealed a statistically significant improvement ( $p < \alpha$ ), thus  $H_0$  is rejected and  $H_1$  is accepted. These improvements ranged from  $6.77^\circ$  for flexion and  $12.69^\circ$  for left rotation. Algometer readings improved by a significant  $0.87 \text{ kg/cm}^2$ .

Comparison of follow up 1 to consultation 2 (table 40) indicated a statistically significant loss of benefit for all measurements ( $p < \alpha$ ) except for right lateral flexion. Algometer readings however, indicated further significant improvement ( $p < \alpha$ ) of  $0.26 \text{ kg/cm}^2$ . This discrepancy may indicate a lack of correlation between pressure sensitivity readings and range of motion.

Comparison of follow up 1 to follow up 2 (table 42) indicated statistically significant improvements for all measurements ( $p < \alpha$ ), thus  $H_0$  is rejected and

H1 is accepted. These benefits ranged from 2.17° for flexion up to 4.74° for right lateral flexion. Algometer readings showed an increase of 0.26 kg/cm<sup>2</sup> ( $p < \alpha$ ).

Comparison of consultation 2 to follow up 2 (table 44) revealed continuing significant improvements for all measurements ( $p < \alpha$ ) thus  $H_0$  is rejected and  $H_1$  is accepted. Flexion improved by 4.03° whilst right rotation improved by 7.63°. The algometer readings again showed significant improvements ( $p < \alpha$ ) of an average 0.52 kg/cm<sup>2</sup>.

### Summary

Following the initial consultation and manipulation, a statistically significant improvement was noted for all range of motion and algometer measurements. These improvements demonstrated a lasting carryover effect which was further improved by a second manipulation.

## **5.4.2. Inter-group analysis**

### **5.4.2.1. Subproblem 3**

Subproblem 3 is to determine the effectiveness of 1 000mg acetaminophen combined with 130mg caffeine as opposed to cervical manipulation in the treatment of tension-type headache in terms of objective findings.

Comparison of Group 1 and Group 2 for consultation 1 (table 54) revealed no statistically significant difference ( $p > \alpha$ ) between groups in respect of flexion

(power = 0.12), right rotation (power = 0.44), right lateral flexion (power = 0.45) and left lateral flexion (power = 0.38). There was however, a statistically significant difference ( $p < \alpha$ ) between groups for extension ( $5.37^\circ$  and power = 0.54), and left rotation ( $6.41^\circ$  and power = 0.71), both of which favoured Group 1. The algometer measurements also revealed a statistically significant difference ( $p < \alpha$ ) of 0.39kg/cm<sup>2</sup> in favour of Group 1, thus  $H_0$  is rejected (power = 0.77).

Comparison of groups for follow up 1 (table 55) showed no statistically significant differences ( $p > \alpha$ ) for all range of motions, thus  $H_0$  is accepted. Power values for each range of motion were as follows:- flexion 0.43, extension 0.09, right rotation 0.33, left rotation 0.22, right lateral flexion 0.48, left lateral flexion 0.87. The algometer measurements were statistically significant in favor of Group 2 ( $p > \alpha$ ), with a differential of 0.38 kg/cm<sup>2</sup> (power = 0.72), thus  $H_0$  is rejected and  $H_1$  is accepted.

Comparison of Group 1 and Group 2 for consultation 2 (table 56) again revealed no statistically significant differences for any range of motion measurements and algometer readings ( $p > \alpha$ ), thus  $H_0$  is accepted. The power values for the respective measurements were as follows:- flexion 0.07, extension 0.05, right rotation 0.06, left rotation 0.06, right lateral flexion 0.10, left lateral flexion 0.37, and algometer 0.16. This data is consistent with the data obtained from follow up 1.

Comparison of the groups for follow up 2 (table 57) indicated statistically significant improvement ( $p < \alpha$ ) in all range of motion measurements in favor of

Group 2, thus  $H_0$  is rejected and  $H_1$  is accepted. The individual improvements were as follows:- flexion  $5.15^\circ$  (power = 0.05), extension  $4.74^\circ$  (power = 0.52), right rotation  $9.09^\circ$  (power = 1.00), left rotation  $8.46^\circ$  (power = 0.99), right lateral flexion  $7.46^\circ$  (power = 1.00), and left lateral flexion  $9.03^\circ$  (power 1.00).

Algometer readings were also statistically significant ( $p < \alpha$ ) in favour of Group 2 with a differential of  $0.72\text{kg/cm}^2$ , thus  $H_0$  is rejected and  $H_1$  is accepted.

### Summary

The results of follow up 1 indicated no statistically significant differences between Group 1 and Group 2. This is in contrast to the data generated from the subjective analysis, where Group 2 clearly demonstrated significant improvements. However, by follow up 2, both subjective and objective data indicated consistent benefits in favor of Group 2.

### **5.5 . PROBLEMS ENCOUNTERED WITH THE SUBJECTIVE AND OBJECTIVE DATA**

Very few problems were encountered during the course of the study. Two patients were excluded from the study for non-compliance, and those that remained were compliant in completing the Pain Intensity and Pain Relief Ordinal Scales, as well as adhering to the treatment protocol and schedule. The main problem that was experienced was that patients in the medication group often requested manipulation which, according to the protocol, had to be refused. Patients involved in the study had a basic knowledge of chiropractic and were

disappointed not to receive manipulation as treatment. It was recommended to the patients who requested manipulation that they return to the Day Clinic as regular patients once the study had been completed. Most patients indicated that they would continue treatment in this manner. No problems were experienced with the subjective questionnaires as they were all completed under the supervision of the researcher, and any queries were immediately resolved. No side effects were noted by any of the patients.

#### **5.6. COMPARISON OF RESULTS OF THIS STUDY WITH PAST RESEARCH**

Patients in this current study complained of occipital, temporal and frontal pain often with a combination of location. Vernon et al. (1992) found that tension-type headache sufferers demonstrated high occurrences of occipital and neck pain during headaches as well as tender points in the cervical region which was consistent with the demographics of this study. These findings support the hypothesis that the neck plays an important role in the manifestation of headache.

Joint fixations were identified in the cervical spines of the patients involved in the current study and often more than one restriction was noted. These findings are comparable to those of Kidd et al. (1993), who found that restrictions of motion were present in more than one direction in many subjects and proposed that musculoskeletal dysfunction of the neck is a contributing factor to the etiology of tension-type headache.

Patients partaking in this current study complained of cervical and pericranial muscle tenderness and were examined for pain pressure threshold. Hyung-Suk et al. (1995) demonstrated that decreased pain pressure threshold of pericranial muscles in the neck is related to tension-type headache and noted that the patients had more occipital and frontal pain.

In this study, patients receiving medication did not demonstrate any improvements in pain pressure threshold, but patients receiving manipulation demonstrated significant lasting improvements. Vernon et al. (1990) demonstrated that manipulation produces significantly higher increases in pressure pain threshold of tender points compared to mobilization and recorded an increase in pressure pain threshold of 40 - 50% with an average increase of 45% in the group receiving manipulation which is reflected in the results of this study.

