THE RELATIVE EFFECTIVENESS OF A CONSERVATIVE MULTI-METHOD TREATMENT PROTOCOL (S.M.T. AND DICLOFENAC) FOR THE MANAGEMENT OF CHRONIC MECHANICAL THORACIC SPINE PAIN

BY

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

I, Nayna Ratilal Bhoola do declare that this dissertation is representative of my own work.

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DEDICATION

This work is dedicated to His Divine Holiness, Pramukh Swami Maharaj, my constant source of inspiration, and to my beloved late father, Ratilal Bhoola, you will always be cherished in my heart. I miss you so much.

To my grandmother, mother Indira and sister Heena, my pillars of strength. I never would have made it without you. I love you all very much.

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Above all, thank you GOD for your grace, love and mercy, throughout all my years of study, you kept me strong.

On September 18, 1895, Harvey Lillard called upon me. He was so deaf for seventeen years that he could not hear the noises on the street. Mr. Lillard informed me that he was in a cramped position and felt something give in his back. I replaced the displaced 4th dorsal vertebra by one move, which restored his hearing fully.

DR. D.D.PALMER

The Science, Art, and Philosophy of Chiropractic

1910

(Plaugher, G. 1993)

ABSTRACT

The aim of this study was to determine the relative effectiveness of the combination of spinal manipulative therapy (SMT) and non-steroidal anti-inflammatory drugs (NSAIDs) versus SMT with the administration of a placebo medication in the treatment of chronic mechanical thoracic facet syndrome. It was hypothesised that SMT and NSAIDs over a three week period would be more effective than SMT and placebo medication in terms of the objective and subjective clinical findings.

The study design was that of a double blind randomized clinical trial. Sixty patients diagnosed with thoracic facet syndrome were randomly assigned to either the manipulation and NSAID group or the manipulation and placebo medication group. The age range of the patients was eighteen to fifty-nine years. Each patient in the NSAID group received 139mg of diclofenac free acid per day over five days. The placebo group received the same dosage of a similar appearance to that of diclofenac free acid over the same period. The placebo medication was in the form of lactose powders. Each group of thirty patients received six treatments of SMT over a three-week period. Group A received SMT and placebo medication while Group B received SMT and NSAIDs.

The patients were assessed by means of obtaining subjective information consisting of three questionnaires; the McGill Short-Form Pain Questionnaire, the Numerical Pain Rating Scale –101 and the Oswestry Pain Disability Index. Objective data was gathered from goniometer measurements. The objective data was collected before the

commencement of the first, third and sixth treatments while the subjective data was collected at the first and sixth treatment respectively.

The data was transferred to spreadsheets and underwent statistical analysis. The Paired t-tests were conducted in order to determine whether there was any significant change within each respective treatment group (intra-group analysis). The Unpaired t-tests were conducted in order to determine whether there was any significant change between the two groups (inter-group analysis). The two-sample unpaired t-tests were used to compare two independent samples with respect to each continuous variable while the two-sample Paired t-tests were used to compare results from related samples with regards to continuous variables. The alpha level was set at the 0.05 level of confidence.

Intra-group comparison of the results showed that only Group B (the NSAID group) showed significant ($p<0.025$) improvements between the first and sixth treatments with respect to the Oswestry Pain Disability Questionnaire and the Short-Form McGill Pain Questionnaire. Inter-group comparison of the results showed that there was no significant difference in the efficacy of the two treatment protocols in terms of objective and subjective clinical findings. In conclusion, it was found that SMT used in combination with NSAIDs was as effective as SMT alone in the treatment of chronic mechanical thoracic facet syndrome. It was recommended that this study be repeated with a more homogenous sample population. Different studies using different NSAIDs for a longer period of time would be warranted as individual response may vary according to the type and duration of NSAID used.

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DEFINITION OF TERMS

CHIROPRACTIC - A discipline of the scientific healing arts concerned with the pathogenesis, diagnostics, 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 (Bergmann 1993:756).

MANIPULATION - Therapeutic application of manual force. Spinal manipulative therapy (SMT) broadly defined includes all procedures where the hands are used to mobilize, adjust, manipulate, apply traction, massage, stimulate or otherwise influence the patient's health (Bergmann 1993:760). For the purpose of this study, the term SMT will be used to denote the chiropractic spinal adjustment.

ADJUSTMENT-The chiropractic adjustment is a specific form of direct articular manipulation utilizing either long or short leverage techniques with specific contacts. It is characterized by a dynamic thrust of controlled velocity, amplitude and direction (Bergmann 1993:754).

FIXATION - The state whereby an articulation has become temporarily immobilized in a position which 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 (Bergmann 1993:758).

PALPATION - The application of variable manual pressure through the surface of the body for the purpose of determining the shape, size, consistency, position, inherent motility, and health of the tissues beneath.

Motion palpation - Palpatory diagnosis of passive and active segmental joint range of motion.

Static palpation - Palpatory diagnosis of somatic structures in a neutral static motion. (Bergmann 1993:762)

JOINT DYSFUNCTION - Joint mechanics showing area disturbances of function without structural change. Subtle joint dysfunction affecting quality and range of joint motion. It is diagnosed with the aid of motion palpation, and stress and motion radiography investigation (Bergmann 1993:759).

MYOFASCIAL TRIGGER POINT- A hyperirritable spot, usually within a taut band of skeletal muscle or in the muscles fascia, that is painful on compression and that can give rise to characteristic referred pain, tenderness and autonomic phenomena (Bergmann 1993:761).

CHAPTER ONE

1.0 INTRODUCTION

Although the first successful chiropractic adjustment recorded was in the thoracic spine by D.D. Palmer in 1910, most of the spinal manipulative therapy (SMT) research has focused on the lumbar spine (Di Fabio1992). The thoracic spine has been conspicuously absent from the picture (Plaugher 1991:243).

In reviewing the literature relating to the thoracic spine it is apparent that in comparison to the cervical and lumbar regions, the thoracic region has largely been neglected. This may be attributed to the technical difficulties associated with movement analysis in this region and the belief that the thoracic spine is less commonly implicated in clinical pain syndromes (Edmonston and Singer 1997). Thoracic spine pain plays a much more important role in the differential diagnosis of chest pain than expected, being third in frequency. Pain of thoracic spine origin can be easily overlooked and result in a number of false diagnoses and insufficient treatment given (Bechgaard 1981). Based on epidemiological studies, thoracic spine pain is a common complaint that can be as disabling as cervical and lumbar pain and deserves wider recognition (Bruckner et al.1987, Dreyfuss et al.1994, Edmonston and Singer 1997).

The high incidence of chronic spinal pain syndromes, their recurrent nature in many patients, and their contribution as a main cause of absence from work is well documented (Giles and Muller, 1999). Due to the lack of standardized examinations and optimal diagnostic methods, the tissues responsible for primary interscapular and atypical chest pain of thoracic spinal origin are poorly recognized or accepted within the literature (Erwin et al.2000).

In pharmacological studies NSAIDs have shown to have anti-inflammatory, analgesic and antipyretic activity (Arky 1997: 833). The first line of treatment of allopathic physicians for the treatment of neck pain is usually NSAIDs, whereas the first line of treatment of chiropractic physicians is usually chiropractic spinal manipulations (Dabbs and Lauretti 1995). The chiropractic adjustment for a facet syndrome has delivered a high degree of patient satisfaction when compared to standard medical care (Cherkin and MacCormack 1989).

Worldwide, NSAIDs seem to be one of the most commonly prescribed medications for musculoskeletal pain (Koes et al. 1997). Jones (1997) postulates NSAID's to be equally effective as the combination of muscle relaxants and opioids for the control of lower back pain, but without the possibility of dependence and potential for abuse. This however, for the thoracic pain, still needs to be determined in a clinical trial.

According to the researcher's knowledge no study existed concerning the treatment of chronic thoracic facet syndrome with chiropractic manipulation and the use of non-steroidal anti-inflammatory drugs. This double-blinded, clinical trial was designed to determine whether a course of NSAIDs combined with manipulation would result in enhanced recovery of patients with thoracic facet syndrome compared to those receiving manipulation alone.
The information obtained and the deductions made from the outcome of this study may help to identify a more effective protocol for treating chronic thoracic facet syndrome.

1.1 STATEMENT OF THE PROBLEM

The purpose of this study was to determine the relative effectiveness of the combination of spinal manipulation used in conjunction with placebo medication as opposed to the combination of manipulation together with NSAIDs in the treatment of chronic mechanical thoracic spine pain.

SUBPROBLEM ONE

To evaluate the relative effectiveness of chiropractic manipulation used in conjunction with placebo medication as opposed to manipulation together with non-steroidal anti-inflammatory drugs in patients with chronic mechanical thoracic pain in terms of subjective clinical findings.

SUBPROBLEM TWO

To evaluate the relative effectiveness of chiropractic manipulation used in conjunction with placebo medication as opposed to manipulation together with non-steroidal anti-inflammatory drugs in patients with chronic mechanical thoracic pain in terms of objective clinical findings.

1.2 HYPOTHESIS

NULL HYPOTHESIS

It was hypothesised that chiropractic manipulation combined with non-steroidal anti-inflammatory drugs will be more effective than SMT with placebo in the management of chronic thoracic spine pain, in terms of subjective and objective clinical findings.

HYPOTHESIS TWO

It was hypothesised that chiropractic manipulation combined with non-steroidal anti-inflammatory drugs will not be more effective in the management of chronic thoracic spine pain, in terms of subjective and objective clinical findings.

CHAPTER TWO

2.0 REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

This chapter gives a comprehensive overview on the available information on chronic thoracic facet syndrome as well as on the drug (diclofenac free acid) used in this study. The evidence for the efficacy of spinal manipulative therapy and the effects it has on the thoracic spine is presented. NSAIDs, their safety and uses are also discussed.

2.2 THE PREVALENCE AND INCIDENCE OF THORACIC SPINE PAIN

In the results of a feasibility study on the prevalence of back pain carried out by Triano et al. (1993) using 186 patients, it was found that thoracic spine pain constituted 13.1% of the distribution of main complaints, while lumbar spine pain constituted 35.0%, cervical spine pain 18.6% and peripheral joints 6.2%.

Troussier et al. (1994) studied 1178 school children in France in order to determine the prevalence of back pain. The cumulative prevalence of back pain was 51.2% that is, 36.3% of the pain was experienced on several occasions, 13.2%of the pain was experienced frequently while 1,7% of the pain was experienced continuously. Lumbar pain constituted 41.0% while thoracic pain accounted for 34.0% of the pain, which was more common than cervical pain, which constituted 27.0%.

As part of a prospective study of overuse injuries, 395 Israeli male infantry recruits were evaluated for back pain during a single basic training course. During the course of 14 weeks of training, 70 recruits (18%) were diagnosed as having overexertional back pain. Thirty-two (8%) had thoracic pain and forty (10%) had lumbar pain. Two recruits had both lumbar and thoracic

pain. In 18 recruits (5%) the pain was paraspinal and in 53 (13%) the pain was elicited over the spinous processes of both thoracic and lumbar vertebrae (Milgrom et al. 1993).

A study by Fairbank et al. (1984) on 466 pupils aged 13-17 years; found 26% to have a history of back pain. In 77 of the 115 pupils complaining of a history of back pain, the anatomic site of pain was identified where15 had thoracic pain, 24 had thoracolumbar pain, and 38 lumbar pain.

In the USA, a comparative survey between six chiropractic college clinics indicated that the number of patients seen for lower back pain ranged between 31-41%, neck pain ranged between 19-27% and mid-back pain ranged between 10-15%. Extremity pain constituted 17-22%, headaches constituted 0-5% while other pain (not stated) constituted 4-14% (Nyiendo et al. 1989).

Bechgaard (1981) investigated the frequency of segmental thoracic pain in 1097 patients admitted to a medical department and coronary unit complaining of chest pain. A specific examination of the thoracic spine was performed with minimal risk to possible coronary patients. Bechgaard found that segmental thoracic pain accounted for 13% of chest pains, making it the third most common cause of chest pain (behind coronary thrombosis 39%, angina pectoris 20%).

The findings of this study support Gillett's theory in that "the mid-thoracic spine seems to be the area where most thoracic fixations are found. It is a region that can give much trouble in analysis and correction because it is the seat of continual recurrent fixations until the focal cause is found and eliminated" (Gillet 1990).

According to Grieve (1994) we seem to overlook biomechanical consequences of the anatomical fact that women have bosoms. He further explains that chronically contracted pectoral soft tissue and undue tightness of the surrounding thoracic musculature could result in chronically stressed upper and mid thoracic segments and associated costal joints.

2.3 FACET SYNDROME

2.3.1 DEFINITION

Facet syndrome may be broadly defined as pain or dysfunction arising primarily from the zygapophyseal joints and their immediately adjacent soft tissues (Panzer 1995: 415). Gatterman (1995: 11) defines it as an aggregate of signs and symptoms that relate to the pathophysiology or dysfunction of spinal motion segments, which is also referred to as the subluxation syndrome. Bourdillon (1987:54) defines it as an aberrant relationship between two adjacent articular structures that may have functional or pathological sequelae, causing an alteration in the biomechanical and/or neurophysiologic reflections of these articular structures, and/or body systems that may be directly or indirectly affected by them.

2.3.2 AETIOLOGY

Interactions between thoracic spine posture and thoracic mobility are believed to play a role in the development of spinal pain syndromes (Edmonston and Singer 1997).

A pilot study on 10 healthy subjects done by Harms-Ringdahl and Ekholm (1986) identified a possible postural cause for thoracic spine pain. Extreme flexion positions of the lower cervical-

upper thoracic spine resembling the sitting posture in certain work conditions caused thoracic spine pain in all 10 experimental subjects within 10 minutes. This pain disappeared within 15 minutes after the end of provocation, but was experienced again by 90% of subjects that same evening or next morning and lasted up to 4 days. The recorded electromyographic levels from the splenius, thoracic spinae, rhomboid and lower trapezius muscles also increased during provocation. Electromyographic activity levels were higher during writing compared to when the arms were at rest. It was thus concluded that pain does occur in healthy persons in common work-sitting postures.

Mechanical joint derangement, which forms part of the facet syndrome, may result from acute injury, repetitive use injury, faulty posture or co-ordination, ageing, congenital or developmental defects, or other primary disease states that could cause postural disturbances. The inflammatory component of facet syndrome may be initiated by joint injury, mechanical joint derangement or joint immobilization (Bergmann et al. 1993: 60).

Panzer (1995: 425) alleges that the occurrence of facet syndrome has been correlated to an increase in facet weight bearing. Peters (1984) supports this by stating that a history of activity involving flexion with rotation will put strain on the facet joint. However, he also states that the cause of facet syndrome is often subtle and that similar symptoms may be produced by forced or postural hyperextension.

Any degenerative thinning of the inter-vertebral disc results in the superior apophyseal facet being forced down on the corresponding inferior apophyseal joint surface resulting possibly in

an inflammatory reaction and stretching of the joint capsule that is seen in the facet syndrome (Peters 1984). Mooney and Robertson (1976) hypothesized that trauma may result in entrapment of the highly innervated synovial villi between the facet surfaces, resulting in irritation of adjacent nerve roots and therefore pain.

2.3.3 DIAGNOSTIC CRITERIA

Neck and lower back sprain are diagnoses commonly used by medical practitioners. A similar pain from the thoracic spine is generally not acknowledged and scarcely mentioned in medical textbooks and literature (Bechgaard 1981). A misdiagnosis of chest pain can easily happen as it mimics a diverse number of musculoskeletal conditions, one of which is thoracic spine dysfunction. A diagnosis of chest pain can cause unnecessary worry when an underlying biomechanical joint dysfunction goes undiagnosed (Gatterman 1990: 186). Referred pain from visceral disease is always a cause for concern but may result in repeated misdiagnosis and mismanagement and even unnecessary surgery (Grieve 1994: 401).

The evaluation of chest pain consumes tremendous amounts of economic and medical resources. It is usually possible to differentiate cardiac or visceral disorders from musculoskeletal disorders on the basis of clinical characteristics and a detailed physical exam. The history taking must focus on location, pattern, character and duration. It is also important to determine exacerbating and relieving factors as well as associated symptoms of the pain. In conjunction with a detailed physical examination a meticulous examination of the ribs, spine, sternum and their articulations will help establish a correct diagnosis. Further diagnostic studies are only necessary when the origin of the chest pain remains in doubt (Kaye 1993, Fam 1988).

