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THE SHORT TERM EFFECTIVENESS OF CERVICAL
SPINE MANIPULATION AS COMPARED TO PIROXICAM
ADMINISTRATION IN THE TREATMENT OF CHRONIC
CERVICAL FACET SYNDROME

BY

BRENDAN JOHN O'CONNOR

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

I, Brendan John O'Connor, do declare that this dissertation is representative of my own work.


Brendan John O'Connor

07. 11. 2001
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Approved for final submission.


Dr T. MacDougall M.T. Chiropractic.

07. 11. 2001
Date

DEDICATION

This dissertation is dedicated to my parents, Jock and Inge O'Connor, for their endless support, understanding and encouragement.

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ABSTRACT

For neck pain, the first-line treatment of allopathic physicians is usually the prescription on non-steroidal anti-inflammatory drugs (NSAIDs), whereas the first-line treatment of chiropractic physicians is usually cervical manipulation. The literature shows that both chiropractic manipulation alone and NSAIDs alone are effective for the treatment of cervical facet syndrome, with chiropractic manipulation being much safer than the use of NSAIDs. Furthermore, patients that receive chiropractic care have been shown to generally be much more satisfied than those that receive conventional medical care. The aim of this study was to determine the short-term effectiveness of cervical spine manipulation as compared to Piroxicam administration in the treatment of chronic cervical facet syndrome.

The study design that was chosen was that of a comparative clinical trial. Forty consecutive patients diagnosed with chronic facet syndrome of the cervical spine were randomly assigned to either the manipulation group or the NSAID group (twenty patients in each group). Each patient in group A received manipulative therapy of the cervical spine on three consecutive days. Each patient in group B received 40 mg of Adco Piroxicam on the first two days of treatment, and 20 mg daily for the remainder of the seven day treatment period.

The patients were assessed by means of objective and subjective data obtained before each consultation on days 1, 3 and 7. The objective data was gathered

from algometric pressure-pain threshold readings over the involved facet joint. The subjective information was obtained from the Short-Form McGill Pain Questionnaire, the Numerical Pain Rating Scale – 101 and the CMCC Neck Disability Index, as well as the patients perceived improvement which was recorded as a percentage on days 3 and 7.

The data obtained was statistically analysed. Wilcoxin Signed Rank Tests were used at a 5% level of significance to determine whether there was any significant improvement within each respective treatment group (intra-group analysis). Mann-Whitney U-Tests were used at a 5% level of significance to determine whether there was any significant difference between the two treatment groups (inter-group analysis).

The intra-group statistical tests show significant ($p < 0.05$) improvement for both groups between all consultations, in terms of quality of pain (Short-Form McGill Pain Questionnaire), disability (CMCC Neck Disability Index), and pain perception (Numerical Pain Rating Scale – 101), with the exception of disability and pain perception in group B between days 3 and 7. The intra-group statistical tests for the patients pressure-pain threshold (algometer readings), show that there was a significant ($p < 0.05$) improvement in both groups between all consultations, except between days 3 and 7 for group B. These results suggest that there was a slightly better clinical improvement in the spinal manipulation

group, although the inter-group statistical tests do not show this. NSAIDs do however provide effective short-term (3 days) relief of pain.

According to the inter-group statistics, neither of the treatment groups showed statistically significant ($p \geq 0.05$) superiority over the other on all days of assessment, with the exception of the patients' perceived improvement on days 3 and 7. The patients' perception of improvement in the manipulation group was significantly ($p < 0.05$) greater than those in the NSAID group. This could be likened to patient satisfaction, and it could be said that the patients that received spinal manipulative therapy were more satisfied than the patients that received NSAIDs.

It is suggested that this study be repeated with a larger sample size and more homogenous research population. Further studies of this nature are required for the results to be conclusive.

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DEFINITION OF TERMS

ADJUSTMENT

The chiropractic adjustment is a specific form of direct articular manipulation using either long or short lever techniques with specific contacts and is characterized by a dynamic thrust of controlled velocity, amplitude and direction (Haldeman, 1992: 621).

END FEEL

The consistency which describes the resistance to further stretch, which is encountered at the end of the joint's passive range of motion (Bryner, 1987: 18).

FIXATION

The state whereby an articulation has become temporarily immobilized in a position that it may normally occupy during any phase of physiological movement (Haldeman, 1992: 623).

MOTION PALPATION

The aspect of palpation, which assesses the physiological range of motion possible in the different axes of motion, both generally and specifically for the joints of the spine. This evaluation determines if a joint or motion unit has natural movement and if it is relatively increased or decreased (Ames, 1987: 14).