Statistical analysis of the results of this current study indicated a cumulative benefit from double manipulation on tension-type headache extending to 24 hours post treatment. These patients also demonstrated a continued decrease in pain intensity and an increase in range of motion which supports the findings of Cassidy et al. (1992a) who demonstrated that both mobilization and manipulation increased range of motion, but manipulation had a significantly greater effect on pain intensity. He demonstrated that a single manipulation was more effective than mobilization in decreasing pain. Cassidy et al. (1992b) demonstrated that

manipulation of the cervical spine had the immediate effect of increasing range of motion and decreasing pain, with the greatest effect on rotation.

All patients in both Group 1 and Group 2 of this current study returned for a second consultation on the return of headache symptoms. The patients receiving manipulation reported a general decrease in pain intensity for the second headache which was not seen in the patients receiving medication. Turk and Ratkolb (1987) demonstrated considerable relief for patients by means of manipulation which was in common with the findings of this study.

Mootz et al. (1994) conducted a small (n = 10) case series analysis of chiropractic treatment on tension-type headache and failed to demonstrate a reduction in self-reported pain intensity, although significant reductions were reported in frequency and duration of headache episodes. Unfortunately, headache frequency was not examined in this current study as the focus was on the initial 24 hour effect. In contrast however, this current study did report significant reductions in headache intensity. No side effects were reported by the manipulation group during the course of the current study which confirmed the findings of Senstad et al. (1997), who reported that it was unusual for side effects to commence later than 24 hours after spinal manipulative therapy.

The acetaminophen-caffeine combination given to Group 1 in this current study was able to induce a significant reduction in pain intensity during the 4 hours post

consultation, but these effects were not sustained. In addition, caffeine intake prior to the treatment was recorded, but not taken into account for the statistical analysis. Migliardi et al. (1994) demonstrated that caffeine-containing analgesics were significantly superior both to placebo and to 1000mg acetaminophen and 1000mg acetaminophen was significantly superior to placebo. It was noted that the greater efficacy of the caffeinated analgesic compared to the noncaffeinated analgesic was similar across all subsets of patients and was independent of their usual daily caffeine consumption.

Boline et al. (1995) compared the effectiveness of spinal manipulation to amitriptyline for the treatment of tension-type headache and demonstrated that spinal manipulative therapy is an effective treatment for tension headaches. The patients who received manipulation experienced a sustained therapeutic benefit in all major outcomes compared to the amitriptyline group who reverted to baseline values, although the amitriptyline was more effective in reducing headache symptoms during the treatment period. The trend of short term relief returning to baseline values for patients receiving medication was reflected in this current study, although the time period of observation was limited to 24 hours. The patients in Group 2 who received manipulation however, revealed a sustained benefit which can be likened to the findings of Boline et al. (1995). The results of this current study also indicated that manipulation was superior to medication in the management of tension-type headache, especially if long term relief with minimal side effects is the objective of the treatment.



## **CHAPTER 6**

### **CONCLUSIONS AND RECOMMENDATIONS**

#### **6.1. CONCLUSIONS**

##### **6.1.1. Subjective data**

Analysis of the results clearly reflects subjective benefits to the patients in Group 2 who received chiropractic cervical manipulation. These benefits were reflected in their responses to all three questionnaires as well as the pain ordinal scales. These improvements were sustained through 24 hours post consultation and there appeared to be a cumulative benefit from two consultations. In contrast, Group 1 who received an acetaminophen-caffeine combination reported no significant benefit with respect to the three questionnaires, but did report significant, rapid reductions in pain intensity which peaked at three hours post consultation, and subsequently declined to levels comparable to baseline values.

##### **6.1.2. Objective data**

Apart from minor insignificant changes, Group 1 failed to demonstrate any improvements with regards to range of motion. On the other hand, Group 2, which received manipulation, demonstrated small improvements in right and left lateral flexion, with significant improvements recorded for flexion and extension. These measurements increased after each consultation thus indicating sustained improvements. In addition, Group 2 demonstrated marked improvement in right

rotation which was not recorded for left rotation. The reason for the variance between left and right rotation measurements within this group is unknown. Pressure pain threshold showed continued improvements during the study for Group 2 whereas Group 1 showed increased sensitivity following consultations.

### **6.1.3. Final conclusions**

In conclusion, results of this study indicate that chiropractic cervical manipulation was able to provide significant subjective relief, coupled with increased range of motion and increased pressure pain threshold in patients suffering from tension-type headaches. In contrast, an acetaminophen-caffeine combination treatment failed to provide any improvements in range of motion or pressure pain sensitivity, but did provide some subjective short term relief. Manipulation would therefore be the recommended treatment of choice in the management of tension-type headache.

## **6.2. RECOMMENDATIONS**

The McGill Pain Questionnaire, Numerical Rating Scale 101 and CMCC Neck Disability Index were easy to administer and are recommended for use in future studies. The Pain Ordinal Scales were easy for the patients to understand and are also recommended for future use. However, it is recommended that an extra column be added to the Pain Ordinal Scale to be labelled Hour 0 in which the degree of pain intensity and pain relief experienced by the patient immediately after treatment is recorded.

The CROM and algometer apparatus were easy to use and no excess discomfort was reported by the patients. The combination of both subjective and objective findings in tension-type headache sufferers indicate that it is worthwhile to view these two sets of data in combination rather than separately, and this design is recommended for future investigations.

A pre-treatment evaluation of a minimum of 2 weeks is recommended to record baseline levels and to plot the natural course of the headache. A headache diary is also recommended for evaluation of long term effects of treatment as well as observation of self medication habits.

The focus of this study was on the 24 hour effect of medication compared to manipulation, thus the follow up was restricted to 24 hours post treatment. It is thus recommended that a future study possibly include a 48 hour and/or 72 hour follow up to evaluate the extent of the sustained benefit. A further month follow up would be ideal. A study comparing the possible benefits of repeat manipulations compared to continued use of over the counter medication, as a means of headache management, is recommended.

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## APPENDIX 1

### COVERING LETTER FOR PATIENTS ENTERING INTO THE STUDY.

Dear Patient

Welcome to my research study in tension headaches. I am investigating the initial effect of chiropractic treatment on tension headaches compared to medication consisting of acetaminophen 1000mg with 130mg caffeine. All treatment will be free of charge and will be conducted at the Technikon Natal Chiropractic Day Clinic. Please be assured that all information will be regarded as strictly confidential.

The group to which you have been assigned has been randomly predetermined, and the following will be required:-

- a. X-rays of your neck, only if indicated by the results of the initial exam.
- b. Treatment for 2 separate headache attacks, at least 48 hours apart. After each treatment, you will be asked to attend a follow-up evaluation. No treatment will be given at the follow-up.
- c. You will be asked to complete a questionnaire during the 4 hours following your treatment, and to return this completed questionnaire at your follow-up.
- d. No additional medication is to be taken during the duration of the study, unless the headache becomes unbearable. You will then be asked to make a note of the medication name and dosage.
- e. Please refrain from taking any pain killers 6 hours prior to the visit, and any alcoholic beverages 8 hours prior to the visit.
- f. Please also refrain from eating or drinking any foods that may contain caffeine for 4 hours after the treatment (for example:- coffee, tea, coke, chocolate)

Side-effects of manipulation may include slight feelings of muscular stiffness and side-effects of the medication may include mild gastrointestinal discomfort, insomnia and restlessness.