Modifying the acronym PARTS from Bourdillon and Day, Bergmann (1993) identifies the five diagnostic criteria for the diagnosis of joint dysfunction. The physical signs indicative of joint dysfunction are pain, abnormalities in alignment, joint mobility and tissue texture.

Pain and tenderness - The perception of pain and tenderness is evaluated in terms of location, quality and intensity. Most primary musculoskeletal disorders manifest by a painful response. Pain and tenderness findings are identified through observation, percussion and palpation.

Asymmetry - Asymmetric qualities are noted on a sectional or segmental level. This includes observation of posture and gait, as well as palpation for misalignment of vertebral segments and extremity joint structures. Asymmetry is identified through observation (posture and gait analysis), static palpation, and static radiography.

Range of motion abnormality - Changes in active, passive, and accessory joint motions are noted. These changes may be reflected by increased, decreased or aberrant motion. It is thought that a decrease in motion is a common component of joint dysfunction. Range of motion abnormalities are identified through motion palpation and stress radiography.

Tone, texture and temperature abnormality - Changes in the characteristics of contiguous and associated soft tissues, including skin, fascia, muscle, and ligaments are noted. Tissue tone, texture, and/or temperature changes are identified through observation, palpation, instrumentation, and tests for length and strength.

Special tests - Finally, diagnosis may require testing procedures that are specific to a technique system such as radiographs.

For the purpose of this study, classifications by Triano et al. (1992) were used to diagnose mechanical spine pain, which does not include pain from a nerve root entrapment or muscular spine pain.

Mechanical spine pain:	-Midline back pain
	-Nondermatomal referred pain difficult to localize
	-No signs of nerve root tension
	-No major neurological deficit
	-Pain with compression into spine extension
	-Reduced range of motion

2.3.4 ANATOMY

In reviewing the literature relating to the vertebral column anatomy and biomechanics it is apparent that, in comparison to the cervical and lumbar regions, the thoracic spine has been largely neglected.

Panjabi et al. (1991) studied the three-dimensional surface anatomy on 144 thoracic vertebrae. The thoracic spine was found to have three distinct regions according to width-to-depth ratios: upper T1-T4, middle T4-T9/10, and lower T10-12.The middle thoracic region is characterized by a relatively narrow end-plate and spinal canal. A small spinal canal makes this region susceptible to cord impingement, although rib articulations add significant stiffness to the region. This

middle region has been called the critical vascular zone, because the blood supply to the spinal cord is the least profuse at this level.

The kyphotic curve is approximately 46.6 degrees for the entire thoracic spine, that is a vertebral wedge angle of 3.8 degrees per vertebra (Punjabi et al. 1991). Muscle activation has little effect on the thoracic kyphosis, which is determined more by the osseous asymmetry of the vertebral bodies. The thoracic spine kyphosis limits the potential for spinal extension during active and passive movement (Edmonston and Singer 1997).

Thoracic kyphotic curvature will most certainly influence patterns of load-bearing and movement, and the greater the stiffness of the thoracic spine the more it may produce compensatory changes and pain in the more mobile lordotic regions (Edmonston and Singer 1997). This kyphotic curve makes the thoracic spine more prone to be unstable in flexion (White and Panjabi 1990:328).

Thoracic disc height, relative to vertebral body height, is less than in the cervical and lumbar regions and the ratio of disc diameter to height is 2-3 times higher in the thoracic than the lumbar segments. This reduces the mobility of a functional spinal unit in the thoracic spine (Edmonston and Singer 1997).

Results obtained from a pilot study by Dreyfuss et al. (1994) indicated that the thoracic zygapophyseal joints could produce both local and referred pain in a reproducible manner. Nine asymptomatic volunteers underwent 40 provocative intra-articular injections of the thoracic

zygapophyseal joints. The purpose of this study was to isolate and stimulate the thoracic zygapophyseal joints via fluoroscopically guided intra-articular injections to determine whether they were potential pain generators. In this asymptomatic population, 72.5% of the joints injected produced a sensation /pain that was different from the sensation of needle advancement through the soft tissues. In 27.5% of the joints injected, there was no evoked pain despite adequate capsular distension. The evoked referral patterns were consistent in all subjects. This study provided preliminary confirmation that the thoracic zygapophyseal joints can cause both local and referred pain.

2.3.5 EVIDENCE OF INFLAMMATION

It would be pointless to initiate a clinical trial using NSAIDs in the treatment of facet syndrome if there was no evidence of any associated inflammation. Anderson (1989: 305) defines inflammation as a 'protective tissue response to injury or destruction of tissues, which serves to destroy, dilute, or wall-off both the injurious agent and the injured tissues'. Chronic inflammation is marked chiefly by new tissue formation; it may be a continuation of an acute form or a prolonged low-grade form.

There is an inflammatory factor in many spinal joint dysfunctions (Bourdillon et al.1992: 283). This factor is a combination of biochemical and cellular events that is mediated by the vascular system, but initiated by local events within the affected tissues (Lantz 1995: 163). Bergmann et al. (1993: 53) include inflammatory response as one of the potential pathological effects of the facet syndrome. They believe that where pain is a constant feature there must be some degree of joint or tissue inflammation. Although this is purely an assumption, it stands to reason that there

cannot be only one pathological component in facet syndrome. This they explain by including mechanical and neurobiologic components.

Roy et al. (1988) deduced that inflammation of the joint capsule with subsequent irritation of the nerve roots was responsible for facet joint pain. Reid (1992: 829) supports this by proposing that it is these inflammatory flare-ups of facet joint pain and synovitis that produce the facet joint syndrome. However no literature was found as to the exact cause of these flare-ups. He also advocates the use of NSAIDs for the treatment of these flare-ups. To counteract this, Bogduk (1994: 433) believes that there are mechanical changes and not inflammatory changes that determine if the zygapophyseal joint becomes symptomatic or not. In a dysfunctional joint, an inflammatory reaction around a nerve or nerve root may cause persistent pain and often NSAIDs are preferable to high velocity manipulation (Bourdillon et al. 1992:301,307). They partially corrected this statement by blaming those who are inexperienced in manipulation in aggravating the condition, by being too slow, or moving the joint too far and compromising the surrounding soft tissue, causing further inflammation.

When the cervical spine is injured, the injury results in the release of leucotrienes producing inflammation, which often leads to the development of trigger points. It is thought that it is this inflammatory reaction that produces restricted ranges of movement, tendon and fascial shortening. Presumably this kind of reaction can be inhibited by non-steroidal anti-inflammatory drugs (Dishman 1988). It is assumed the same would apply to the thoracic spine.

Mechanical factors, such as decreased movement, may be a result of the primary inflammatory response, resulting in edema and subsequent pressure on structures primarily concerned with movement (Gifford 1994: 507,508). Manipulation may aid in the dispersal of edema resulting in decreased pressure within the joint complex, with a succeeding increase in short-term movement.

2.4. MANIPULATION

2.4.1 DEFINITION

According to Brunarski (1984) chiropractic is the principle proponent of spinal manipulative therapy, while Fitz-Ritson (1987) states that spinal manipulative therapy has been the primary treatment modality used by the chiropractic profession since its inception.

In chiropractic the term 'manipulation' is used interchangeably with the 'chiropractic adjustment', and is defined by Mierau et al. (1998) as an abrupt, quick, low-amplitude force skillfully applied to the apophyseal joints of a specific spinal segment to increase range of motion in that segment. The manipulative manouver is usually associated with an audible cracking sound, and it is the joint crack that separates manipulation in general from mobilization. Haas (1990) however, believes that cavitation is not a necessary criterion to characterize the completion of an adjustment.

2.4.2 CONTRA-INDICATIONS

Accidents that have occurred in SMT appear to have occurred because the diagnosis was in error or because the manipulative technique used was not accurately applied (Bourdillon et al.1992: 129, Bergmann et al. 1993: 132).

Patients who have the following conditions should not receive chiropractic manipulation: Tumours, dislocations, fracture, infection, instability, hematoma, myelopathy, radiculopathy, congenital anomalies, Arnold Chiari malformation, basilar invagination and cerebral ischemic syndromes (Wyatt 1992: 199-200). Bourdillon et al. (1992:286) includes osteoporosis and hyper mobility as contra-indications to manipulation, but Mootz (1995:180) believes that manipulation of an unstable segment is unlikely to promote greater instability and may provide the patient with relief. Both authors however, state that the presence of a hyper mobile segment does indicate the presence of a hypo mobile segment in the vicinity.

It is clear that there are many conditions that are contra-indicated to SMT and that even with all of its benefits, it is not beneficial to all patients.

2.4.3 EFFECTS OF MANIPULATION

One of the goals of manipulation is to enable the patient to have maximal pain-free movement of the musculoskeletal system (Bourdillon et al. 1992: 295). According to numerous authors, the end result of an adjustment is a joint cavitation with the release of gas from the joint fluid followed by an increase in range of motion of that joint (Haas 1990, Bergman et al. 1993:140, Bourdillon et al. 1992:297, Mierau et al. 1988).

Zusman (1994:651) proposes that structures such as loose bodies, disc material, synovial fringe or entrapped meniscoid may cause a joint to lock and become fixated, and at the same time cause stimulation of pain sensitive structures. It is hypothesized that manipulation may free these

structures, restoring movement and stopping nociceptive input and associated reflex muscle spasm (Zusman 1994:651).

A recent study was conducted by Giles and Muller (1999) to compare needle acupuncture, medication in the form of NSAIDs (tenoxicam with ranitidine) and spinal manipulation for managing chronic (>13 weeks) spinal pain syndromes. Seventy-seven patients were recruited for the study. The study design was that of a prospective, randomized, independently assessed pre-intervention and post-intervention clinical pilot trial. Results revealed that spinal manipulation was the only intervention that achieved statistically significant improvement with (1) a reduction of 30.7% on the Oswestry scale, (2) reductions on the visual analogue scale of 50.0% for low back pain, 46.0% for upper back/thoracic pain and 33.0% for neck pain (all $p<0.001$). The consistency of the results suggests that in patients with chronic spinal pain syndromes, spinal manipulation, if not contraindicated, results in greater improvement than acupuncture and medication.

In a pilot study done by Schiller (1999) into the efficacy of spinal manipulative treatment in the management of mechanical thoracic pain it was found that spinal manipulative therapy had greater benefits than placebo treatment. The study design was that of a single-blind, randomized, comparative, controlled pilot study. Thirty subjects were selected from the general population, diagnosed as having mechanical thoracic spine pain, were randomly divided into two different treatment groups. Each group consisted of fifteen patients between the ages of sixteen to sixty years. The research project was carried out where both groups received a maximum of six treatments over a minimum period of two weeks. Thereafter a one-month follow-up treatment

was scheduled to assess the long-term benefits of the two treatments. The study suggested that SMT may be more effective than placebo therapy in the short-term management of mechanical thoracic spine pain. Due to the small sample size, the findings of the trial study could not be considered conclusive, but rather used as a foundation to plan future studies. With the above in mind the present study included a larger sample size of sixty patients and also aimed at treating chronic as opposed to acute mechanical thoracic spine pain.

With regards to the effects of manipulation on a patient suffering from facet syndrome, Panzer (1995:424) proposes the following:

- Resultant reduced weight bearing on the posterior facets.
- Unlocking of osseous restrictions.
- Reduction of local vascular stasis.
- Freeing of capsular adhesions.
- Breaking of post-immobilization links.
- Pain relief by stimulation of certain receptors.
- Release of entrapped meniscoids.

2.4.4 SAFETY OF MANIPULATION IN THE THORACIC SPINE

According to Bergmann (1993) the main complication from manipulative therapy in the thoracic spine is rib fracture. Sprain to the costovertebral and costotransverse articulations with concomitant strain to the intercostals muscles may occur. Additionally, transverse process fracture and hematomyelia have been identified in rare instances. These problems are usually due

to excessive force in relation to the patient's size and physical condition. They can be avoided by appropriate technique selection and application as well as an adequate evaluation

2.4.5 MOTION PALPATION OF THE THORACIC SPINE

The main purpose of motion palpation is to detect fixation dysfunction. Unless a fracture is present, an adjustment is not given unless there is a fixation of the motion segment. Hypermobilities, which appear to be due to direct injury, pathology, or as a compensatory reaction, are usually indistinguishable from normal segments, unless extreme.

The doctor should motion palpate flexion and extension, lateral flexion, rotation and coupled extension, lateral flexion, and rotational movements. In flexion and extension, interspinous separation and approximation are detected. The upper thoracic spine is usually evaluated by extreme extension of the cervical spine or the patient elevating and crossing the arms and the examiner raising and lowering them while digitally evaluating the interspinous space closure and opening. Lateral flexion is palpated by pushing the spinous process opposite from the side of passive lateral flexion. Rotation and coupled movements are usually determined by applying digital pressure against the spinous or transverse process (Plaugher 1993:253).

2.5 NON STEROIDAL ANTI-INFLAMMATORY DRUGS

2.5.1 INTRODUCTION

Worldwide, non-steroidal anti-inflammatory drugs (NSAIDs) seem to be the most commonly prescribed medications for treating musculoskeletal conditions (Koes et al.1997). Bellamy (1996) states that NSAIDs are the mainstay of treatment for most musculoskeletal disorders in

the western world. They are prescribed extensively for their anti-inflammatory, analgesic and anti-pyretic properties (Goodman and Simon 1994, Dabbs and Lauretti 1995).

Diclofenac has been established as a leading NSAID in worldwide studies during the past 12 years and has been successfully used for acute as well as chronic or relapsing syndromes marked by pain and inflammation (Kantor 1986).

Despite their widespread use and perceived safety, NSAIDs have a significant risk of severe complications. The most frequent and serious adverse effects associated with NSAIDs are gastrointestinal ulcers and haemorrage (Dabbs and Lauretti 1995).

There are many different NSAIDs available from a variety of chemical classes, including Aspirin, Mefenamic acid, Tolmetin, Diclofenac, Ibuprofen and Piroxicam, to name but a few (DiPiro et al. 1989).

The NSAID used in this study was Diclofenac free acid 46.5mg (equivalent to 50mg diclofenac sodium) under the propriety name Cataflam D Dispersible Tablets.

2.5.2 DICLOFENAC

Diclofenac is the first series of phenlyacetic acid derivatives that have been developed as anti-inflammatory agents (Goodman Gilman et al.1990: 669). It designated chemically as 2-[2.6-dichlorophenyl amino] benzeneacetic acid, monosodium or monopotassium salt (Arky 1997:833).

In clinical conditions marked by acute or chronic pain and inflammation, diclofenac sodium has shown to be an effective anti-inflammatory and analgesic agent (Kantor 1986).

2.5.2.1 MECHANISM OF ACTION

NSAIDs inhibit the synthesis of prostaglandins and thus act as mediators of inflammation. The prostaglandins responsible are prostaglandins I_2 and E_2, which are formed as end products of the transformation of arachidonic acid. These prostaglandins are prime peripheral pain receptor sites for further action by histamine and bradykinin. The result of the interaction between prostaglandins and bradykinins or histamines in subcutaneous muscle tissue is immediate pain and inflammation. NSAIDs inhibit the action of prostaglandin synthesis, an intermediary in the transformation of arachidonic acid to prostaglandins (Kantor 1986).

2.5.2.2 PHARMACOLOGICAL PROPERTIES

Diclofenac possesses analgesic, antipyretic and anti-inflammatory activities (Goodman Gilman et al. 1990: 669, Arky 1995:833). Although the exact mechanism of action is unknown (DiPiro 1989:908, Arky 1995:83), the postulated mechanism is that it is an inhibitor of cyclooxygenase (Goodman Gilman et al. 1990: 669).

Cyclooxygenase is the enzyme that catalyses the synthesis of cyclic endoperoxidases from arachidonic acid to form prostaglandins. Each respective NSAID varies in its ability to inhibit cyclooxygenase, however the degree of cyclooxygenase inhibition has not been correlated with anti-inflammatory efficacy in individual patients (Goodman and Simon 1994).

All NSAIDs appear to be absorbed completely, are highly protein bound to albumin (>90%; 99,7% for diclofenac) and have low volumes of distribution. Only 5% of the unchanged drug is excreted in the urine and the bile (DiPiro 1989: 908). The half-lives after single doses vary greatly and are the most variable property of the various NSAIDs. The anti-inflammatory effect generally peaks after 2-3 weeks irrespective of the half-life. However, once a steady state is achieved, saturation of the metabolic pathways increases the half life (DiPiro 1989:908-909, Arky 1995:834, Goodman Gilman et al. 1990: 669, Goodman and Simon 1994).