PALPATION

The use of the tactile senses to determine variations in tissue consistency to recognize whether these variations are normal or abnormal (Haldeman, 1992:304).

STATIC PALPATION

Palpatory diagnosis of somatic structures in a neutral static position (Bergmann, 1993: 762).

VERTEBRAL MOTION SEGMENT

The consideration of the anatomical and functional relationship of two vertebrae, the mechanical integration of their articular processes and the related musculature, ligaments and synovial membranes (Bergmann, 1993: 766).

CHAPTER ONE

1. INTRODUCTION

Bovim et al. (1994: 1307) conducted one of the largest surveys to date addressing the question of neck pain in the general population, and concluded that neck pain may affect one third of the adult population from time to time and may persist for 6 months or longer in 10% to 15% of these patients. This is supported by Pikula (1999: 112), who states that neck pain is a frequent and disabling complaint in the general population. According to Cassidy et al. (1992: 495), the cause of neck pain in most cases is attributed to mechanical dysfunction of the cervical spine, although the exact nature of the pathology remains obscure.

Facet syndrome may be broadly defined as pain or dysfunction arising primarily from the zygapophyseal joints and their immediately adjacent soft tissues (Gatterman, 1995: 415). Panzer (1995: 420) claims that injection of local anaesthetic or cortisone into a specific facet joint, followed by relief of pain, is generally considered diagnostic of facet syndrome.

The opinion of Plaughner (1993: 216) is that the primary causative factor in facet syndrome is facet joint overriding, stretching of the articular capsule and bone to bone contact of the facet joints, with manipulation being the treatment of choice. Cumulative evidence from five randomized controlled trials reviewed by Gross et al. (1996: 588-591) demonstrates that manual therapies used in combination with

other treatments have been shown to be effective for the short-term relief of mechanical neck pain in adults, however no one treatment protocol has been shown to be optimal as specific types of manual therapies have not been investigated in detail.

According to Dishman (1988: 102) cervical spine injury results in the release of several chemical mediators of inflammation with accompanying decrease in muscle length, producing the restricted range of joint movement and tendon and fascial shortening. These chemical reactions are inhibited by anti-inflammatories such as steroids and non-steroids (Dishman, 1988: 102).

Koes et al. (1997: 214) states that non-steroidal anti-inflammatory drugs (NSAIDs) appear to be the most commonly prescribed type of medication worldwide. NSAIDs have shown anti-inflammatory, analgesic and antipyretic activity (Arky, 1997: 2008), and Adco Piroxicam, which is the NSAID of choice in this study, is indicated for a variety of conditions requiring anti-inflammatory and analgesic activity [Adco Piroxicam package insert (Appendix G)], including musculoskeletal conditions.

According to Arky (1997: 2008), gastrointestinal symptoms are the most commonly encountered side effects of Adco Piroxicam use, with peptic ulceration and gastrointestinal bleeding having been reported. Twenty percent of all hospital

admissions for bleeding ulcers in patients over the age of 60 are directly attributable to taking NSAIDs (Edwards and Bouchier, 1993: 773).

Dabbs and Lauretti (1995: 530) performed a series of Medline literature searches, and reviewed materials from 1966 to 1994, however they were unable to locate even one randomized, controlled trial examining NSAID use specifically for the treatment of neck pain. In a study conducted by Williamson (1998: 112), comparing manipulation of the cervical spine in conjunction with NSAIDs to manipulation of the cervical spine in conjunction with placebo, both protocols proved to be effective in the treatment of cervical facet syndrome, however neither showed a statistically significant superiority over the other. Hepburn (2000: 66) conducted a study in which he compared the use of NSAIDs (Adco Piroxicam) to a homoeopathic complex (Traumeel S) for the treatment of cervical facet syndrome. The results of this study showed that both medications were effective, however neither group was statistically better than the other in overall improvement.

The first-line of treatment of allopathic physicians for the treatment of neck pain is usually NSAIDs, whereas the first-line treatment of chiropractic physicians is usually chiropractic manipulation (Dabbs and Lauretti, 1995: 530). According to Dabbs and Lauretti (1995: 530), cervical manipulation for neck pain is much safer than the use of NSAIDs, by as much as a factor of a 'several hundred times'. This conclusion was arrived at after reviewing six studies on the estimated

probability of stroke after cervical manipulation, and five studies on the estimated probability of serious ulcers or death from ulcers caused by the use of NSAIDs (Dabbs and Lauretti: 1995: 530).