You will remain in the study as long as you commit to the appointment schedule. Each treatment will be followed by a 24 hour re-evaluation during which no treatment will be given. You will receive treatment for only 2 headaches with a total number of 4 consultations. For the duration of this programme you may not receive any other form of chiropractic, physiotherapy, or massage. At this point I also ask that you be truthful and as accurate as possible in your responses to all questions. There are no wrong or right answers, but your specific answers will affect the outcome of the study.

Yours sincerely  
Deborah Thomson.

## APPENDIX 2

### INFORMED CONSENT FORM

(to be completed in duplicate by patient/subject\*) \*Delete which ever is not applicable.

#### TITLE OF RESEARCH PROJECT

A RANDOMISED CLINICAL TRIAL TO COMPARE THE INITIAL EFFECTS OF ACETAMINOPHEN WITH CAFFEINE TO CERVICAL MANIPULATION IN TENSION-TYPE HEADACHE.

#### NAME OF SUPERVISOR

DR. BRIAN NOOK

#### NAME OF RESEARCH STUDENT

DEBORAH THOMSON

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? yes/no
2. Have you had opportunity to ask questions regarding this study? yes/no
3. Have you received satisfactory answers to your questions? yes/no
4. Have you had opportunity to discuss this study? yes/no
5. Have you received enough information about this study? yes/no
6. Who have you spoken to? \_\_\_\_\_
7. Do you understand the implications of your involvement in this study? yes/no
8. Do you understand that you are free to withdraw from this study? yes/no
  - a. at any time
  - b. without having to give a reason for withdrawing, and
  - c. without affecting your future health care?
9. Do you agree to voluntarily participate in this study? yes/no

PATIENT/SUBJECT\* Name: \_\_\_\_\_  
(in block letters)

Signature \_\_\_\_\_

PARENT/GUARDIAN\* Name: \_\_\_\_\_  
(in block letters)

Signature \_\_\_\_\_

WITNESS: Name: \_\_\_\_\_  
(in block letters)

Signature \_\_\_\_\_

RESEARCH STUDENT Name: Deborah Thomson

Signature \_\_\_\_\_

## APPENDIX 3

### TECHNIKON NATAL CHIROPRACTIC DAY CLINIC CASE HISTORY

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

#### FOR CLINICIAN'S USE ONLY

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

#### Case History:

##### Examination:

Previous:

Current:

##### X-Ray Studies:

Previous:

Current:

##### Clinical Path. lab:

Previous:

Current:

#### Case Status:

PTT:            Conditional:            Signed Off:            Final Sign out:

Recommendations:

#### Intern's Case History

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

3. Present Illness:

- ▶ Location
- ▶ Onset
- ▶ Duration
- ▶ Frequency
- ▶ Pain (Character)
- ▶ Progression
- ▶ Aggravating Factors
- ▶ Relieving Factors
- ▶ Associated S & S
- ▶ Previous Occurrences
- ▶ Past Treatment and Outcome

4. Other Complaints:

5. Past Medical History:

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

6. Current health status and life-style:

- ▶ Allergies
- ▶ Immunizations
- ▶ Screening Tests
- ▶ Environmental Hazards (Home, School, Work)
- ▶ Safety Measures (seat belts, condoms)
- ▶ Exercise and Leisure
- ▶ Sleep Patterns
- ▶ Diet
- ▶ Current Medication
- ▶ Tobacco
- ▶ Alcohol
- ▶ Social Drugs

7. Immediate Family Medical History:

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



8. Psychosocial history:

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

9. Review of Systems:

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

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

## PHYSICAL EXAMINATION

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

1. VITALS

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

2. GENERAL EXAMINATION

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

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

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

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

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

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

**Percussion:** - borders of heart

**Auscultation:**

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

#### **4. RESPIRATORY EXAMINATION**

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

**Inspection**

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

**Palpation**

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

**Percussion**

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

**Auscultation**

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

#### **5. ABDOMINAL EXAMINATION**

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

**Inspection**

- Shape:
- Scars:
- Hernias:

**Palpation**

- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

**Percussion** - Rebound tenderness:

- Ascites:
- Masses:

**Auscultation** - Bowel sounds:

- Arteries (aortic, renal, iliac, femoral, hepatic)

**Rectal Examination**

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

## 6. G.U.T EXAMINATION

External genitalia:

Hernias:

Masses:

Discharges:

## 7. NEUROLOGICAL EXAMINATION

**Gait and Posture**

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

**Higher Mental Function**

- Information and Vocabulary:
- Calculating ability:
- Abstract Thinking:

**G.C.S.:**

- Eyes:
- Motor:
- Verbal:

**Evidence of head trauma:**

**Evidence of Meningism:**

- Neck mobility and Brudzinski's sign:
- Kernigs sign:

**Cranial Nerves:**

**I** Any loss of smell/taste:  
Nose examination:

**II** External examination of eye:

- Visual Acuity:
- Visual fields by confrontation:

- Pupillary light reflexes      = Direct:  
   = Consensual:
- Fundoscopy findings:
- III    Ocular Muscles:  
       Eye opening strength:
- IV    Inferior and Medial movement of eye:
- V     a.      Sensory      - Ophthalmic:  
                             - Maxillary:  
                             - Mandibular:  
       b.      Motor        - Masseter:  
                             - Jaw lateral movement:  
       c.      Reflexes    - Corneal reflex  
                             - Jaw jerk
- VI    Lateral movement of eyes
- VII   a.      Motor - Raise eyebrows:  
                             - Frown:  
                             - Close eyes against resistance:  
                             - Show teeth:  
                             - Blow out cheeks:  
       b.      Taste - Anterior two-thirds of tongue:
- VIII   General Hearing:  
       Rinnes = L:            R:  
       Webers lateralisation:  
       Vestibular function - Nystagmus:  
                                     - Rombergs:  
                                     - Wallenbergs:  
       Otoscope examination:
- IX & 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:

# APPENDIX 5

## 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

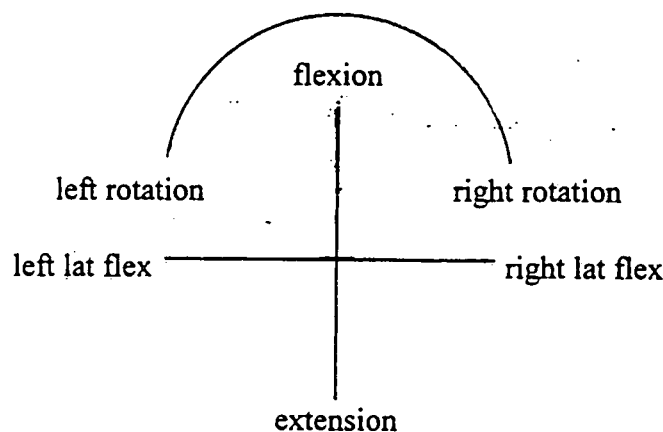
### RANGE OF MOTION:

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:

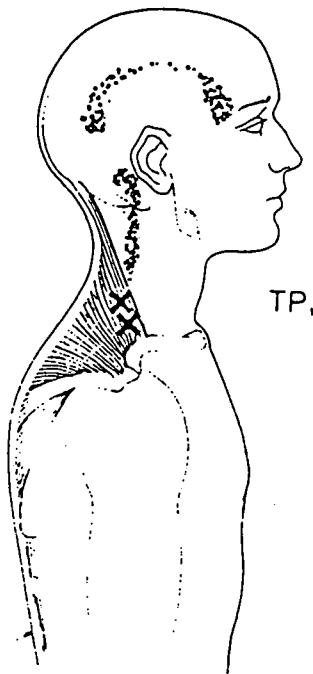


Figure 6.1. Referred pain pattern and location (x) of trigger point 1 in the upper trapezius muscle. Solid red shows the essential referred pain zone; stippling maps the spillover zone.