All NSAIDs appear to be as effective as aspirin in terms of analgesic and anti-inflammatory properties but have shown to cause fewer side effects than aspirin and diclofenac does provide a longer period of analgesia (DiPiro 1989: 908, Arky 1997: 834). NSAIDs penetrate the joint fluid in concentrations generally half those found in the blood (DiPiro 1989:908). Diclofenac accumulates in synovial fluid after administration, which may explain the duration of the therapeutic effect that is, considerably longer than the plasma half-life (Goodman Gilman et al.1990: 669). This makes it an excellent choice for the treatment of facet syndrome since it is available within the joint for maximum effect.

2.5.2.3 INDICATIONS AND THERAPEUTIC USES

Diclofenac is indicated for the acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis (Arky 1997:834). It may be useful for short-term treatment of musculo-skeletal injury (Goodman Gilman et al.1990: 669).

Koes et al. (1997), in their review of randomized clinical trials (n=26) on the efficacy of NSAIDs for low back pain, concluded that NSAIDs are effective for short term symptomatic relief in

patients with uncomplicated low back pain, but are less effective in patients who are suffering from back pain and nerve root symptoms respectively.

2.5.2.4 TOXIC EFFECTS

Diclofenac produces side-effects in approximately 20% of patients with about 2% of patients stopping therapy as a result (Goodman Gilman 1990:669). Gastrointestinal symptoms such as indigestion , nausea and dyspepsia are the most common side-effects associated with diclofenac (Goodman and Simon 1994). In extreme cases, (bleeding and ulceration or perforation of the intestinal wall may occur (Goodman Gilman et al. 1990:669).

Other side-effects as a result of diclofenac administration include central nervous system effects, disturbances of vision, skin rashes, edema and fluid retention, renal function impairment, hepatitis, allergic reactions, aplastic anemia and cardio-vascular problems (Cataflam D package insert: Appendix L).

2.5.2.5 EFFICACY OF DICLOFENAC

According to Goodman Gilman et al. (1990:669) the potency of diclofenac appears to be substantially greater than that of indomethacin, naproxen, or several other agents. In one study of chronic pain in patients with osteoarthritis (n=196) diclofenac 50mg was comparable in efficacy to ibuprofen 800mg (Arky 1997: 834).

In a pharmacy-based survey (n=82) of diclofenac, it was found that the majority of purchases were for musculoskeletal conditions and headache. Over two-thirds of the respondents (71%) indicated either moderate or complete relief of their symptoms after taking diclofenac. Sixteen

percent of the respondents claimed to have experienced adverse reactions from diclofenac usage, however none of these reactions were severe enough to prompt the user to notify his or her pharmacist or doctor. Eighty–three percent of the respondents indicated their willingness to use diclofenac again in the future (Emmerton et al. 1995). When using post-marketing surveillance research methods it would seem that larger sample sizes would be required (>1000), in order to accurately determine the information portrayed in this survey. Other factors influencing the outcome of surveys like this would depend on the quality of data obtained and the efficacy of administration.

The reason that diclofenac has a prolonged antinociceptive effect when compared to other NSAIDs is that there is evidence that this agent is transferred across the synovial membrane to the synovial fluid, from which it is eliminated more gradually than from plasma as compared to other drugs. It has been suggested that the clearance of diclofenac from synovial fluid to blood occurs slowly because the drug binds with high affinity to the albumin that is expropriated into the synovial space in joint disease. Thus, the prolonged effect of diclofenac can be attributed to the notion that it is more readily retained by the albumin-enriched synovial fluid when compared to other NSAIDs (Torres-Lopez et al.1997).

It is however difficult to determine which NSAID is superior to the next, because patient response to the NSAIDs is typically variable and highly individualistic. A patient may respond well to one drug in a particular chemical class but have little or no benefit from another NSAID in the same class (Di Piro 1989: 909).

In a randomized clinical trial ($p<0.05$) comparing the effectiveness of diclofenac, chiropractic manipulation, physiotherapy, bed rest, back school and placebo on low back pain it was found that in acute patients, chiropractic was the superior regime. In patients with chronic low back pain it was found that physiotherapy and back school were the treatment that scored the highest on the mean improvement scale (Postacchini et al. 1988). The above study design correlated with the present study under investigation in terms of comparing diclofenac and SMT for the treatment of chronic thoracic spine pain.

2.6.2.6 SAFETY

The use of NSAIDs is associated with a 2% to 4% annual incidence of serious gastrointestinal complications (Goldstein et al. 1997). Although this incidence is low, the widespread use of these drugs and the fact that patients may suffer major morbidity or mortality means that the possibility of side effects must be taken seriously and looked for (Goodman and Simon 1994). Case control studies suggest that a fifth of all admissions to hospitals in patients over the age of 60 with bleeding gastric or duodenal ulcers is directly attributable to the long term use of NSAIDs (Edwards and Bouchier 1992: 773). It is estimated that, at any given time, the chance of a patient on NSAID therapy having a gastric ulcer is 10% to 20%, a rate 5 to10 times greater than non-users (Dabbs and Lauretti 1995).

2.6 CONCLUSION

It may well be argued that patients are put at unnecessary risk when receiving both NSAIDs and thoracic manipulation for the treatment of thoracic facet syndrome. This is certainly true. Goodman and Simon (1994) suggest that it is important to be wary of patients who are on non-

prescription NSAIDs, who often have not informed their physicians. Emmerton et al. (1995), in their findings, report that of the people surveyed who purchased diclofenac over the counter, 58.4% were using it for the relief of musculoskeletal pain. Chiropractic has become synonymous with the treatment of musculoskeletal treatment (Haldeman 1992). It seems logical that those who primarily treat musculoskeletal conditions should have some control over NSAID administration to patients. This could ensure proper screening of potential users, and thereby decreasing the possibility of NSAID abuse by nonprescription users (Goodman and Simon 1994).

Perhaps a study of this nature is premature by combining two treatment protocols together for the treatment of thoracic pain. Some may argue that we should rather endeavor to find better chiropractic techniques for the treatment of thoracic pain, instead of leaning on allopathic medicine for the answers. Perhaps chiropractic research should also rather focus on the justification and efficacy of chiropractic care.

However, according to Haldeman (1992), medical and chiropractic researchers should no longer work in isolation. Controlled trials of various medical and chiropractic treatment approaches are going to have to increase so that decisions can be reached as to when medical intervention is appropriate and when it is not. With the uprising cost of medication, chiropractic treatment may prove to be more cost-effective in the long-term management of chronic pain. Chiropractic treatment for pain in the chronic stages would be well supplemented by the use of NSAID's, for the benefit of the patient.

The fact that chiropractic science has survived in an era of overwhelming dominance of spinal research by medical scientists, which is of worldwide acceptance, is a tribute to the chiropractic profession (Haldeman 1992).

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 INTRODUCTION

This chapter gives a detailed description of the design, primary and secondary data, the subjects and intervention utilized. An overview of each questionnaire used and the validity of each measurement parameter are discussed. The methods used for statistical analysis and the process in which the data was evaluated is also included.

The study design chosen was that of a double blind, comparative, clinical trial. This involved two treatment groups, with both groups receiving chiropractic manipulation and each group receiving either NSAID's or placebo medication respectively.

3.2 THE DATA

The data consisted of primary and secondary data.

3.2.1 The primary data

- The case history, physical examination and thoracic regional examination of the patients used in this study.
- The patient's perception of their disability (Oswestry Back Pain Questionnaire) (Appendix I).
- The patient's perception of the level of their pain (Numerical Pain Rating Scale-101) (Appendix H).
- The patient's perception of the sensory dimension of their pain (McGill Short-Form Pain Questionnaire) (Appendix J).

- The range of motion in the thoracic spine was measured with a goniometer (Brom II).

3.2.2 The secondary Data

Relevant literature was obtained from various sources, including journal articles, books, pharmaceutical research, Medline, Mantis, the Internet and its relevant search engines.

3.3 THE SUBJECTS

The patients were invited to participate in the research study by means of advertisements placed on notice boards in gyms, corporate offices and tertiary institutions in the greater Durban area. Sixty patients were selected from those who responded and randomly assigned to either Group A or Group B. No bias was given to gender, racial group, occupation or economic status of the patient.

Each research patient who presented to the Technikon Natal Chiropractic Clinic with chronic mid-back pain was given a brief assessment to determine if they would be a suitable candidate for the study. This assessment consisted of questions pertaining to the nature and progression of the pain and the presence of any hard neurological signs and symptoms as contained in Appendix A.

If the patient was deemed likely by the researcher to meet criteria necessary for acceptance into the study, he or she underwent a case history (Appendix E), physical examination (Appendix F) and a thoracic spine regional examination (Appendix G).

3.4 INCLUSION AND EXCLUSION CRITERIA

The criteria were as follows:

- Only patients between the ages of sixteen to sixty were included.
- Only patients diagnosed by the researcher as having mechanical thoracic spine pain were included in the study.
- From the case history, physical examination, thoracic regional examination the patients had to meet the criteria necessary for a diagnosis of thoracic facet syndrome as advocated by Schafer and Faye (1990:150-159) and Bergmann et al. (1993:63).
    - Pain or tenderness over the involved osseous and soft tissue areas,
    - Asymmetry/misalignment qualities identified through observation and static palpation,
    - Range of motion restriction identified actively and through motion palpation,
    - Palpable tissue tone differences over the area of dysfunction,
    - Special tests that include a positive Kemps test and facet joint challenge, done at the level of dysfunction.
- Using motion palpation a thoracic fixation was found in one or more directions for inclusion of the subjects into the study.
- Patients were asked to refrain from taking analgesics and receiving other treatment for their condition or any other co-existing condition during the research period. They were asked to inform the researcher if this was the case.
- Those patients with active or latent myofascial trigger points were not excluded from the study.

- Any condition that contra-indicated NSAID administration resulted in the patient being excluded from the study.
- Patients taking aspirin, anti-coagulants, digoxin, methotrexate, cyclosporin, lithium, oral hypoglycemics, diuretics or Phenobarbital were not included in the study due to the varied interaction these drugs have with the medication to be used viz. diclofenac (Arky 1997:835-6).
- If any patient developed side effects (Arky 1997:836) related to the medication given, such a patient was excluded from the study.
- Patients with osteoporosis, inflammatory arthritides or any condition contra-indicating spinal manipulation were excluded from the study.

3.5 ETHICS

Each patient was required to complete and sign an informed consent form (Appendix B); prior to the commencement of treatment. Each patient was told the precise nature of the study, including the possible side effects of manipulation and the NSAID used. They were informed that they had a 50% chance of receiving placebo or real medication. The patients were free to withdraw from the study at anytime and for whatever reason they so wished.

3.6 THE SAMPLE GROUP

The sample group consisted of 60 patients that were conveniently selected that conformed to the admission criteria governing the study, and was randomly divided into 2 groups of 30 each. An objective observer was appointed by the researcher who then conducted the randomization procedure, as this study was of a double-blind nature. Groups A and B were identified by placing numbers 1-30 in envelope 1 and an equal number of A's and B's in envelope 2. Prior to this, A

and B were deemed by the objective observer as either the experimental (NSAID) or control placebo medication group. As each number was drawn from envelope 1 a corresponding letter was drawn from envelope 2. The sequence was then given to the researcher prior to the commencement of the study. This allowed the researcher to know which sachet (labelled A or B) to give to each patient. The letter A or B indicating either the NSAID or placebo medication was inscribed on each set of 30 sachets. The nature of group A or B was withheld from the researcher by the objective observer until the study was completed.

3.7 ASSESSMENTS

Those patients eligible for the study were required to complete the NRS-101 (Jensen et al. 1986), the Short-Form McGill Pain Questionnaire (Melzack 1987) and the Oswestry Back Pain Disability Questionnaire (Fairbank et al. 1980) at the initial and final treatment. The thoracic spine range of motion was measured by using a goniometer produced by Performance Attainment Associates (St. Paul, MN). Measurements were taken prior to the commencement of the first, third and sixth treatments.

3.8 INTERVENTIONS

Every patient who qualified to participate in the study received 6 treatments over a period of 3 weeks. If the patient became asymptomatic before the final treatment, the patient continued to be assessed and treated for the remainder of the treatment period.

As it transpired, patients in Group A were treated using SMT and received placebo medication. Patients in Group B were treated using SMT and received NSAIDs.

3.8.1 SPINAL MANIPULATIVE THERAPY

Both treatment groups received standard, manual thrust, chiropractic adjustments to the thoracic spine. The level and direction of the thrust was chosen according to motion palpation findings. With all manipulative techniques the joint slack was taken out to the elastic barrier and a high velocity, low amplitude thrust was delivered at the level, and in the direction, of the loss of joint motion (fixation).

The manipulations employed were diversified techniques according to the "Compendium of Chiropractic Technique" (Szaraz 1990:96,98,102,103).

HYPOTHENAR THENAR TRANSVERSE (Szaraz 1990)

This technique is indicated for either extension or rotation dysfunctions from T1-T12.The patient is prone lying with headpiece adjusted in neutral. Contact with the hypothenar eminence is made with the caudad hand by the doctor on the side of the lesion. Contact hand is against the facet joint or transverse process while the indifferent hand is placed on the contra lateral TVP of the same vertebra. Line of drive is posterior to anterior. A body drop thrust is applied at the point of joint resistance.

CROSSED BILATERAL (Szaraz 1990)

This technique is used for rotation type dysfunctions of T4-T12. The patient lies prone with the doctor on the side of the lesion facing cephalad. The final position for the doctor's torso is determined by the level of the lesion and the patient's dorsal curve. A pisiform contact onto the ipsilateral TVP is taken up. The indifferent hand (superior hand) is crossed over the contact hand and placed on the contralateral TVP. Joint and soft tissue slack is taken up in a cephalad

direction with the contact hand. A single, high velocity body drop type thrust in a cephalad direction along the facet facings is executed.

STERNAL SPINOUS STANDING OR SEATED (Szaraz 1990)

This technique is indicated for extension, rotation or lateral flexion fixations. The patient is standing or seated with arms crossed, neck and upper thoracic spine is flexed. Doctor stands behind the patient. A sternal contact onto the tip of the fixated spinous process is taken up by the doctor. Both hands of the doctor wrap around the patient and contract their folded arms. Thrust is inferior to superior and posterior to anterior. Patient is positioned into the direction of the fixation i.e. with extension fixation, the patient is positioned in extension. Joint slack is taken out till resistance is felt and a thrust with the sternum is applied by the doctor, hyper extending his thoracic spine.

ANTERIOR SUPINE FIST (Szaraz 1990)

This technique is indicated for extension fixations. The patient is supine with the arms crossed over the chest. The doctor assumes a lunge position facing cephalad. A fist contact is taken with the knuckles on one side of the spinous process and the thenar on the other side. Thrust is inferior to superior with the fist as you thrust from anterior to posterior on the chest. The patient is positioned in extension with the head and neck extended. Joint slack is taken out till resistance is felt and a body drop thrust is applied through the arms.

3.8.2 MEDICATION

The NSAID used in this study was a diclofenac-based preparation(diclofenac acid-free 46.5mg equivalent to diclofenac sodium 50mg) with the trade name of Cataflam, which was used for the following reasons (Arky 1997:833) :

-Measurable plasma levels are observed within 10 minutes of dosing with peak plasma levels occurring in one hour.

- Cataflam diffuses into and out of synovial fluid.
- Cataflam comes in convenient blister packs and can be taken on an empty stomach or with food, which can improve patient compliance.
- In one study of chronic pain, in patients with osteoarthritis (N=196), Cataflam was comparable in efficacy to ibuprofen 800mg and diclofenac delayed-release tablets 50mg.
- Novartis, the pharmaceutical company that manufactures the product, kindly agreed to sponsor the medication for this trial.
- It is classed as a NSAID and is a freely available over the counter drug.

The NSAID tablets were individually crushed using a pestle and mortar and placed in identical empty paper sachets. The placebo medication consisted of lactose powder with a pinch of salt added to make the taste somewhat similar to the NSAID being used. The placebo medication was then also placed in the same type of sachets the NSAID medication was contained in.

The dosage for patients in the experimental group was 139.5mg per day (three crushed tablets) of Cataflam over five days. Each daily dosage was taken in three separate doses at equally spaced intervals. Patients in the placebo group took the same number of sachets and for the same duration as those in the experimental group. Each patient was required to complete a medication diary (Appendix M).