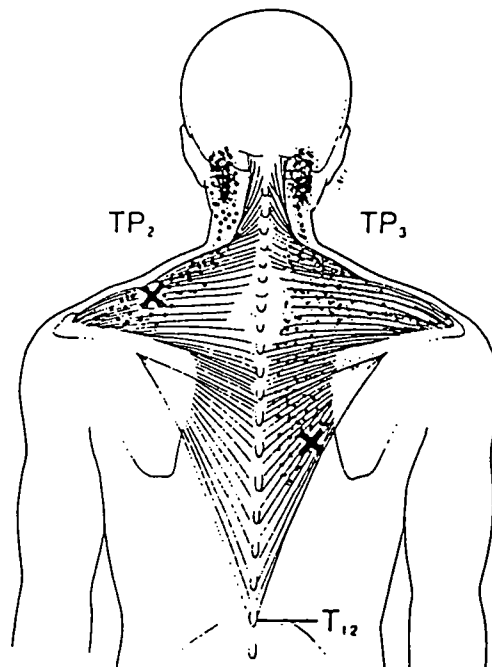


Figure 6.2. Referred pain patterns and locations (x) of trigger point 2 in the left upper trapezius, and of trigger point 3 in the right lower trapezius. (Conventions are as in Figure 6.1).

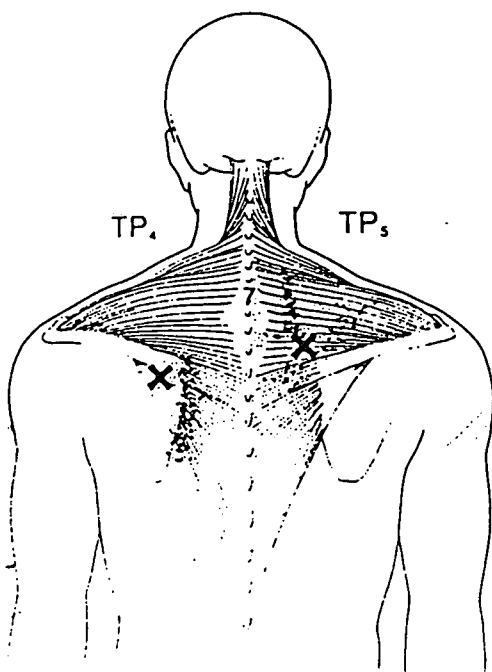


Figure 6.3. Referred pain patterns and locations (x) of trigger point 4 in the left lower trapezius, and of trigger point 5 in the right middle trapezius. (Conventions are as in Figure 6.1).

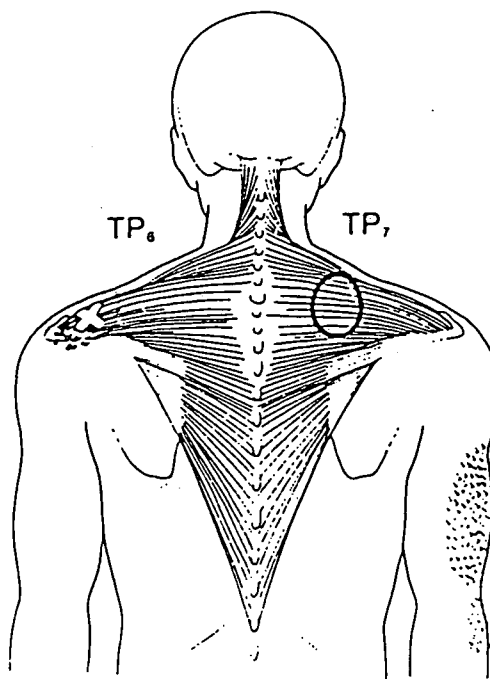


Figure 6.4. Referred pain pattern and location of trigger point 6 (x) in the left middle trapezius. (Conventions are as in Figure 6.1). Trigger point 7 on the right lies within the encircled area of the middle trapezius. The zone to which it refers pilomotor activity, or "gooseflesh," is identified on the right upper extremity by "x" symbols.

Taken from:

Travell, J.G. and Simmons, D.G. 1983. Myofascial pain and dysfunction. Baltimore: Williams & Wilkins. vol 1 713p. ISBN 0-683-08366-X.

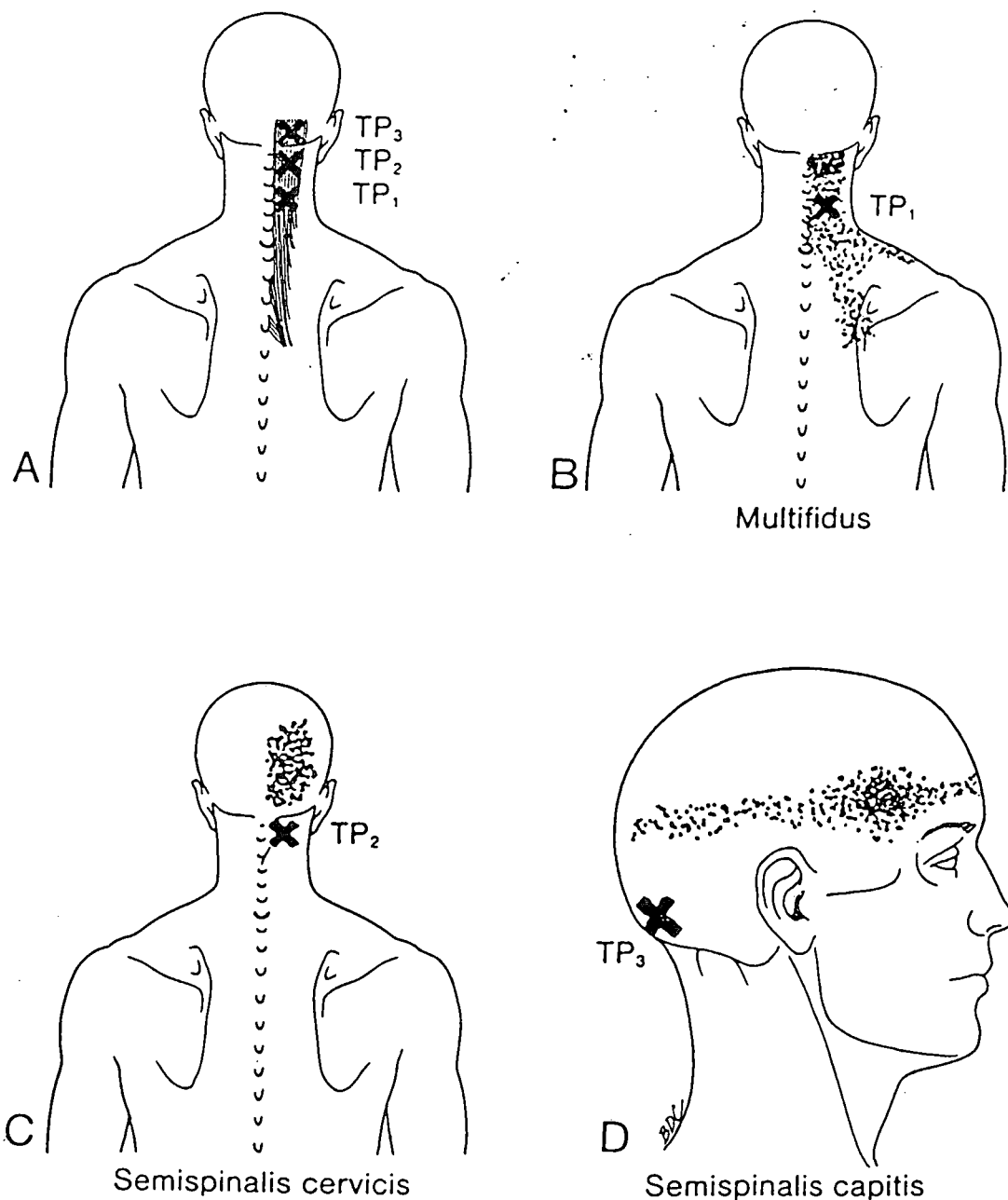


Figure 16.1. Referred pain patterns (red) and their trigger points (x's) in the medial posterior cervical muscles. A, three major trigger point locations. B, TP<sub>1</sub> lies deep at the C<sub>4</sub> or C<sub>5</sub> level in the multifidi or rotatores; it is the posterior cervical trigger point most commonly found and often leads to entrapment of the greater occipital nerve. C, TP<sub>2</sub> in the third-layer semispinalis cervicis. D, the uppermost TP<sub>3</sub> in the semispinalis capitis.

Taken from:

Travell, J.G. and Simmons, D.G. 1983. Myofascial pain and dysfunction.  
Baltimore: Williams & Wilkins. vol 1 713p. ISBN 0-683-08366-X.

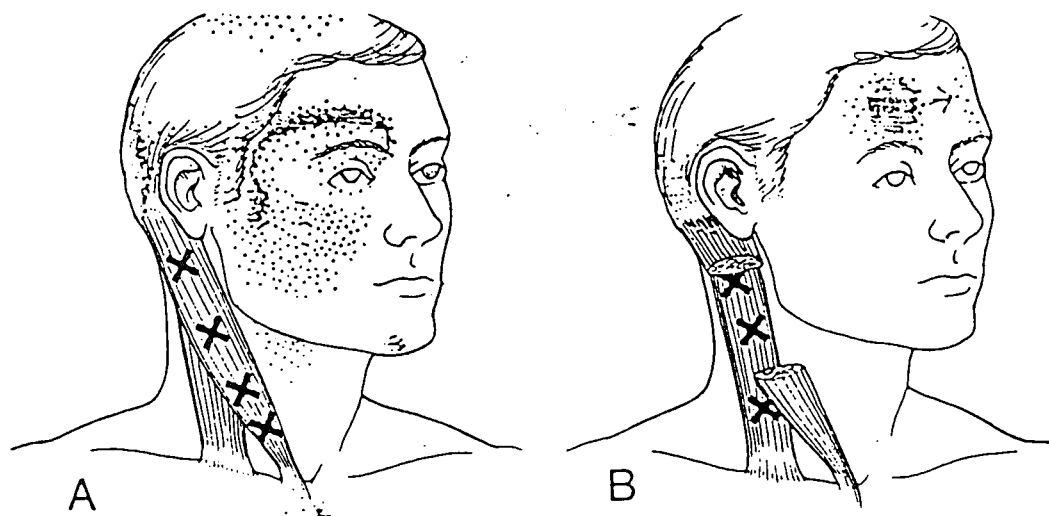


Figure 7.1. Referred pain patterns (solid red shows essential zones and stippling shows the spillover areas) with location of corresponding trigger points (Xs) in the right sternocleidomastoid muscle. A, the sternal (superficial) division. B, the clavicular (deep) division.

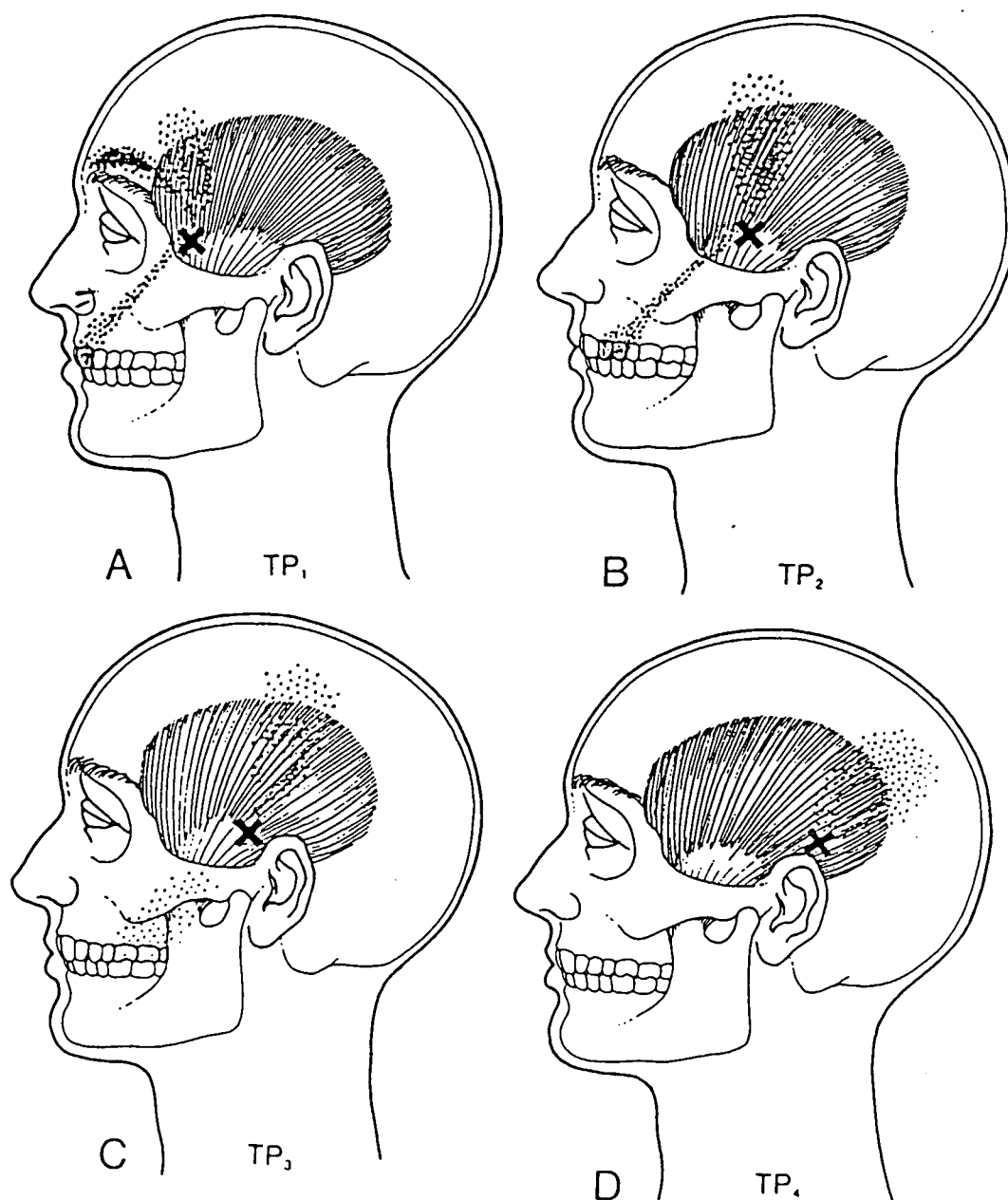


Figure 9.1 Referred pain patterns from trigger points (Xs) in the left temporalis muscle (essential zone solid red, spillover zone stippled). A, anterior "spokes" of pain arising from the anterior fibers (trigger point one region). B and C, middle "spokes" (trigger point two and trigger point three regions). D, posterior supra-auricular "spoke" (trigger point four region)

Taken from:

Travell, J.G. and Simmons, D.G. 1983. Myofascial pain and dysfunction.