3.9 MEASUREMENTS

3.9.1 OBJECTIVE MEASUREMENTS

The objective data was obtained by means of a goniometer. The readings were taken before the commencement of the first, third and sixth treatments and was recorded on the form provided (Appendix K).

3.9.1.1 The Goniometer

The BROM II produced by Performance Attainment Associates (St. Paul, MN) was used to measure thoracic ranges of motion in flexion, extension, bilateral rotation and bilateral lateral flexion. The ranges of motion were measured in degrees according to the protocol laid out in the manufacturers procedure manual. The BROM II was found to be a reliable instrument in the measurement of mobility in forward flexion and lateral flexion of the lumbar spine, in a study conducted by Breum et al. (1995) using 47 asymptomatic subjects. Rotation and extension received less support. Although, for the purpose of this study BROM II was used to measure movement in the thoracic spine, subsequent movement in the lumbar spine cannot be overlooked.

3.9.2. SUBJECTIVE MEASUREMENTS

3.9.2.1 Oswestry Back Pain Disability Questionnaire (Fairbanks et al.1980)

This questionnaire indicates how their pain affects the everyday life of the patient. It determines the amount of disability experienced by the patient.Triano et al. (1993) used 145 patients to test-retest the reliability and validity of six questionnaires. Overall, the Oswestry and Visual

Analogue pain scale were both more reliable and valid than other questionnaires. They were also the most responsive to clinical change for musculoskeletal disorders. Fairbanks et al. (1980) in a group of 25 patients found this questionnaire to be a valid and reliable indicator of the disability experienced by the patient.

The patient answers 10 sections, each with 6 questions on the Oswestry questionnaire. Each question scores a maximum of 5 points and a minimum of 0. The total score is therefore out of 50 and is represented as a percentage disability. This percentage was recorded for statistical analysis.

3.9.2.2 McGill Short-Form Pain Questionnaire (Melzack 1987)

The McGill Short-Form Questionnaire (Melzack 1987) is a subjective questionnaire that pertains specifically to the sensory and affective dimensions of pain. It is used to measure the extent of pain experienced by the patient. The questionnaire is divided into two sections. Questions 1-11 represent sensory dimension of pain and question 12-15 represents the affective dimension; it assesses the behavioral and emotional aspects of pain. Each adjective was ranked on an intensity scale of :- 0=none, 1=mild, 2=moderate, 3=severe. The sum of all the completed sections were calculated and given a percentage of the highest possible score. If all sections were completed the highest possible score was forty-five and decreased by three for each section not completed.

3.9.2.3 Numerical Pain Rating Scale-101 Questionnaire (Jensen et al. 1986)

This questionnaire is extremely simple to administer (written or verbal) and score, it assesses with ease the patient's perceived level of pain intensity. Jensen et al. (1986) established its

validity and reliability when providing subjective information about pain levels. The NRS-101 consists of asking the patient to rate their perceived level of pain intensity on a numerical scale from 0-100, with 0 being no pain and 100 being the worst pain. The patient indicates by means of a percentage on a 10cm line, when the pain was at its worst and again when it was at its least. The average pain intensity was calculated by adding the percentages representing the worst pain and the least pain and then dividing the total by two. The average pain intensity values were then used for statistical analysis.

3.10 STATISTICAL PROCEDURES

The Statistical Package for the Social Sciences, SPSS, (version 9.0) was used for data entering analysis.

3.10.1 Inter-group comparison (experimental versus control)

Since the sample size was large ($n \geq 30$) the t-test was used to compare groups A and B with respect to each variable of interest. In each test, the null hypothesis states that there is no difference between groups A and B with respect to the variable under consideration, at the α=0.05 level of significance. The alternative hypothesis is that there is a difference.

The decision rule: The null hypothesis is rejected at the α level of significance if $p < \alpha/2$ where p is the observed level of significance or P-value. Otherwise, the null hypothesis is accepted at the same level.

3.10.2 Experimental: intra-group comparison

The paired-t test was used to compare results from related samples in each of the 6 clinical procedures in the study. In each test, the null hypothesis states that there is no statistically significant difference between the two related samples being compared, at the α level of significance. The alternative hypothesis states that there is a difference.

Decision rule: The null hypothesis is rejected at the α 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.

3.10.3. Control: intra-group comparison

The procedure in 3.10.2 was repeated within the control group with the same decision rule.

3.10.4 Summary statistics

The summary statistics consisted of medians, averages and variances for each variable of the study. These results were needed for the construction of bar charts.

3.10.5. Comparison using bar charts

Selected visual summaries of analytical findings were given by the use of bar charts to compare groups A and B with respect to selected variables of interest. Median readings were used to construct bar charts.

CHAPTER FOUR

4.0 THE RESULTS

4.1 INTRODUCTION

This chapter covers the results obtained from the statistical analysis of the subjective and objective data, for both the control and experimental group.

Control group – manipulation and placebo (Group A)

Experimental group – manipulation and NSAIDs (Group B)

4.2 DISCUSSION OF THE RECRUITMENT

A total of seventy-five people were screened, of which sixty were accepted into the study. The fifteen patients were excluded either because of failure to complete the treatment (8), presence of urinary infection (1), development of influenza after the 5th treatment (1), adverse reaction to the medication (5).

4.3 DEMOGRAPHIC DATA

Table 4.1 Gender Distributions:

GENDER	GROUP A	GROUP B	TOTAL
MALES	10 (33%)	6 (20%)	16 (27%)
FEMALES	20 (67%)	24 (80%)	44 (73%)

The overall male: female ratio was 4:11.

Table 4.2 Age Distributions:

AGE INTERVALS	GROUP A	GROUP B	TOTAL
16-24	10	6	16 (27%)
25-34	8	9	17 (28%)
35-44	2	2	4 (7%)
45-54	8	10	18 (30%)
55-64	2	3	5 (8%)

The average age for group A was 35.2 years.

The average age for group B was 37.3 years.

The average age for group A and B was 36.2 years.

Table 4.3 Occupation of patients

GROUP A	N	%	Group B	N	%
Laundry Supervisor	2	7	Caterer	1	3
Student	8	27	Student	8	27
Pharmacist	1	3	Pharmacist	1	3
Administration Officer	1	3	Electrician	1	3
Truck Driver	1	3	Teacher	1	3
Sales Representative	2	7	Domestic Worker	1	3
Matron Nurse	1	3	Field Marketer	1	3
Bank Clerk	1	3	Insurance Consultant	1	3
Staff Nurse	1	3	Gymnast	1	3
Librarian	1	3	Receptionist	1	3
Scholar	1	3	Hairdresser	1	3
Accountant	1	3	Retired saleslady	1	3
Packer	1	3	Crèche Supervisor	1	3
Unemployed	1	3	Unemployed	1	3
Self-employed	2	7	Self-employed	1	3
Housewife	5	17	Housewife	8	27

Table 4.4 Race distributions:

RACE	GROUP A	GROUP B
INDIAN	25	23
BLACK	1	3
WHITE	3	3
COLOURED	1	1

TABLE 4.5 Presence of fixations at the different thoracic spine levels:

THORACIC SPINE LEVELS	GROUP A	GROUP B
T1-3	10	13
T4-8	29	30
T9-12	4	2

The most prevalent fixation was found to be in extension.

The prone bilateral hypothenar technique was the commonest adjustment technique used.

Of incidental finding, most women with a heavy breast structure seemed to complain of chronic dull mid-back pain. Two patients from group A and three patients from group B reported having breast reduction surgery due to their mid-back pain.

4.4 THE ANALYSED DATA

P-VALUE $\alpha = 0.05$

For the one-tailed tests:

Reject H_0 if $P \leq \alpha$

Accept H_0 if $P > \alpha$

As $\alpha=0.05$, the P-value must be less than or equal to 0.05 in order to reject Ho.

For the two-tailed tests:

Reject H_0 if $P \leq \alpha/2$

Accept H_0 if $P > \alpha/2$

P was the observed level of significance

As $\alpha/2 = 0.025$, the P-value must be less than or equal to 0.025 in order to reject H_0.

4.4.1 The Inter-group analysis using the t- tests:

Table 4.4 **Comparison of groups A and B using the Unpaired t-test to analyse the results collected from the subjective data at treatment one and six**

OSWESTRY AND McGill QUESTIONNAIRES									
	GROUP A					GROUP B			
	MEDIAN	MEAN	S.E.	S.D.	P-VALUE	MEDIAN	MEAN	S.E.	S.D.
OSW1	10	11.8	1.56	8.58	0.176	14	14.93	1.66	9.13
McGILL1	6	8.03	1.27	6.97	0.319	4.5	6.40	1.27	5.53
OSW6	2	6.50	1.71	9.40	0.741	4	5.80	1.22	6.71
McGILL6	2	1.56	0.76	4.20	0.085	0	1.56	0.56	3.07

The null hypothesis is accepted for Oswestry Back Pain Questionnaire and Short Form McGill Pain Questionnaire which indicates that at $\alpha = 0.05$ level of significance there was no statistically significant difference between groups one and two at treatments one and six.

Table 4.5 **Comparison of groups A and B using the Unpaired t-test to analyse results collected from the objective data at treatment one**

TREATMENT ONE									
	GROUP A					GROUP B			
	MEDIAN	MEAN	S.E.	S.D.	P-VALUE	MEDIAN	MEAN	S.E.	S.D.
FLEX	10	11.2	0.76	4.19	0.771	10	10.83	0.99	5.45
EXT	10	9.0	0.60	3.33	0.870	10	9.00	0.60	3.33
R.LAT.FLEX	20	19.7	1.06	5.81	0.503	20	19.7	1.06	5.81
L.LAT.FLEX	20	20.06	1.02	5.61	0.156	20	20.06	1.02	5.61
R.ROT	20	22.03	1.15	6.34	0.682	20	22.03	1.15	6.34
L.ROT	20	22.0	1.48	8.15	0.307	20	22.00	1.48	8.15

The null hypothesis is accepted for all the thoracic ranges of motion as there were no statistically significant differences at treatment one for both groups.

Table 4.6 **Comparison of groups A and B using the Unpaired t-test to analyse results collected from the objective data at treatment three**

TREATMENT THREE									
	GROUP A					GROUP B			
	MEDIAN	MEAN	S.E.	S.D.	P-VALUE	MEDIAN	MEAN	S.E.	S.D.
FLEX.	10	11.4	0.58	3.19	0.690	10	11.0	0.80	4.43
EXT.	10	10.0	0.71	3.93	0.854	10	9.86	0.73	4.00
R.LAT.FLEX.	20	19.5	0.87	4.76	0.448	20	18.66	0.79	4.34
L.LAT.FLEX.	20	19.6	0.78	4.30	0.329	20	18.53	0.79	4.36
R.ROTN.	20	20.9	1.22	6.72	0.356	20	22.6	1.35	7.39
L.ROTN.	20	19.8	1.09	5.97	0.449	20	21.00	1.13	6.21

The null hypothesis is accepted for all the thoracic ranges of motion as there was no statistically significant difference at treatment three for both groups.

Table 4.7 **Comparison of groups A and B using the Unpaired t-test to analyse results collected from the objective data at treatment six**

TREATMENT SIX									
	GROUP A					GROUP B			
	MEDIAN	MEAN	S.E.	S.D.	P-VALUE	MEDIAN	MEAN	S.E.	S.D.
FLEX.	12.5	13.66	1.01	5.56	0.744	15	14.1	0.84	4.64
EXT.	10	10.83	0.73	4.02	0.891	10	11.0	0.73	4.02
R.LAT.FLEX	20	20.00	0.58	3.19	0.700	20	20.3	0.58	3.19
L.LAT.FLEX.	20	19.66	0.79	4.36	0.402	20	20.33	0.58	3.19
R.ROTN.	20	24.00	1.32	7.23	0.986	20	24.00	1.32	7.23
L.ROTN.	20	22.13	1.37	7.54	0.985	20	22.16	1.16	6.39

The null hypothesis is accepted for all thoracic ranges of motion as there was no statistically significant difference at treatment six for both groups.

Table 4.8 **Comparison of groups A and B using the Unpaired t-test to analyse results from the Numerical Rating Scale 101 at treatments one and six**

NUMERICAL RATING SCALE-101									
	TREATMENT 1					TREATMENT 6			
	MEDIAN	MEAN	S.E.	S.D.	P-VALUE	MEDIAN	MEAN	S.E.	S.D.
NRS1	45	43.60	2.08	11.39	0.317	40	40.43	2.34	12.86
NRS6	25	25.43	3.21	17.61	0.393	22.5	21.70	2.84	15.59

The null hypothesis is accepted for the numerical rating scale 101 as there was no statistically significant difference for both groups at treatment one and six.

4.4.2 The Intra-group analysis using the Paired t-tests:

Table 4.9 Comparison of results within group A using the Paired t-test to analyse subjective data collected between treatment one and six

GROUP A									
	TREATMENT 1					TREATMENT 6			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
OSW	10	11.8	8.58	1.56	0.001	2	6.50	9.40	1.71
SFM	6	8.03	6.97	1.27	0.001	2	3.23	4.20	0.76

The null hypothesis is rejected for Oswestry Back Pain Questionnaire and the Short Form McGill Questionnaire, which indicate that at the α=0.05 level of significance there was a statistically significant improvement between treatments one and six.

Table 4.10 **Comparison of results within group A using the Paired t-test to analyse objective data between treatment one and three**

GROUP A									
	TREATMENT 1					TREATMENT 3			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
FLEXION	10	11.20	4.19	0.76	0.763	10	11.40	3.19	0.58
EXTENSION	10	9.00	3.33	0.60	0.301	10	9.66	4.34	0.79
R.LAT.FLEX.	20	19.70	5.81	1.06	0.912	20	19.56	4.76	0.87
L.LAT.FLEX.	20	20.06	5.61	1.02	0.735	20	19.63	4.30	0.78
R.ROTN	20	22.03	6.34	1.15	0.492	20	20.96	6.72	1.22
L.ROTN	20	22.00	8.15	1.48	0.169	20	19.8	5.97	1.09

The null hypothesis is accepted as there was no significant difference between treatment one and three for thoracic ranges of motion in group one.

Table 4.11 Comparison of results within group A using the Paired t-test to analyse objective data between treatment three and six

GROUP A									
	TREATMENT 3					TREATMENT 6			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
FLEXION	10	11.40	3.19	0.58	0.053	12.5	13.66	5.56	1.01
EXTENSION	10	9.66	4.34	0.79	0.129	10	10.83	5.26	0.96
R.LAT.FLEX.	20	19.56	4.76	0.87	0.556	20	20.00	3.47	0.63
L.LAT.FLEX.	20	19.63	4.30	0.78	0.967	20	19.66	2.91	0.53
R.ROTN.	20	20.96	6.72	1.22	0.055	20	23.96	7.91	1.44
L.ROTN.	20	19.80	5.97	1.09	0.112	20	22.13	7.54	1.37

The null hypothesis is accepted as there was no significant difference between treatment three and six for thoracic ranges of motion in group one.

Table 4.12 **Comparison of results within group A using the Paired t-test to analyse objective data between treatment one and six**

GROUP A									
	TREATMENT 1					TREATMENT 6			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
FLEXION	10	11.20	4.19	0.76	**0.034**	12.5	13.66	5.56	1.01
EXTENSION	10	9.00	3.33	0.60	**0.032**	10	10.83	5.26	0.96
R.LAT.FLEX.	20	19.70	5.81	1.06	0.814	20	20.00	3.47	0.63
L.LAT.FLEX.	20	20.06	5.61	1.02	0.721	20	19.66	2.91	0.53
R.ROTN.	20	22.03	6.34	1.15	0.218	20	23.96	7.91	1.44
L.ROTN.	20	22.00	8.15	1.48	0.938	20	22.13	7.54	1.37

The null hypothesis is rejected at the $\alpha = 0.05$ level of significance for flexion and extension, therefore demonstrating an improvement between treatment one and six for group A.

The null hypothesis is accepted for right and left lateral flexion and right and left rotation and therefore there was no difference between treatment one and six for group A.

Table 4.13 Comparison of results within group A using the Paired t-test to analyse NRS-101 between treatment one and six

GROUP A									
	TREATMENT 1					TREATMENT 6			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
NRS101	45	43.60	11.39	2.08	**0.000**	25	25.43	17.61	3.21

The null hypothesis is rejected for NRS-101, which indicate that at the α=0.05 level of significance there was a statistically significant objective improvement between treatment one and six for group 1.