Baltimore: Williams & Wilkins, vol 1 713p. ISBN 0 682 08266 X

## APPENDIX 7

### SHORT-FORM MCGILL PAIN QUESTIONNAIRE ( SF-MPO)

Ronald Melzack

Patients Name: \_\_\_\_\_ File #: \_\_\_\_\_ Date: \_\_\_\_\_

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

## APPENDIX 8

Patient name: \_\_\_\_\_ Res.No: \_\_\_\_\_ Date: \_\_\_\_\_

### 7.4 NUMERICAL RATING SCALE-101 QUESTIONNAIRE

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

\_\_\_\_\_

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

\_\_\_\_\_

## CMCC NECK DISABILITY INDEX

PATIENT NAME: \_\_\_\_\_ FILE #: \_\_\_\_\_ DATE: \_\_\_\_\_

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

## Section 1 - Pain Intensity

- ☐ I have no pain at the moment.  
☐ The pain is very mild at the moment.  
☐ The pain is moderate at the moment.  
☐ The pain is fairly severe at the moment.  
☐ The pain is very severe at the moment.  
☐ The pain is the worst imaginable at the moment.

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

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

## Section 3 - Lifting

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

## Section 4 - Reading

- ☐ I can read as much as I want to with no pain in my neck.  
☐ I can read as much as I want to with slight pain in my neck.  
☐ I can read as much as I want with moderate pain in my neck.  
☐ I can't read as much as I want because of moderate pain in my neck.  
☐ I can hardly read at all because of severe pain in my neck.  
☐ I cannot read at all.

## Section 5 - Headaches

- ☐ I have no headaches at all.  
☐ I have slight headaches which come in-frequently.  
☐ I have moderate headaches which come in-frequently.  
☐ I have moderate headaches which come frequently.  
☐ I have severe headaches which come frequently.  
☐ I have headaches almost all the time.

## Section 6 - Concentration

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

## Section 7 - Work

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

## Section 8 - Driving

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

## Section 9 - Sleeping

- ☐ I have no trouble sleeping.  
☐ My sleep is slightly disturbed (less than 1 hr. sleepless).  
☐ My sleep is mildly disturbed (1-2 hrs. sleepless).  
☐ My sleep is moderately disturbed (2-3 hrs. sleepless).  
☐ My sleep is greatly disturbed (3-5 hrs. sleepless).  
☐ My sleep is completely disturbed (5-7 hrs. sleepless).

## Section 10 - Recreation

- ☐ I am able to engage in all my recreation activities with no neck pain at all.  
☐ I am able to engage in all my recreation activities, with some pain in my neck.  
☐ I am able to engage in most, but not all of my usual recreation activities because of pain in my neck.  
☐ I am able to engage in a few of my usual recreation activities because of pain in my neck.  
☐ I can hardly do any recreation activities because of pain in my neck.  
☐ I can't do any recreation activities at all.

APPENDIX 10

Patient name:\_\_\_\_\_ File no.\_\_\_\_\_

Treatment no:\_\_\_\_\_

Group :\_\_\_\_\_

PAIN INTENSITY AND PAIN RELIEF ORDINAL SCALE.

<u>Pain Intensity</u>		<u>Score</u>	1st hour	2nd hour	3rd hour	4th hour	24th hour
	None	0					
	Mild	1					
	Moderate	2					
	Severe	3					
<u>Pain Relief</u>							
	all gone	4					
	More than half gone	3					
	Half gone	2					
	Less than half gone	1					
	No relief	0					

Taken from:  
Migliardi,J.R., Armellino,J.J., Friedman,M., Gillings,D.B., Beaver,W.T. 1994.  
Caffeine as an analgesic adjuvant in tension headache. Clinical Pharmacology and Therapeutics. 56(5):576-586.



## CROM Procedure Manual

### Procedure for Measuring Neck Motion with the CROM

CROM (Cervical Range of Motion Instrument) is a product of:

*Performance Attainment Associates  
3600 Labore Road, Suite 6  
St. Paul, MN 55110-4144*

## Introduction

Pain and loss of motion in the cervical region are common problems that increase with age. Over 40 million adult Americans suffer from some form of osteoarthritis or degenerative joint disease, and 50 to 85 percent of these people will experience debilitating back or neck pain of a temporary or chronic nature.

Accurate measurement of cervical motion during the course of a therapeutic regime can provide objective data on the benefits of the selected treatment. However, currently available measurement devices are time consuming, cumbersome, poorly standardized and poorly accepted by practitioners. In response to this lack of an acceptable means of measurement, existing devices were evaluated and the following design criteria established:

- easily applied
- measures all planes of motion
- comfortable
- time efficient
- easily adjusted

- quickly read
- standardized landmarks and positioning
- standardized protocol
- reproducibility
- simple design
- reasonable cost

Based on these criteria, the CROM instrument, accessories and protocol were developed. The CROM accurately and quickly measures the range of sagittal, coronal and horizontal movements that can be performed by the head and neck.

To perform and document accurate cervical measurements you will need the following items:

- CROM Instrument, including the rotation arm and the forward head arm
- magnetic yoke
- vertebra locator
- tape measure
- recording sheets
- procedure manual

The CROM Instrument is aligned on the nose bridge and ears and is fastened to the head by a velcro strap (see figure 1).

Three dial angle meters are used to take most of the measurements. The sagittal plane meter and the lateral flexion meter are gravity meters. The rotation meter is magnetic and responds quickly to the shoulder-mounted magnetic yoke, accurately measuring cervical rotation. Because the rotation meter is controlled by the magnetic yoke, shoulder substitution is eliminated.

Two frequently observed problems seen in patients with cervical dysfunction are forward head (cranio-thoracic postures) and rounded shoulders (scapular protraction). Forward head is the anterior glide of the cervical spine and head with cervical hyperextension. The CROM Instrument, with the forward head arm and the vertebra locator, accurately measures forward head (see figure 2).

Rounded shoulder is the anterior movement of the scapula (shoulder and upper extremity) on the thorax. Rounded shoulder measurements are taken with the tape measure.



Figure 1: CROM with rotation arm and magnetic yoke

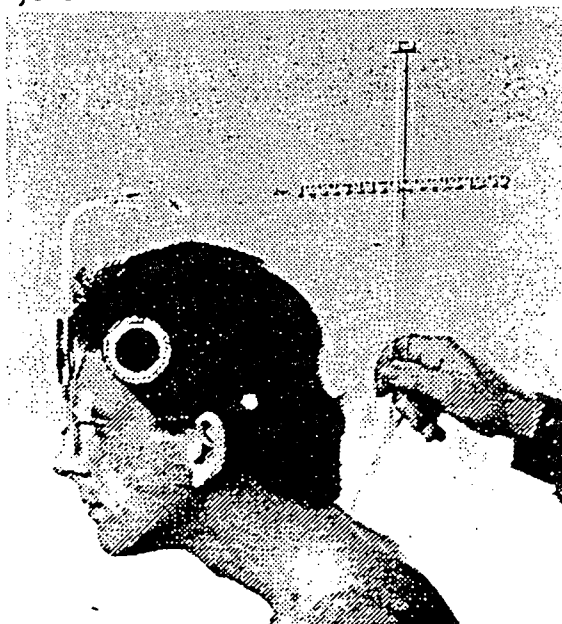


Figure 2: CROM with forward head arm and vertebra locator

## Suboccipital Flexion and Extension

Instruct the subject to position the CROM Instrument as if putting on a pair of glasses. Fasten the velcro strap in line with the bows. You will not need the magnetic yoke, rotation arm, forward head arm or vertebra locator for these measurements. Instruct the subject to stand facing away from an outside corner of a wall or edge of a open door frame. The subject's sacrum, thoracic spine and occiput must be in contact with the corner of the wall or door edge (see figure 3). Instruct the subject to maintain constant pressure to prevent substitution movements. Since the sagittal plane meter normally reads zero when the ear bows are parallel to the horizontal plane, this reading (zero or otherwise) indicates the subject's resting suboccipital posture; record it on the recording sheet\*.

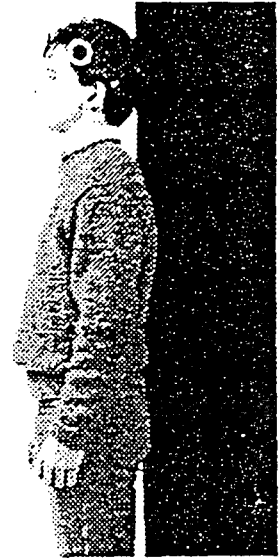


Figure 3: Resting posture

Instruct the subject to flex the suboccipital area as much as possible while maintaining equal pressure at the skull, thorax and sacrum (see figure 4). Record this measurement.



Figure 4: Flexion

Instruct the subject to extend the suboccipital area as much as possible without allowing the skull, thorax and sacrum to leave the contact surface (see figure 5). Record this measurement.



Figure 5: Extension

\*A sample recording sheet is provided in the back of this manual. Tablets of the recording sheet may be ordered from your dealer as PAA Form 101.

## Cervical Flexion and Extension

Instruct the subject to sit erect in a straight-back chair with the sacrum against the back of the chair, the thoracic spine away from the back of the chair, arms hanging at sides and feet flat on the floor. Next, instruct the subject to position the CROM instrument as if putting on a pair of glasses. Fasten the velcro straps snugly in line with the bows. You will not need the magnetic yoke, rotation arm, forward head arm or vertebra locator for these measurements.

To assure full flexion in this multi-joint area, first instruct the subject to "nod your head to make a double chin" (suboccipital flexion). Then encourage the subject to flex further until full cervical flexion is obtained (see figure 6). To take the reading on the sagittal plane meter, read through the meter's beveled edge; from this angle the pointer will be magnified to the dial edge. Record this measurement in the appropriate space on the recording sheet.



Figure 6: Cervical flexion

To measure cervical extension, first instruct the subject to "nod your head back" (suboccipital extension). Then have the subject extend further until full extension is achieved (see figure 7). Record this measurement also.



Figure 7: Cervical extension

## Lateral Flexion

Instruct the subject to sit erect in a straight-back chair with the sacrum against the back of the chair, the thoracic spine away from the back of the chair, arms hanging at sides and feet flat on the floor. Note: to eliminate rotation during lateral flexion the subject should focus on a point on a wall straight ahead. The sagittal plane meter will read zero if the subject is looking straight ahead. The lateral flexion meter will also read zero if the head is not laterally flexed. If the lateral flexion meter does not read zero, record the reading as lateral flexion at rest. You will not need the magnetic yoke, rotation arm, forward head arm nor vertebra locator for these measurements.

Instruct the subject to flex the head laterally to the left, keeping the shoulders level and without rotating the head (see figure 8). Monitor for shoulder elevation by lightly placing your hand on the right shoulder, and correct manually any head motion outside the coronal plane. Note and record the measurement from the lateral flexion meter.



Figure 8: Left lateral flexion

Now instruct the subject to flex the head laterally to the right, again keeping the shoulders level without rotating the head (see figure 9). As before, monitor for left shoulder elevation and correct head motion.



Figure 9: Right lateral flexion

## Rotation

You will need to use the CROM instrument plus the magnetic yoke and rotation arm for these measurements. To obtain an accurate rotation measurement, first determine which direction is north.\*

Next, place the magnetic yoke on the subject's shoulders with the arrow pointing north (see figure 10). Instruct the subject to sit erect in a straight-back chair with the sacrum against the back of the chair, the thoracic spine away from the back of the chair, arms hanging at sides and feet flat on the floor. The lateral flexion and sagittal plane meters must read zero for the rotation meter to be level; if necessary, assist the subject into the correct position. As the subject faces straight ahead, grasp the rotation meter between your thumb and index finger and turn the meter until one of the pointers is at zero.

Instruct the subject to focus on a horizontal line on the wall so the head is not tipped during rotation. Have the subject turn the head as far to the left as possible (see figure 11), and to ensure that no shoulder rotation occurs, lightly stabilize the right shoulder with your hand. (Note: if the head and shoulders are rotated together the pointer will not move because the magnetic yoke positioned on the shoulders eliminates shoulder substitution.) Record this measurement in the appropriate place on the recording sheet.

While you lightly stabilize the left shoulder, instruct the subject to turn the head as far as possible to the right (see figure 12). Record this measurement also.

\*You can find magnetic (map) north by noting the direction of the red needle on the rotation meter when it is at least four feet from the magnetic yoke.

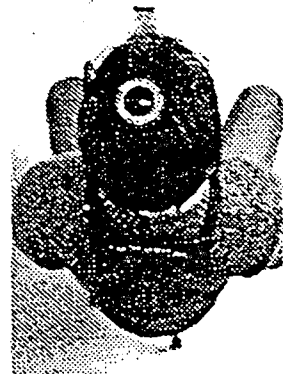


Figure 10: Magnetic yoke pointing north



Figure 11: Left rotation



Figure 12: Right rotation

## Forward Head

Instruct the subject to sit erect in a straight-back chair with the sacrum against the back of the chair, the thoracic spine away from the back of the chair, arms hanging at side and feet flat on the floor. You will need to use the CROM instrument plus the forward head arm and the vertebra locator for this measurement, but not the magnetic yoke nor the rotation arm.

Attach the forward head arm on the CROM in place of the rotation arm (see figure 13). Stand to the subject's left side so you can read the sagittal plane meter. To assure that the forward head arm is horizontal, assist the subject to position the head with the sagittal plane meter reading zero. While the subject maintains this position, locate the seventh cervical vertebra and place the foot (bottom tip) of the vertebra locator on the spinous process. Position the locator so the bubble is centered within the vertical lines on the vial. The forward head arm is calibrated in centimeters for the horizontal distance from the nose bridge to the locator contact point with the seventh vertebra.