Table 4.14 Comparison of results within group B using the Paired t-test to analyse subjective data collected between treatment one and six

GROUP B									
	TREATMENT 1					TREATMENT 6			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
OSW	14	14.93	9.13	1.66	**0.000**	4	5.8	6.71	1.22
SFM	4.5	6.40	5.53	1.00	**0.000**	0	1.56	3.07	0.56

The null hypothesis is rejected for the Oswestry Back Pain Questionnaire and Numerical Pain Rating Scale101 Questionnaire, which indicate that at the α=0.05 level of significance there was a statistically significant improvement between treatments one and six for group B.

Table 4.15 Comparison of results within group B using the Paired t-test to analyse objective data collected between treatment one and three

GROUP B									
	TREATMENT 1					TREATMENT 3			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
FLEXION	10	10.83	5.45	0.99	0.854	10	11.00	4.43	0.80
EXTENSION	10	9.16	4.44	0.81	0.301	10	9.86	4.00	0.73
R.LAT.FLEX.	20	18.80	4.44	0.81	0.903	20	18.66	4.34	0.79
L.LAT.FLEX.	20	18.03	5.33	0.97	0.612	20	18.53	4.36	0.79
R.ROTN.	20	21.33	6.81	1.24	0.326	20	22.66	7.39	1.35
L.ROTN.	20	20.13	5.63	1.02	0.489	20	21.00	6.21	1.13

The null hypothesis is accepted, as there was no statistically significant difference for thoracic ranges of motion in group B.

Table 4.16 Comparison of results within group B using the Paired t-test to analyse objective data collected between treatments three and six

GROUP B									
	TREATMENT 3					TREATMENT 6			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
FLEXION	10	11.00	4.43	0.80	**0.000**	15	14.11	4.64	0.84
EXTENSION	10	9.86	4.00	0.73	0.141	10	11.00	4.02	0.73
R.LAT.FLEX.	20	18.66	4.34	0.79	0.057	20	20.33	3.19	0.58
L.LAT.FLEX.	20	18.53	4.36	0.79	0.107	20	20.33	3.19	0.58
R.ROTN.	20	22.66	7.39	1.35	0.293	20	24.00	7.23	1.32
L.ROTN.	20	21.00	6.21	1.13	0.409	20	22.16	6.39	1.16

The null hypothesis is rejected at the α=0.05 level of significance for flexion, therefore demonstrating an improvement between treatment one and three for group B. The null hypothesis is accepted for extension, right and left lateral flexion, right and left rotation and therefore there was no significant difference between treatment one and three for group B.

Table 4.17 Comparison of results within group B using the Paired t-test to analyse objective data collected between treatment one and six

GROUP B									
	TREATMENT 1					TREATMENT 6			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
FLEXION	10	10.83	5.45	0.99	**0.003**	15	14.10	4.64	0.84
EXTENSION	10	9.16	4.44	0.81	**0.031**	10	11.00	4.02	0.73
R.LAT.FLEX.	20	18.88	4.44	0.81	0.086	20	18.80	4.44	0.81
L.LAT.FLEX.	20	18.03	5.33	0.97	0.060	20	20.33	3.19	0.58
R.ROTN.	20	21.33	6.81	1.24	0.103	20	24.00	7.23	1.32
L.ROTN.	20	20.13	5.63	1.02	0.190	20	22.16	6.39	1.16

The null hypothesis is rejected at the α=0.05 level of significance for flexion and extension, therefore demonstrating an improvement between treatment one and six for group B.

The null hypothesis is accepted for right and left lateral flexion, right and left rotation and therefore there was no difference between treatment one and six for group B.

Table 4.18 Comparison of results within group B using the Paired t-test to analyse NRS-101 collected between treatment one and six

GROUP B									
	TREATMENT 1					TREATMENT 6			
	MEDIAN	MEAN	S.D.	S.E.	P-VALUE	MEDIAN	MEAN	S.D.	S.E.
NRS101	40	40.43	12.86	2.34	**0.000**	22.5	21.73	15.59	2.84

The null hypothesis is rejected at the α=0.05 level of significance for the Numerical Rating Scale 101, therefore demonstrating an improvement between treatment one and six for group B.

4.5 BARCHARTS

Figures 4.1-4.9 are visual representations of the median value changes of group A and group B found within the first, third and sixth consultations. These values are not meant to be used to draw comparisons between the two groups but are given to show possible trends.

Figure 4.1

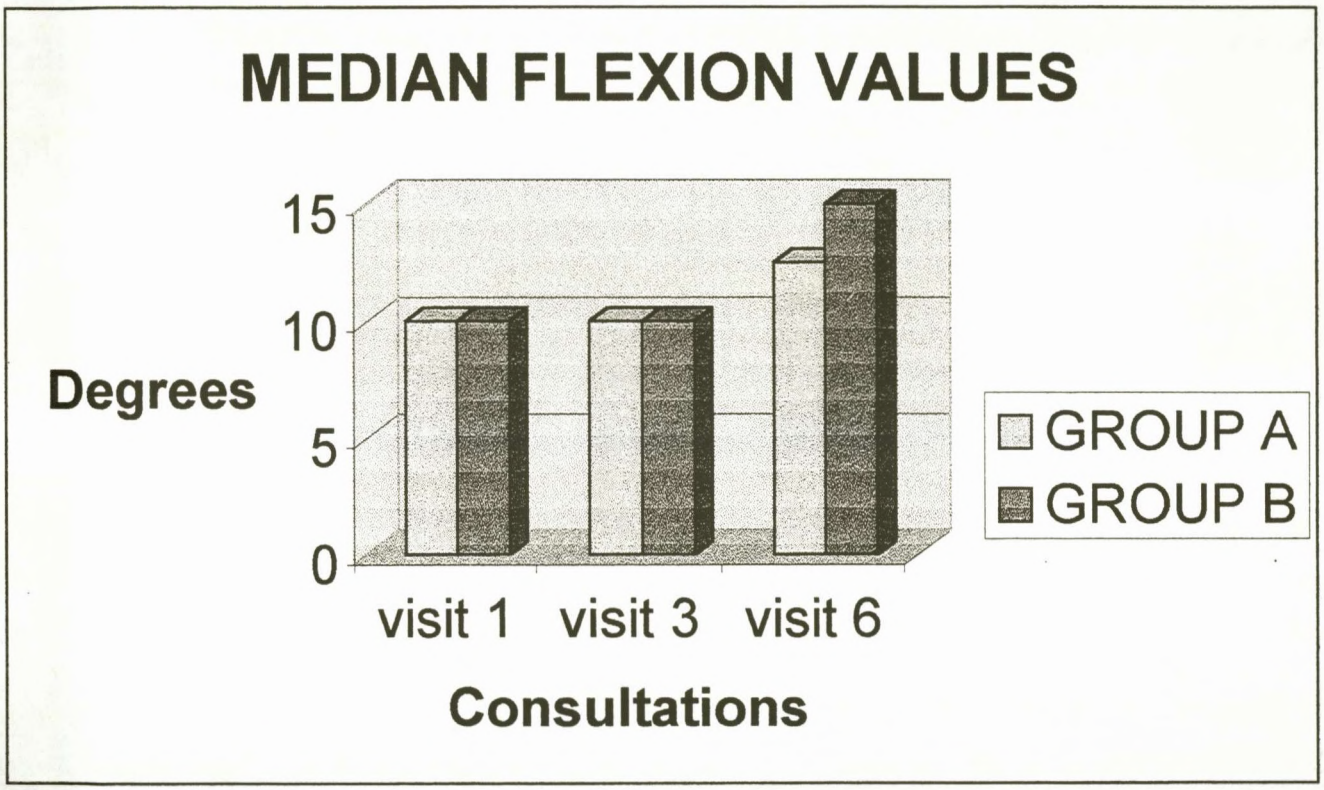

MEDIAN FLEXION VALUES
Degrees
15
10
5
0
visit 1
visit 3
visit 6
Consultations
GROUP A
GROUP B

Figure 4.2

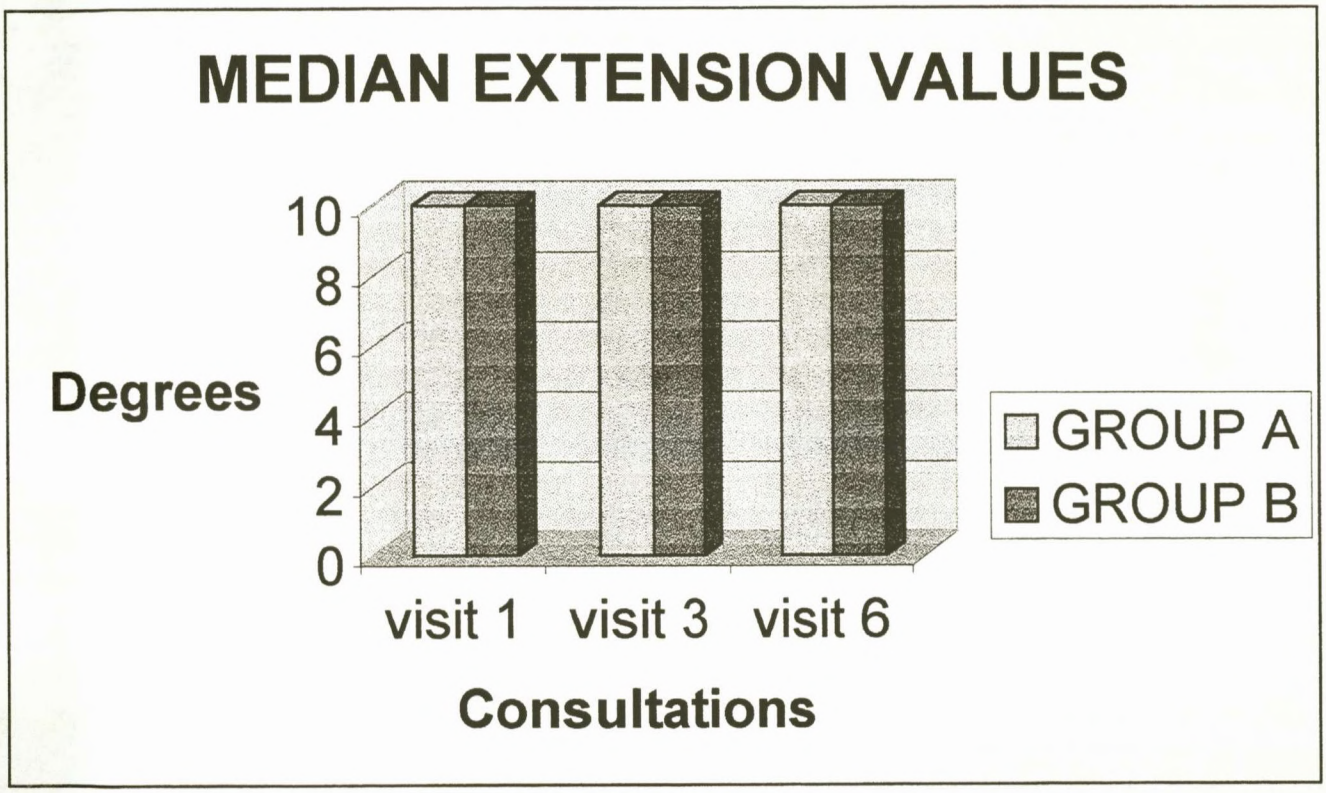

MEDIAN EXTENSION VALUES
Degrees
10
8
6
4
2
0
visit 1
visit 3
visit 6
Consultations
GROUP A
GROUP B

Figure 4.3

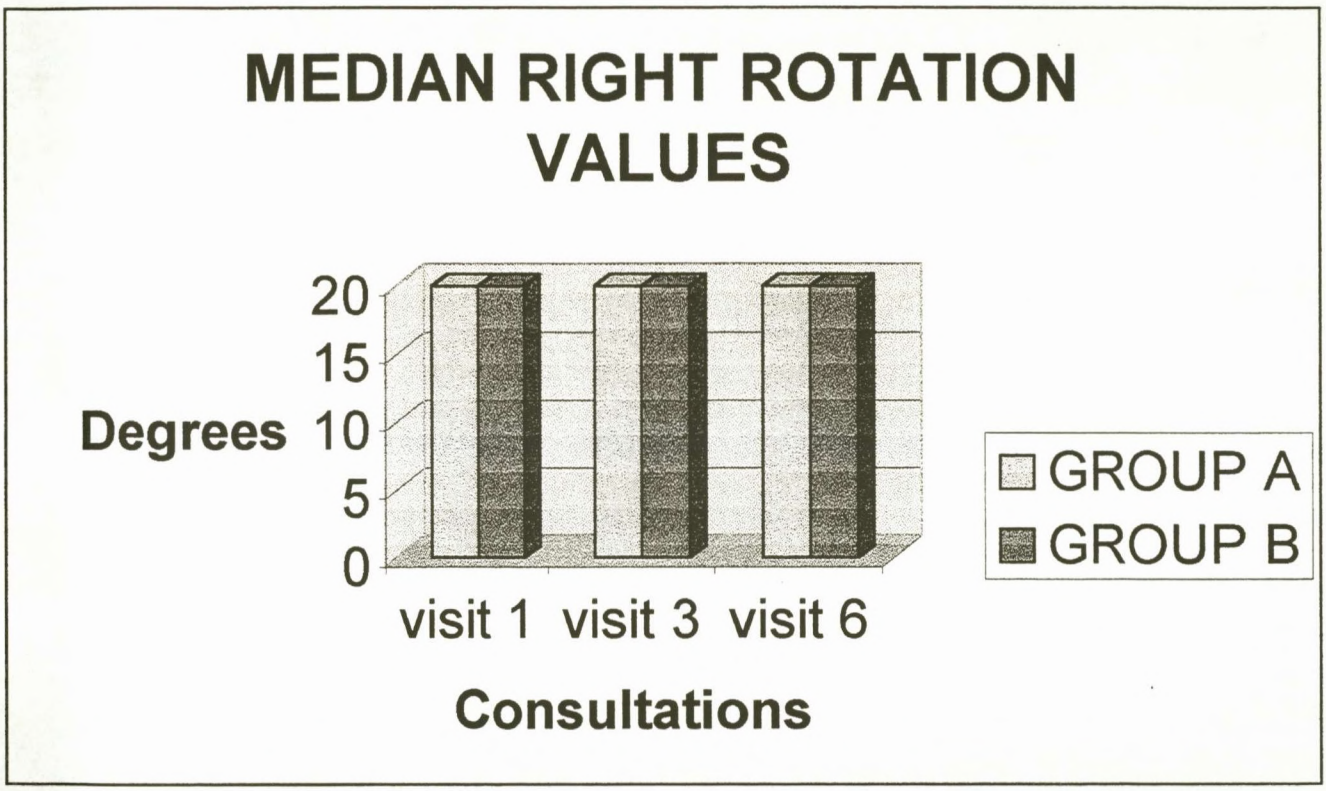

MEDIAN RIGHT ROTATION VALUES
Degrees
20
15
10
5
0
visit 1
visit 3
visit 6
Consultations
GROUP A
GROUP B