Now, instruct the subject to slide the head as far back as possible, while keeping the chin level. Note the measurement at the junction of the forward head arm and the vertebra locator and record it as retraction.

Next, instruct the subject to relax and record this measurement as the resting posture.

Then, instruct the subject to protract or protrude the head forward as much as possible, while keeping the chin level. Record this measurement as protraction.

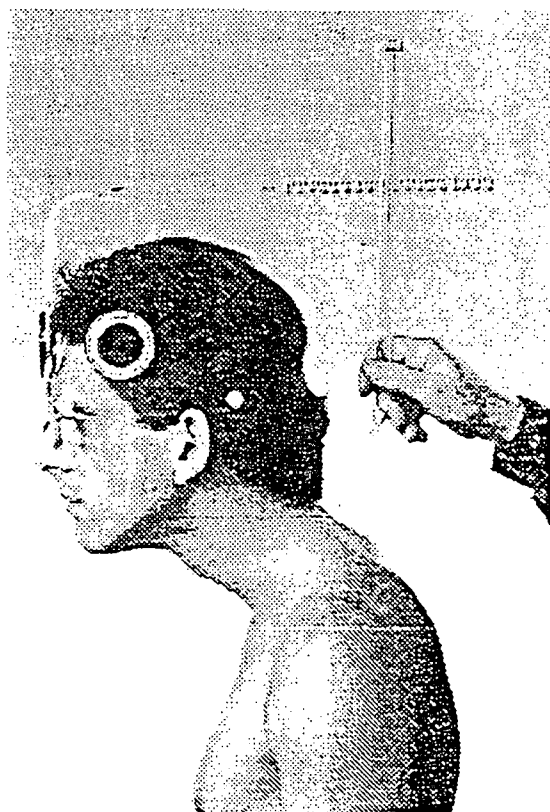
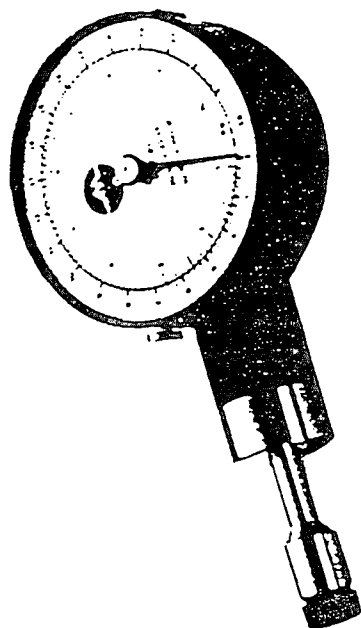


Figure 13: CROM with forward head arm and vertebra locator





**Activator Methods, INC.**

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(602) 224-0220

### ALGOMETER INSTRUCTIONS

#### Background:

Pressure pain threshold (PPT) has been used by many authors to quantify palpatory pain findings for myofascial trigger points and pain over bone using an algometer (1-7).

#### Description:

The pressure algometer consists of a force dial which reads in pounds or kilograms and a 1 cm diameter rubber tipped stylus. Pain threshold is determined by the amount of force/cm<sup>2</sup> required for a person to first perceive pain.

#### Procedure:

Prior to recording the pain threshold, discuss the procedure with the patient. Before taking a measurement, you may wish to demonstrate the process to the patient by pressing the algometer into the palm of their hand.

1. Localize any sensitive areas you wish to measure by gentle but firm palpation.
2. Hold the meter in the palm of your hand between your thumb and index finger.
3. Place the rubber tipped stylus over the pre-determined trigger point or area of palpable tenderness you wish to

measure. Make sure the force dial is perpendicular to the skin surface. Stabilize any nodular muscular regions between the middle and index finger of your indifferent hand.

4. Apply steady, gentle pressure at a rate of 1kg/cm<sup>2</sup>/sec. until the patient first feels pain and responds by saying "now."
5. Remove the stylus and record the value and locations of the tender areas in your notes or on a diagram for follow-up examination.
6. Reset the meter prior to making another reading.

#### References:

1. Fischer AA. Pressure algometry over normal muscles: Standard values, validity, reproducibility of pressure threshold. *Pain* 1986; 30:115-126.
2. Hsieh J, Hong CZ. Effect of chiropractic manipulation on the pain threshold of myofascial trigger point: a pilot study. Presented at the FCER's 2nd Annual International Conference on Spinal Manipulation, May 11-12, 1990, Washington, D.C.
3. Maloney P, Tepe R, Buerger D, et al. Evaluating the algometer as a diagnostic instrument. Presented at the FCER's 1st

### GENERAL INFORMATION

The algometer is most accurate in the range which is 75% from full scale. In the range below 25% of full scale, the gauge will give consistent readings, however, with less accurate results. This inaccuracy is inherent to the design of mechanical gauges. (Note: several studies have demonstrated reliability in a clinical setting.)

The algometer requires no lubrication or other form of service.

The face of the meter has no zero setting because the zero has no significance in the calibration or accuracy of the gauge.

### CALIBRATION

Activator Methods certifies that all algometers have been properly calibrated and are accurate to  $\pm 1\%$  of full scale. The calibration of the algometer may be checked by attaching the pull hook and suspending test weights at 1/4, 1/2, 3/4, and full capacity in the vertical position. The weight of the plunger, flat tip, and pull hook (15 g.) should be subtracted from the test results. If it is determined that calibration is required, the instrument should be returned to the factory.

Annual International Conference on Spinal Manipulation, March 31-April 1, 1989, Washington, D.C.

4. Osterbauer PJ, Fuhr AW, DeBoer KF, et al. Preliminary clinical and biomechanical assessment patients with chronic sacroiliac syndrome. Presented at the FCER's 2nd Annual International Conference on Spinal Manipulation, May 11-12, 1990, Washington, D.C.
5. Reeves JL, Jaeger B, Graff-Radiard S. Reliability of the pressure algometer as a measure of myofascial trigger point sensitivity. *Pain* 1986; 24:313-21.
6. Vernon HT. Pressure pain threshold evaluation of the effect of spinal manipulation on chronic neck pain: a single case study. *J Can Chiropr Assoc* 1988; 32(4):191-4.
7. Vernon HT, Acker P, Burns S., et al. Pressure pain threshold evaluation of the effect of spinal manipulation in the treatment of chronic neck pain: a pilot study. *J Manipulative & Physiol Ther* 1991; 13(1):13-16.

**THIS INSTRUMENT CARRIES A  
ONE YEAR WARRANTY  
FROM DATE OF PURCHASE.**

## APPENDIX 13

ALGOMETER READINGS.

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

FILE NO. \_\_\_\_\_

TREATMENT NO. \_\_\_\_\_

GROUP: \_\_\_\_\_

ALGOMETER READINGS.

[illegible]

APPENDIX    14

GONIOMETER READINGS.

PATIENT NAME: \_\_\_\_\_                      FILE NO. \_\_\_\_\_  
TREATMENT NO. \_\_\_\_\_                      GROUP: \_\_\_\_\_

GONIOMETER READINGS.

	<u>Before treatment</u>	<u>Follow-up</u>
Flexion		
Extension		
R. lateral flexion		
L. lateral flexion		
R. rotation		
L. rotation		