Figure 4.4

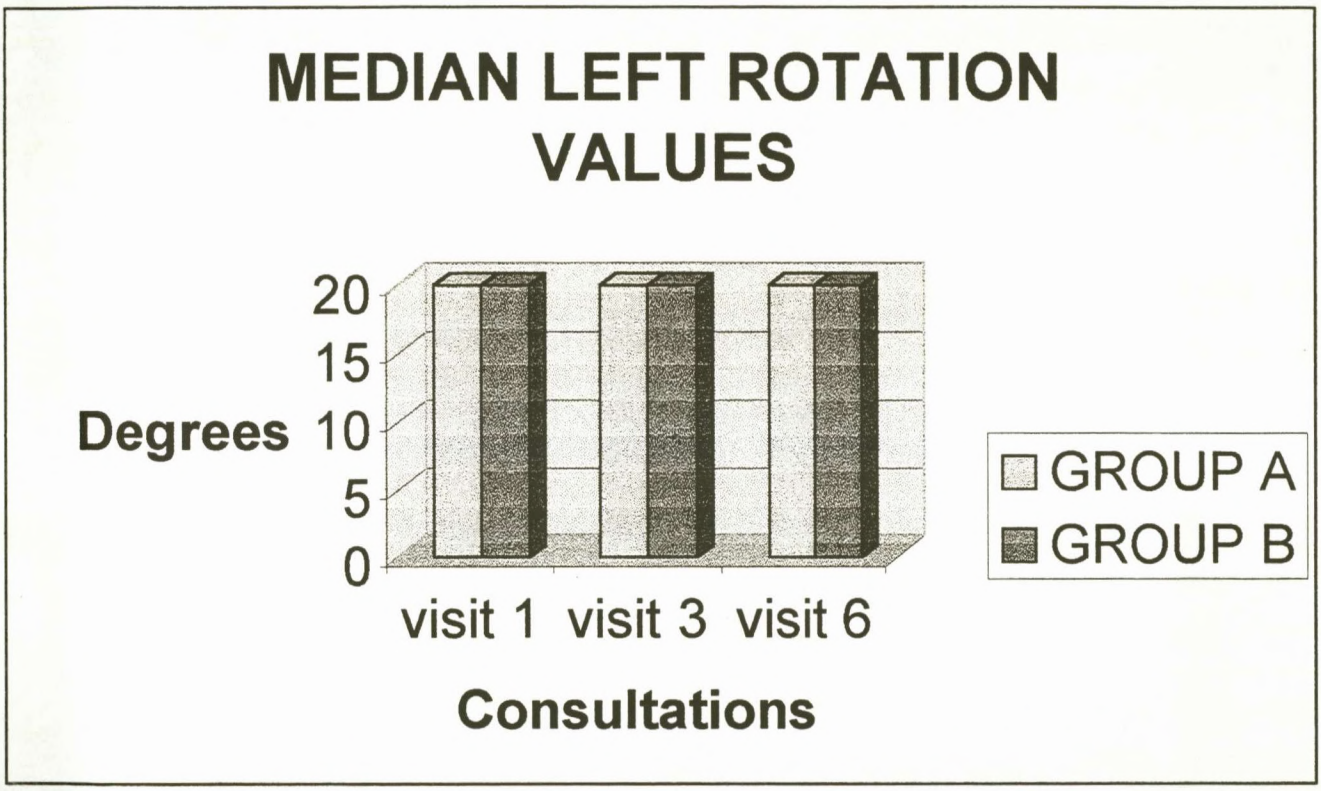

MEDIAN LEFT ROTATION VALUES
Degrees
20
15
10
5
0
visit 1
visit 3
visit 6
Consultations
GROUP A
GROUP B

Figure 4.5

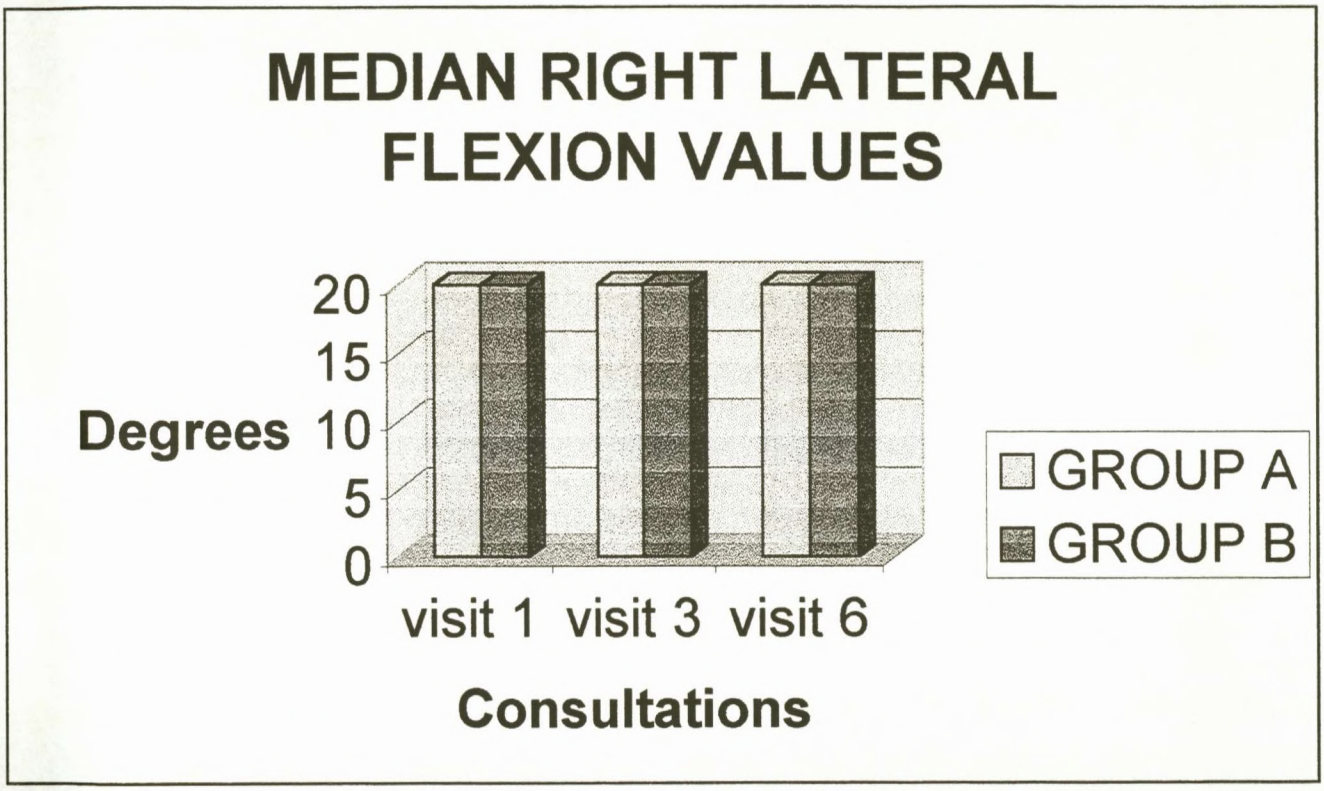

MEDIAN RIGHT LATERAL FLEXION VALUES
Degrees
20
15
10
5
0
visit 1
visit 3
visit 6
Consultations
GROUP A
GROUP B

Figure 4.6

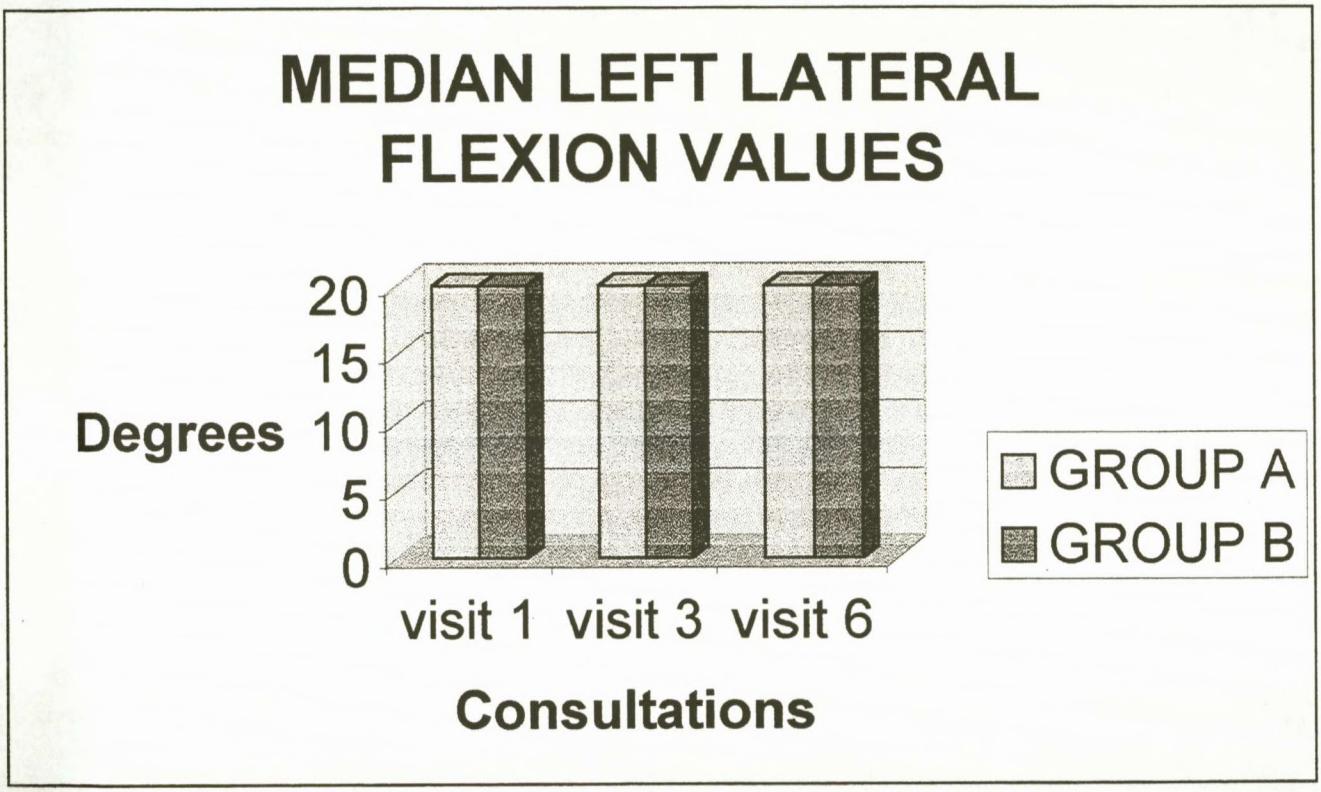

MEDIAN LEFT LATERAL FLEXION VALUES
Degrees
20
15
10
5
0
visit 1
visit 3
visit 6
Consultations
GROUP A
GROUP B

Figure 4.7

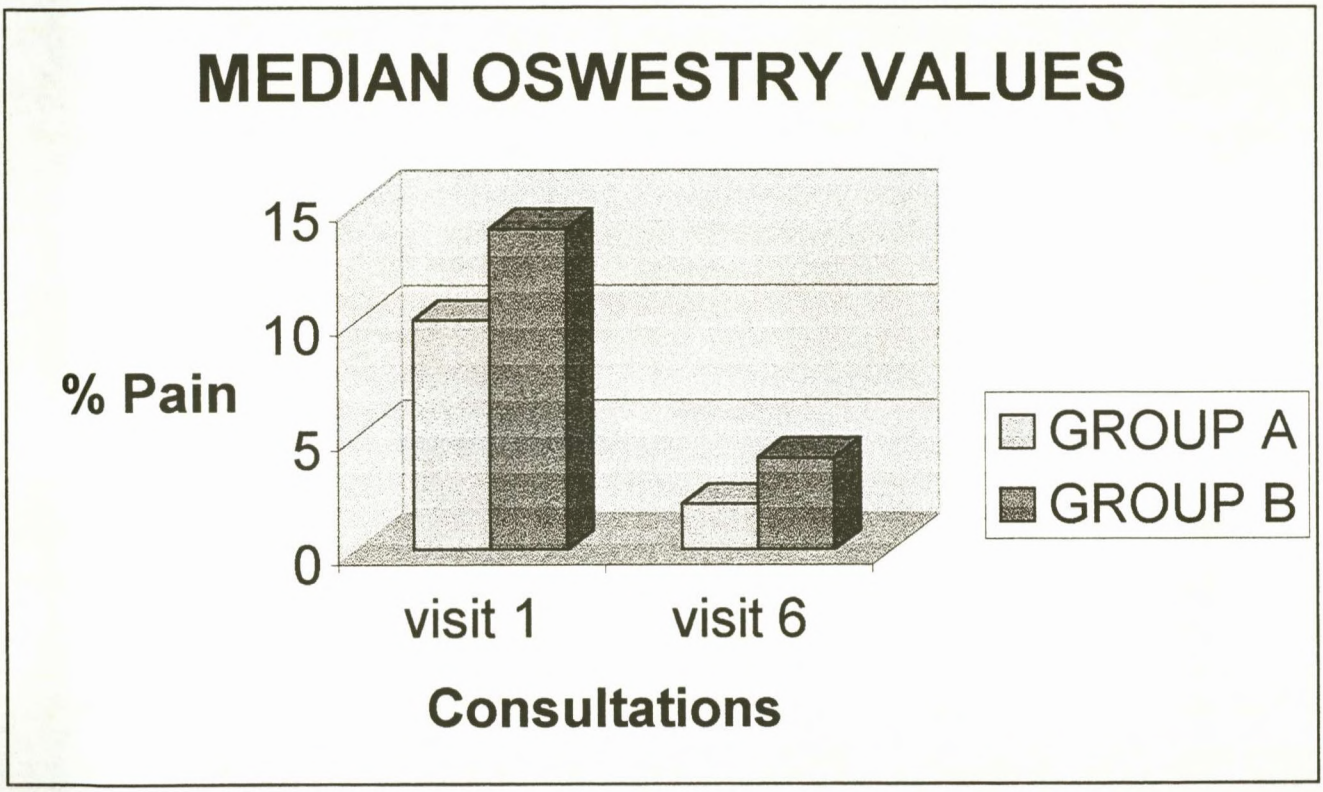

MEDIAN OSWESTRY VALUES
% Pain
15
10
5
0
visit 1
visit 6
Consultations
GROUP A
GROUP B

Figure 4.8

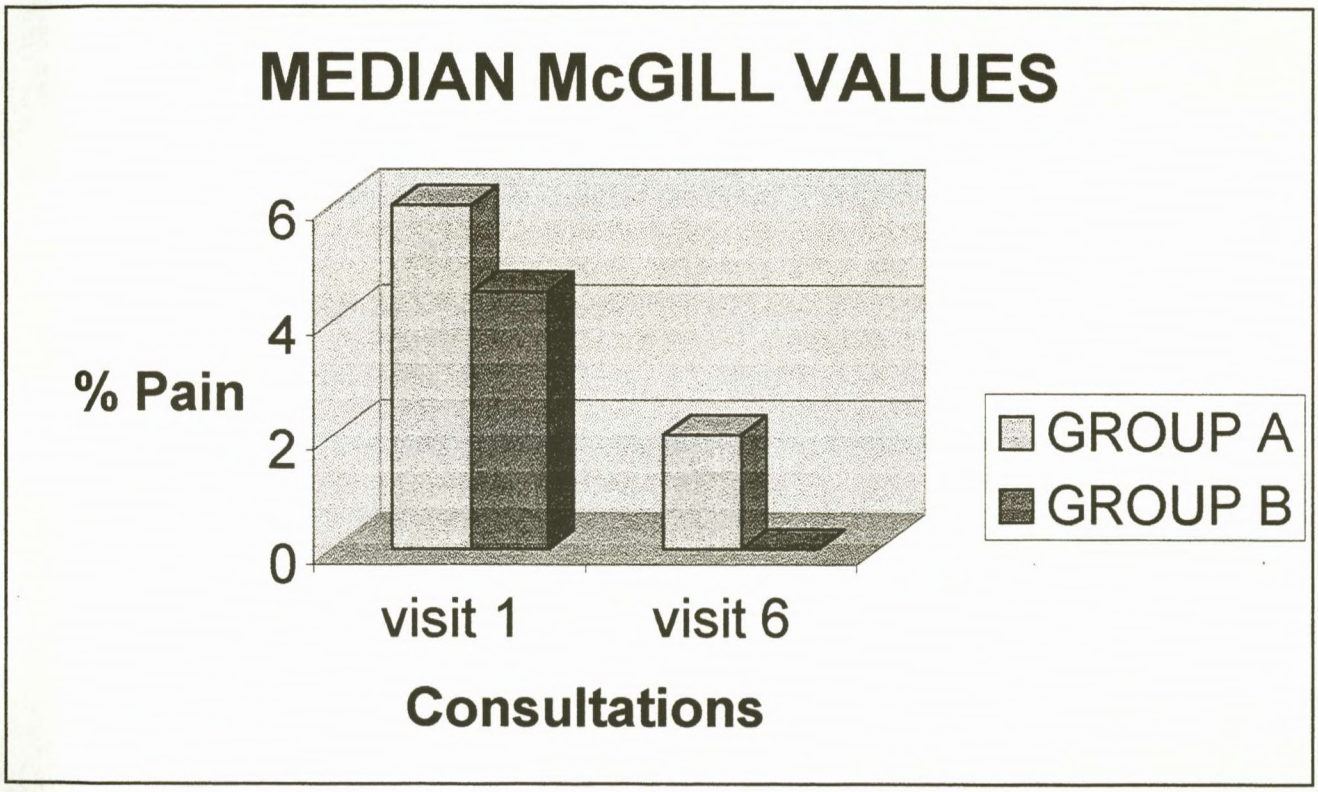
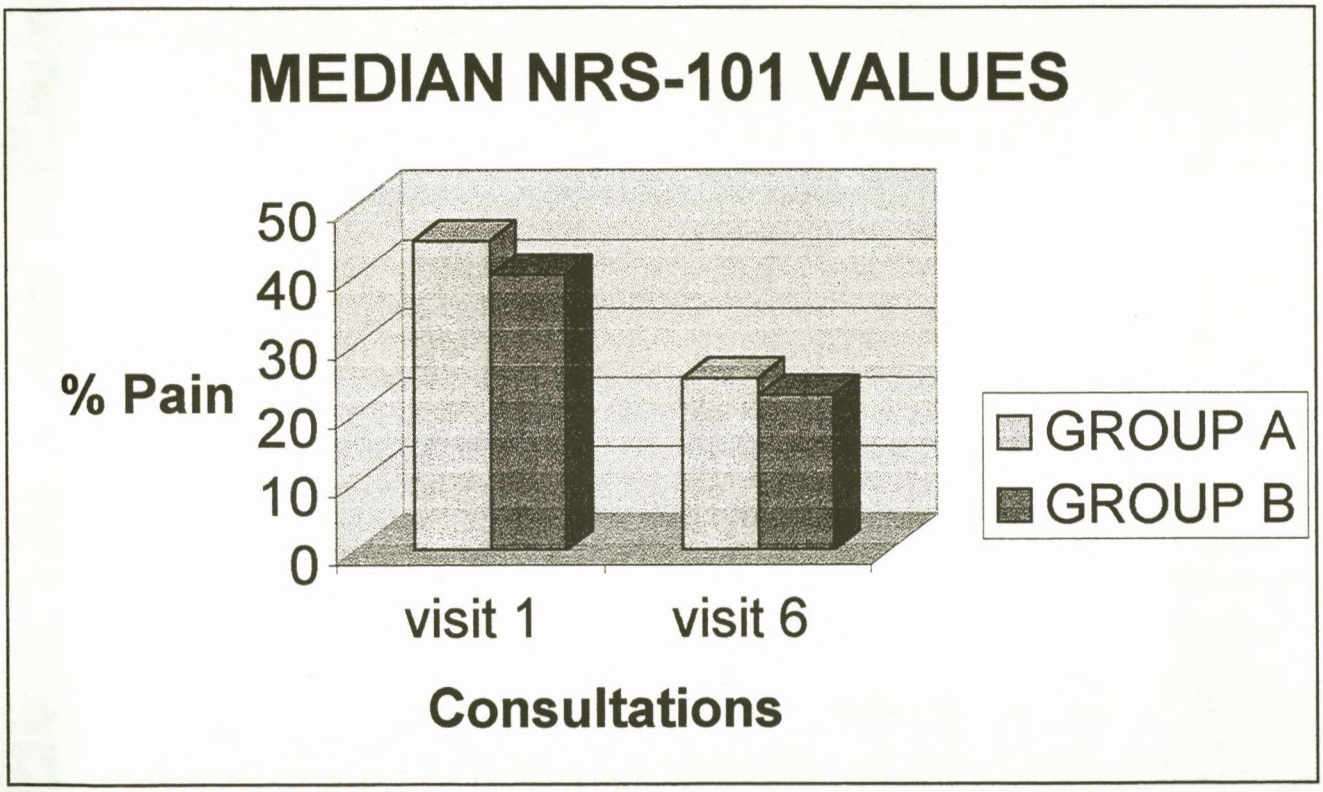

MEDIAN McGILL VALUES
% Pain
6
4
2
0
visit 1
visit 6
Consultations
GROUP A
GROUP B

Figure 4.9


MEDIAN NRS-101 VALUES
% Pain
50
40
30
20
10
0
visit 1
visit 6
Consultations
GROUP A
GROUP B

CHAPTER FIVE

CHAPTER FIVE

5.0 DISCUSSION OF THE RESULTS

5.1 INTRODUCTION

This chapter is concerned with the discussion of the objective and subjective data obtained from the first, third and final treatments.

Objective data: Goniometer

Subjective data: Numerical Pain Rating Scale –101

Short Form McGill Pain Questionnaire

Oswestry Back Pain Disability Index

The results are discussed in two sections :-

Inter-group results :-

The data from the first consultation from both groups is assessed to determine if there was any difference between the two groups in terms of signs and symptoms of the presenting condition. It further provides baseline information as to whether subjects from both groups differed in terms of the intensity of their pain. A comparison of the sixth consultations for both groups indicates which treatment regime was more effective.

Intra-group results :-

The evaluation of the data obtained from the first, third and sixth consultations represent the "the time response" of the treatment regime. A comparison of the first and sixth consultation indicates to what extent the clinical condition of the patient has improved.

5.2 INTER-GROUP COMPARISON

5.2.1. The Subjective data

The statistical data can be found in table 4.4.On statistical analysis, no significant differences could be detected between the two groups at the first treatment. This suggests that the clinical picture caused by chronic thoracic facet syndrome was similar between the two groups initially. Statistical analysis of the Short Form McGill Pain Questionnaire and Oswestry Back Disability Index revealed no significant difference between the two groups at any period of time throughout the study. This indicates that both treatment approaches were as effective in the amount of disability and sensory dimension of pain experienced by the patient.

The median values (refer to figures 4.7-4.9) for both groups do not tend to indicate a similar response to the respective treatments. The median Oswestry values were lower for group A than for group B at the final treatment, while the median McGill values for group B far exceeded that of group A at the final treatment.

5.2.2 The Objective Data

The statistical data for the thoracic ranges of motion measurements can be found in tables 4.5-4.8.On statistical analysis, no significant difference could be detected between the two groups at the first, third and sixth treatments suggesting that both groups were fairly linear. This suggests that benefits of both treatment protocols are similar. Comparison of the median value changes showed that group B demonstrated greater movement in flexion than group A at the final treatment. The median value changes for thoracic ranges of motion (figures 4.1-4.6) for the

groups tend to show differences in treatment response at the final treatment, favouring a combination of SMT with NSAIDS as opposed to SMT alone.

5.3 INTRA-GROUP COMPARISON

5.3.1 The Subjective Data

The statistical data can be found in table 4.9. Statistical analysis within the NSAID group revealed a significant improvement for all the subjective measurements taken from the first to the final treatments. This suggests that SMT combined with NSAIDs is clinically effective for reduction of disability, percentage pain and sensory dimension of pain for chronic thoracic facet syndrome.

Within the placebo group, statistical analysis revealed a significant improvement for the Oswestry Back Disability Index and the Short Form McGill Pain Questionnaire while the Numerical Rating Scale-101 revealed no significant difference.

5.3.2 The Objective Data

The statistical data for the thoracic ranges of motion can be found in tables 4.10-4.18.

Group B showed a statistically significant improvement in thoracic ranges of motion especially in flexion during the period between the first and the sixth, and the third and the sixth treatments respectively.

In comparison, statistically significant improvement could only be found within the placebo group in all objective measurements during the period between the first and final treatments indicating that placebo therapy is effective in improving thoracic ranges of motion.

To conclude, the data suggest that NSAIDs and SMT were more effective in terms of mean improvement per treatment than SMT alone as well as in terms of pain and disability in treating chronic thoracic facet syndrome.

5.4 DISCUSSION OF THE DEMOGRAPHIC DATA

The gender distribution was similar in the two groups with a higher ratio of females (Table 4.1). Table 4.2 regarding the prevalence of age shows that both groups had a relatively equal distribution in the 25-34 and 35-44 age group interval. Patient age distribution in Group A was higher in the 16-24 age group interval, while Group B had a higher distribution in the 45-54 age group interval. Even with these inequalities, the mean age for each group was similar as seen in table 4.2.

The occupation of the patients are shown in table 4.3.The fact that 50% of the patient occupations involved sitting, deskwork posture, may give an insight into the types of musculoskeletal conditions that may prevail as more and more occupations involve deskwork.

5.4 STUDY LIMITATIONS

When comparing the baseline characteristics between the patients in each group, it can be seen that although the ratio of male to females within each group was unequal, it was comparative between the two groups. Although not exact, age distribution was relatively the same in each group. Patient occupations seemed to have varied between the two groups. This may have had an impact on the study, as some patients may have returned from the treatment to adopt a stressful

position related to their occupation, possibly causing their pain and distribution to return relatively quickly.

The subjective measurements that the patients had to complete were not designed specially for determining the pain and disability of patients suffering from chronic thoracic facet syndrome or for the treatment methods used in this trial. It is also possible that some patients may not have fully understood the method of completing each questionnaire, thus affecting their response negatively or positively. Some patients may have enhanced their improvement responses so as to please the researcher.

The objective measurements have the possibility of containing some error due to human reliability in taking the readings.

Although every effort was made to ensure all the patients took their medication as prescribed, this may not have been the case. Patient medication diaries were screened at the first three consultations, but there is the possibility that this still did not ensure that complete compliance existed. Patients may have falsely filled in medication times so as not to disappoint the researcher. One aspect of this research that may well be criticised is that the manipulative procedures were performed by a student, and not a therapist who had many years of experience.

CHAPTER SIX

CHAPTER SIX

6.0 RECOMMENDATIONS AND CONCLUSION

6.1 RECOMMENDATIONS

SAMPLE SIZE:

A larger sample size should have been selected using a stratified random sampling procedure taking into account age, gender, duration of complaint, location of pain and occupation. These factors could aid in making the sample more representative of the population and thus produce more valid trial conclusions.

MEDICATION:

Of concern, when involving medication in a clinical trial, is patient compliance. Therefore future trials should endeavor to provide a live-in environment for the research patients in order to ensure that medication, both placebo and experimental is taken timeously and correctly. This however, would be financially impossible for most research projects.

HOMOGENEITY

Location of pain in the thoracic spine should be taken into account. The study should be limited to only the middle region of the thoracic spine (T5-T9) due to the differences in anatomy and biomechanics of the 3 regions (Edmonston and Singer1997); this would allow for greater accuracy and specification of results.

ONE MONTH FOLLOW-UP TREATMENT

In order to determine a long term response to the treatment administered, especially for chronic pain, it is recommended that a one month follow-up treatment be included in future studies.

ACCURACY OF MEASUREMENTS:

As techniques advance more sensitive instruments should be introduced into clinical trials. This should allow for more accurate readings and greater detection of small but significant differences in effects of treatments.

CHILDREN:

It is also recommended that a study investigating the prevalence and incidence of thoracic spine pain be undertaken in school children as there is increasing evidence that mid-back pain is common in this age group.

THORACIC MUSCULATURE:

It is also recommended that research into the treatment of myofascial trigger points in the thoracic musculature together with chiropractic manipulation be investigated thus assessing treatment for the muscle and joint complex.

6.2 CONCLUSION

The results of this study indicate both treatment protocols were effective in treating thoracic facet syndrome. At a 95% confidence level neither group showed statistically significant intergroup differences over the other in treatment effectiveness. The median and mean data taken from the subjective measures did however suggest the possibility that thoracic spine manipulation and NSAIDs as a treatment protocol may be more effective in relieving pain and disability than thoracic spine manipulation alone. This is not conclusive, as it does not fit into the statistical confidence parameter this trial employed, and will only be clarified by future research trials of this nature.

The use of NSAIDs combined with manipulation for the treatment of chronic thoracic facet syndrome may present the consulting doctor with moral and clinical dilemmas. The inclusion of an allopathic approach into a chiropractic one, may lead to the jeopardy of a distinction the chiropractic profession as held from other health professions, which has perhaps ensured the survival of chiropractic over the last 105 years. The decreased prevalence of thoracic pain is reflected in the paucity of literature regarding the diagnosis and treatment of thoracic spine pain syndromes. However, this does not negate the importance of managing mid-back pain, which can be as disabling as cervical and lumbar pain. Will anything be gained by the use of NSAID's for the benefit of the patient? Maybe the increased side-effects and increase in deaths (bleeding to death) will nullify the benefits of minor increased pain relief.

In conclusion, this study has demonstrated that the use of NSAIDs combined with chiropractic manipulation, is as effective as chiropractic manipulation alone in treating chronic mechanical thoracic facet syndrome.

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Appendix A

TECHNIKON NATAL CHIROPRACTIC CLINIC

Chiropractic Research on Chronic Mechanical Thoracic Pain

Dear Patient

Thank you for considering enrolling in this research programme. Outlined below is a brief explanation of what the research programme entails as well as what would be expected of you, the patient.

The research project in which you will participate, will endeavour to determine if Non-Steroidal Anti-Inflammatory drugs (NSAID's) will provide a more effective treatment protocol, when combined with manipulation, in treating chronic mechanical thoracic pain or mid-back pain. You will be randomly assigned to one of two groups. The first group will receive Cataflam (the NSAID to be used in this study) and manipulation of the mid-back. The second group will receive a substance that has no medicinal properties and manipulation of the mid-back. So, as you can see both groups of people will receive chiropractic treatment for their mid-back pain. Neither you, nor I (the researcher) will know which group you are in.

You will be required to take the medication prescribed to you by Dr. Moodley (a medical doctor) three times a day for five days. The powder in the sachet must be dissolved in water and then drunk. Please fill in your medication diary each time you take your medication. You will be treated six times over a three-week period. You are expected to be present at all of these sessions.

If you develop any symptoms during the course of this research project that are not related to your existing back complaint, please inform me so that we can make due arrangements to stop your medication and remove you from this clinical trial.

You are please asked not to alter your lifestyle for the sake of this research project. eg. if you spend two hours a day typing, continue to do so. You are also asked not to take any other medication while you are a candidate of this research project as it will alter the outcome of your treatment.

Please feel free to voice any concerns to me. Thank you for volunteering to participate in this clinical trial.

Nayna Bhoola
(Chiropractic Intern)

INFORMED CONSENT FORM

(To be completed by patient / guardian)

Appendix B

Date :_____

Title of research project : **The relative effectiveness of a conservative multi-method treatment protocol (S.M.T. and Diclofenac) for the management of chronic mechanical thoracic spine pain.**

Name of supervisor : **Dr. Heidi Kretzmann**

Name of research student : **Nayna Bhoola**

Please circle the appropriate answer

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

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

Please Print in block letters:

Patient /Subject Name:_____ Signature:_____

Parent /Guardian Name:_____ Signature:_____

Witness Name:_____ Signature:_____

Research Student Name:_____ Signature:_____

INDEMNITY

WHERE THE FOLLOWING REQUIRE SIGNATURES, IT WILL BE THAT OF THE PATIENT IF OVER 21 YEARS OF AGE, OR BY THE PATIENT AND PARENT IF UNDER 21 YEARS

1. While every effort has been made to screen the patient for possible drug interactions or effects, the research team cannot be held responsible for ad hoc reactions that may develop. While all patients may be protected by common laws , it is also imperative that the patient specifically indemnifies the research team, including Doctor D.R. Moodley and Technikon Natal against prospective legal action.

_____

2. Telephonic or other consultations are a necessary part of the research. The patient acknowledges this and makes no claim against default in such cases

_____

3. Any consultation or special investigation deemed necessary by the research team will be followed by the patient concerned, failing which the patient is freely entitled to be excluded from the study. This clause does not revoke the constitutional rights of the patient in terms of freedom of will.

_____

4. I am prepared to undertake emergency or other treatment at a government hospital hospital should the need arise. Private or attached costs will not be borne by Technikon Natal, Dr Moodley or any member of the research team.

_____

SIDE EFFECTS OF ANTI- INFLAMMATORY DRUGS :

1. Gastro-intestinal symptoms including heartburn, acid reflex, indigestion, nausea , vomiting, bleeding, peptic ulcers.
2. Oedema (swelling of body) especially at ankles.
3. Transcient hepatitis
4. Transcient renal dysfunction
5. Skin and allergic reactions including urticaria and angiooedema
6. Blood disorders e.g. aneamia, decreased platelets, decreased white blood cells
7. Wheeze related to bronchoconstriction
8. Dizziness and headaches

**I have been advised of all the above side-effects that can occur in a small minority of patients

_____

**I will inform the research team should any of the above side-effects develop

PATIENT: _____

PARENT : _____

DATE : _____

DR D.R. MOODLEY

(B. Med.Sc. Hons ; MBCHB) PRACTICE NO : 1565192

GENERAL MEDICAL PRACTITIONER & CLINICAL ANATOMIST

23 KLAARWATER RD
SHALLCROSS
4093
TEL : 491471
FAX : 491371

16 AUTUMN GROVE
MALVERN
4093
TEL : 4631162
CELL : 0824659742

Appendix D

VAT NO : 4560179642

PATIENT PROFILE AND DRUG INFORMATION SCREENING FOR PROSPECTIVE STUDIES INVOLVING ANTI-INFLAMMATORY DRUGS AT TECHNIKON NATAL CHIROPRACTIC DEPARTMENT

QUESTIONNAIRE :

1. Have you had any reaction, allergic or otherwise to any inflammatory drug, or drug used in the management of pain or musculo-skeletal disorders (e.g. Aspirin, Disprin, Voltaren, Feldene) ?

   YES _____
   NO _____

2. Have you ever had any disorder of the liver, biliary tract or pancreas ?

   YES _____
   NO _____

3. Have you ever suffered with recurrent heartburn, peptic ulcers, bleeding disorders, including the vomiting of blood or passage of blood rectally or otherwise ?

   YES _____
   NO _____

4. Are you currently taking Warfarin, Aspirin, other anticoagulants or anti-inflammatory agents or any other drug at all, whether allopathic, herbal or otherwise, including steroid based agents ?

   YES _____
   NO _____

5. Have you ever suffered any dysfunction of the kidneys, bladder or urinary system ?

   YES _____
   NO _____

6. Have you ever suffered from any medical condition not disclosed above

   YES _____
   NO _____

   DETAILS _____

7. Have you had any surgery previously ?

YES _____
NO _____

DETAILS_____

_____

8. Have you received a blood transfusion in the last 5 years ?

YES _____
NO _____

REASON_____

_____

9. Have you had endoscopy, radiographs or other investigations done to you ?

YES _____
NO _____

DETAILS_____

_____

_____

10. Are you asthmatic, or do you suffer with chronic disease of the lungs or respiratory system ?

YES _____
NO _____

11. Have you been diagnosed with any psychiatric disorder including depression, manic depression, or are you on anti-psychotic medication or Lithium therapy

YES _____
NO _____

FEMALE PATIENTS:

1. Are you pregnant now ?

YES _____
NO _____

2. State the onset date of your last period_____

3. Are your periods regular ?_____

THE ABOVE DETAILS ARE TRUE TO THE BEST OF MY ABILITY_

Patient_____ I.D._____

Parent if under 21_____ I.D._____

Appendix E

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

Appendix F

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:

REGIONAL EXAMINATION - THORACIC SPINE

Patient: _____ File #: _____ Date: _____

Intern: _____ Signature: _____

Clinician: _____ Signature: _____

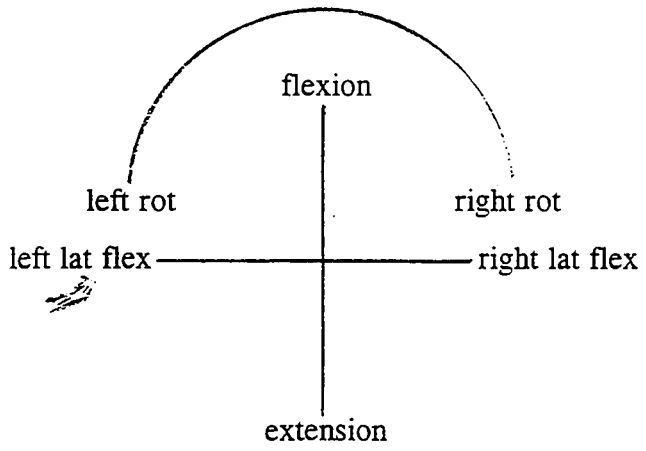
STANDING

Posture (incl. L/S & C/S):
Muscle Tone:
Skyline view - Scoliosis
Spinous Percussion
Breathing (quality, rate, rhythm, effort):
Deep inspiration

Scars:
Chest Deformity
(pigeon, funnel,
barrel):

RANGE OF MOTION

Forward flexion	20 - 45 degrees (15cm from floor)
Extension	25 - 45 degrees
L/R Rotation	35 - 50 degrees
L/R Lateral Flexion	20 - 40 degrees



RESISTED ISOMETRIC MOVEMENTS: (in neutral)

Forward flexion — Extension
L/R Rotation — L/R Lateral Flexion

SEATED:

Palpate Auxillary Lymph Nodes
Palpate Ant/Post Chest Wall
Costovertabral Expansion (3 - 7cm diff. at 4th intercostal space)
Slump Test (dural stretch test)

SUPINE:

Rib Motion
Soto Hall Test (#, sprains)
SLR
Palpate Abdomen

PRONE:

Passive Scapular Approximation
Facet Joint Challenge
Vertebral Pressure (P-A central, unilateral, transverse)
Active Myofascial Trigger Points:

- Rhomboid Major
- Lower Trapezius
- Serratus Posterior
- Pectoralis Major
- Quadratus Lumborum
- Rhomboid Minor
- Spinalis Thoracic
- Serratus Superior
- Pectoralis Minor

COMMENTS: _____

_____

NEUROLOGICAL EXAMINATION:

DERMATOMES

	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
Left												
Right												

Basic LOWER LIMB neuro: Myotomes:
Dermatomes: Reflexes:

KEMPS TEST:

MOTION PALPATION:

Ribs: Calliper: Left:
Right:
Joint Play:
Bucket handle: Left:
Right:
Joint Play:
Motion Palpation and Joint Play: Left:
Right:

Basic Lumbar Exam:
History:
ROM:
Neuro/Ortho:

Basic Cervical Exam:
History
ROM:
Neuro/ortho:

Numerical Rating Scale - 101 Questionnaire

Date:_____ **File no:**_____ **Visit no:**_____

Patient name:_____

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

Please write only **one** number.

_____

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

Please write only **one** number.

_____

OSWESTRY BACK DISABILITY INDEX

Appendix I

Patient Name:_____ File no:_____Date_____

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

Section 1 - Pain Intensity

- ☐ 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 ...)

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

Section 3 - Lifting

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

Section 4 - Walking

- ☐ Pain does not prevent me walking any distance.
- ☐ Pain prevents me walking more than 1 mile (2.2km).
- ☐ Pain prevents me walking more than ½ mile (1.1km).
- ☐ Pain prevents me walking more than 1/4 mile (0.5km).
- ☐ I can only walk using a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 - Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than ½ hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6 - Standing

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want, but it gives extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than ½ hour.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7 - Sex life

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes extra pain.
- ☐ My sex life is nearly normal but it is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 8 - Social life

- ☐ My social life is normal and gives no extra pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, for example: dancing.
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

Section 9 - Sleeping

- ☐ I have no trouble sleeping.
- ☐ I can sleep well only by using pills.
- ☐ Even when I take pills I have less than 6 hours sleep.
- ☐ Even when I take pills I have less than 4 hours sleep.
- ☐ Even when I take pills I have less than 2 hours sleep.
- ☐ Pain prevents me from sleeping at all.

Section 10 - Traveling

- ☐ I can travel anywhere without extra pain.
- ☐ I can travel anywhere but it gives extra pain.
- ☐ Pain is bad but I manage trips over 2 hours.
- ☐ Pain restricts me to trips less than 1 hour.
- ☐ Pain restricts me to trips under 30 minutes.
- ☐ Pain prevents me from traveling, except to the doctor and / or hospital.

Adapted from Fairbanks (1980)

Short-form McGill Pain Questionnaire (SF-MPQ)

Ronald Melzack (1984)

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

Patient name:_____

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

Appendix K

NAME :_____

FILE NO :_____

GROUP :_____

GONIOMETER READINGS

Visit	1	3	6
Flexion			
Extension			
Right Rotation			
Left Rotation			
Right Lateral Flexion			
Left Lateral Flexion			

MANIPULATION DATA

Treatment no.	1	2	3	4	5	6
MP finding						
Adj.Technic						

Scheduling Status S3

Proprietary name (and dosage form)

Cataflam® D Dispersible Tablets

Appendix L

Composition

One CATAFLAM D Tablet contains 46,5 mg of diclofenac free acid, which is equivalent to 50 mg diclofenac sodium.

Pharmacological classification

A 3.1 Antirheumatics (anti-inflammatory agents)

Pharmacological action

CATAFLAM D is a non-steroidal compound with antirheumatic, anti-inflammatory, analgesic and antipyretic properties. *In vitro*, its active substance strongly inhibits prostaglandin-synthetase and also has an inhibitory effect on platelet aggregation.
Inhibition of prostaglandin biosynthesis, which has been demonstrated experimentally, is regarded as having an important bearing on its mechanism of action. Prostaglandins play a major role in the causation of inflammation, pain and fever.
Pharmacokinetics
Absorption:
Absorption of diclofenac from CATAFLAM D sets in rapidly after administration. The plasma concentrations show a linear relationship to the size of the dose. Peak levels are attained in 20 to 60 minutes after ingestion on an empty stomach.
The active substance is subject to first-pass metabolism.
Protein binding: 99,7 %
The mean terminal elimination half-life of the unchanged drug is 1 to 2 hours.
Excretion:
Approximately 60 % of the dose administered is excreted via the kidneys in the form of metabolites and less than 1 % in the unchanged form. About 30 % of the dose is excreted in metabolised form in the faeces.

Indications

As short-term treatment in the following acute conditions:
Flare-up of osteoarthrosis.
Painful musculoskeletal conditions.
Non-articular rheumatism.
Acute attacks of gout.
Painful post-operative and post-traumatic inflammation and swelling, pain following dental surgery.
Symptomatic treatment for primary dysmenorrhoea.

Contra-indications

Gastric or intestinal ulcer. Allergy to the active substance. CATAFLAM D is also contra-indicated in asthmatic patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or by other medicines with prostaglandin-synthetase inhibiting activity.
CATAFLAM D should not be used in patients with porphyria.
Pregnancy.
CATAFLAM D is not suitable for use in children under 14 years of age.

Warnings

It should be noted that only short-term treatment is recommended with CATAFLAM D.
Strict accuracy of diagnosis and close medical surveillance are imperative in patients with symptoms indicative of gastro-intestinal disease, a case history suggestive of gastro-intestinal ulceration, ulcerative colitis, Crohn's disease, in patients suffering from impaired hepatic function and pre-existing dyshaemopoiesis or disorders of blood coagulation.
CATAFLAM D should be administered with caution in patients with hepatic or renal failure.
Serious interactions have been reported after the concomitant use of methotrexate and diclofenac.

Dosage and directions for use

Adults
For the relief of acute pain, the tablets should preferably be taken on an empty stomach. The tablets are dropped into a glass of water and the liquid stirred to aid dispersion before swallowing. Since a proportion of the active substance may remain in the glass after swallowing, it is advisable to rinse the glass with a small amount of water and to swallow again.
As a rule, the initial daily dosage is 2 to 3 CATAFLAM D tablets. In milder cases, 2 CATAFLAM D tablets daily are usually sufficient.
The maximum daily dose is 3 CATAFLAM D tablets.
The daily dosage should generally be prescribed in two to three fractional doses.
In primary dysmenorrhoea the daily dosage, which should be individually adapted, is 1 to 3 CATAFLAM D tablets. Treatment should be started upon appearance of the first symptoms and, depending on their intensity, continued for a few days.

Side-effects and special precautions

Gastro-intestinal tract
More frequently: Epigastric pain, nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, eructation, anorexia, local irritation.
Less frequently: Gastro-intestinal bleeding may occur, haematemesis, melaena, bloody diarrhoea, gastric or intestinal ulcer with or without bleeding or perforation.
Lower gut disorders such as non-specific haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's proctocolitis, aphthous stomatitis, glossitis, oesophageal lesions, diaphragm-like intestinal strictures, constipation and pancreatitis.
Central Nervous System
More frequently: Headache, dizziness, vertigo and nervousness.
Less frequently: Tiredness. Disturbances of sensation (including paraesthesia) and memory, disorientation, insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reactions, aseptic meningitis.
Special senses
Less frequently: Disturbances of vision (blurred vision, diplopia), impaired hearing, tinnitus, taste alteration disorders.
Skin
More frequently: Rash and skin reactions.
Less frequently: Urticaria. Bullous eruptions, eczema, erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome (acute toxic epidermolysis), erythroderma (exfoliative dermatitis), loss of hair, photosensitivity reaction, purpura including allergic purpura.
Kidney
Less frequently: Oedema, acute renal failure, urinary abnormalities such as haematuria, proteinuria, interstitial nephritis, nephrotic syndrome, papillary necrosis.
Liver
More frequently: Elevated transaminase levels (SGOT, SGPT).
Less frequently: Hepatitis with or without jaundice. Fulminant hepatitis.
Blood
Less frequently: Dyshaemopoiesis (leucopenia, thrombocytopenia, aplastic anaemia, haematolytic anaemia and agranulocytosis).
Hypersensitivity
Less frequently: Allergic reactions (eg bronchospasm, anaphylactic / anaphylactoid systemic reactions including hypotension).
Vasculitis, pneumonitis.
Cardiovascular system
Less frequently: Palpitation, chest pain, hypertension, congestive heart failure.
Precautions
Gastro-intestinal bleeding or ulcerations / perforations can occur at any time during treatment, with or without warning symptoms or a previous history. The elderly must receive close monitoring. Dosage may have to be reduced in the elderly. In particular it is recommended that the lowest effective dosage be used in frail, elderly patients or those with a low body mass.
In the instances where peptic ulceration or gastro-intestinal bleeding occur in patients under treatment with CATAFLAM D, the medicine should be withdrawn.
In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.
Owing to the importance of prostaglandins for maintaining renal blood flow, patients suffering from impairment of hepatic, cardiac or renal function, as well as the elderly, patients being treated with diuretics and those with extracellular volume depletion from any cause, eg the peri- or post-operative phase of major surgical operations, should be carefully monitored.
Elevation of one or more liver enzymes may occur with CATAFLAM D.
During prolonged treatment with CATAFLAM D, blood counts and monitoring of hepatic and renal function are indicated.
If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (eg eosinophilia, rash, etc), CATAFLAM D should be discontinued. Hepatitis may occur without prodromal symptoms.
Caution is called for when using CATAFLAM D in patients with hepatic porphyria, since CATAFLAM D may trigger an attack.
Allergic reactions, including anaphylactic / anaphylactoid reactions, can also occur without earlier exposure to the medicine.
CATAFLAM D may mask the signs and symptoms of infection due to its pharmacodynamic properties.
Patients experiencing dizziness or other central nervous disturbances should refrain from driving a vehicle or operating machines.
Interactions
When given together with preparations containing lithium or digoxin, CATAFLAM D may raise their plasma concentrations.
Concomitant administration of glucocorticoids or other non-steroidal anti-inflammatory agents, may aggravate gastro-intestinal side-effects.
Concurrent treatment with two or more non-steroidal anti-inflammatory agents may promote the occurrence of side-effects.
The bioavailability of CATAFLAM D is reduced by acetylsalicylic acid, and that of acetylsalicylic acid by CATAFLAM D, when the two agents are administered together.
There are reports of an increased risk of haemorrhage with the combined use of diclofenac and anticoagulant therapy. Therefore close monitoring of such patients is recommended.
Both hypoglycaemic and hyperglycaemic effects in the presence of CATAFLAM D which necessitated changes in the dosage of hypoglycaemic agents have been reported.
Increased nephrotoxicity of cyclosporin may occur through effects of CATAFLAM D on renal prostaglandins.
There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.
Lactation
Following oral doses of 100 mg daily, no active substance could be found in the breast milk (limit of detection: 10 ng/ml).

Known symptoms of overdosage and particulars of its treatment

See side-effects and special precautions.
Treatment
There is no specific antidote. Symptomatic and general supportive measures.
Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation and respiratory depression.
Specific therapies such as forced diuresis, dialysis, or haemoperfusion are probably of no help in eliminating CATAFLAM D because of its high protein-binding rate and extensive metabolism.
Absorption from tablets should be prevented as soon as possible after the overdosage by means of gastric lavage and treatment with activated charcoal.

Identification

White, flat, triangular tablets with bevelled edges. One side bears the imprint CG, the other side a raised V. Width, measured from flattened vertex: approximately 9 mm. Thickness: approximately 3,9 mm.

Presentation

CATAFLAM D is supplied in packs of 15 tablets.

Storage instructions

Store below 25 °C and protect from moisture.
Keep out of the reach of children.

Registration number

28/3.1/0306

Name and business address of the applicant

NOVARTIS SOUTH AFRICA (Pty) Ltd
72 Steel Road
Spartan
Kempton Park, 1619

Date of publication of this package insert 03/12/1993

®Registered Trade Mark

55760

PATIENT MEDICATION DIARY

Patient Name :_____

File No :_____

Group :_____

	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
1st DOSE					
2ND DOSE					
3RD DOSE					

The dosage is three sachets spread at equal time intervals during the day.
Please indicate in each block the time at which you took the medication.

Appendix M