Peterson (1993: 137) claims that, in the past, the chiropractic adjustment and the efficacy of manipulative therapy for facet syndrome has delivered a higher degree of patient satisfaction when compared to standard medical care. Cherkin and MacCormack (1989: 351) support this, stating that patients of chiropractors were three times as likely as patients of family physicians to report that they were 'very satisfied' with the care they received for low back pain (66% versus 22%, respectively). They arrived at this conclusion after conducting a study on patients' evaluations of low back pain care, 215 of which received care from family physicians, and 242 of which received care from chiropractors. 'Simple masking or altering of symptoms is insufficient, and the development of a therapy for the cervical spine that restores normal function, reverses pathomechanics and prevents recurrence becomes the treatment of choice (Vernon, 1988: 112).'

This randomized controlled trial was designed to determine the treatment of choice for chronic cervical facet syndrome over a short time period (7 days), by directly comparing two of the most common treatments, viz NSAIDs and chiropractic manipulation. To my knowledge, no study has been conducted which directly compares these two treatments, with no co-intervention for this condition. If chiropractic manipulation proves to be equal or superior to NSAIDs in efficacy it

may provide a much safer conservative approach for future care of patients suffering from chronic cervical facet syndrome without the risk of commonly encountered side effects of NSAIDs.

CHAPTER TWO

2. REVIEW OF THE RELATED LITERATURE.

2.1 INTRODUCTION

'It is almost impossible for all other systems of the nervous system to function normally when there is lack of stability, coordination and purposeful movement patterns at the cervical level of the body' (Byfield, 1991: 45). This chapter endeavours to explain one of the most common causes of uncomplicated pain of the cervical spine viz cervical facet syndrome. The two treatments that will be used in this study are then explained and the literature is reviewed, proving the efficacy of these two treatment protocols.

2.2 INCIDENCE AND PREVALENCE

Jordan et al. (1998: 311) claim that neck pain is extremely common, costly to treat and debilitating. According to Hardin and Halla (1995: 136), neck pain may affect one third of the adult population from time to time, and may persist for six months or longer in 10% to 15% of these patients. Aker et al. (1996: 1291) state that neck pain is a common complaint, with a point prevalence of nearly 13% and a lifetime prevalence of nearly 50%.

Linton et al. (1998: 1457) claim that pain from the spinal region is a frequent and costly problem in the Western World. They performed a population-based study of spinal pain among 35 to 45 year-old individuals, and of their 66,3%

respondents that reported having experienced back or neck pain during the past year, 44% of them had suffered from neck pain. They also reported that the prevalence rate was slightly higher for women (69,5%) than for men (63,2%). This was supported by Cote et al. (1988: 1695), who stated that more women seem to be affected by high-disability neck pain than men. Of the 2184 randomly selected Saskatchewan adults in their study, 58,8% (95% confidence interval) of the women and 47,2% (95% confidence interval) of the men had experienced neck pain in the last 6 months. No reasons for this were given.

In the case of neck pain being caused by injury to the cervical spine after motor vehicle accidents, most authors report a higher incidence of injury in women than in men (Foreman and Croft, 1995: 311). The most likely explanation for this is that men generally have a heavier musculature in the cervical and thoracic spine and so are more resistant to injury (Foreman and Croft, 1995: 311).

According to Pikula (1999: 112), neck pain is a frequent and disabling complaint in the general population, and in the neck pain studies which he reviewed, the prevalence ranged from 10% to 72% depending on work tasks, type of design, or activities of daily living. Pikula (1999: 112) also believes that most patients with neck pain will improve with time, but as many as one-third can suffer recurring pain up to fifteen years later.

Cote et al. (1998: 1689) drew the following conclusions from a study involving 2184 randomly selected Saskatchewan adults aged 20 to 69 years. The age-standardized lifetime prevalence of neck pain was 66,7% (95% confidence interval), and the point prevalence was 22,2% (95% confidence interval). The age-standardized 6 month prevalence of low-intensity and low-disability neck pain was 39,7% (95% confidence interval), whereas it was 10,1% (95% confidence interval) for high-intensity and low-disability neck pain and 4,6% (95% confidence interval) for significant disabling neck pain.

In a study conducted by Lau et al. (1996) involving 800 Hong Kong Chinese subjects all over the age of 30 years, a one year prevalence of neck pain was found in 15% of the men and 17% of the women.

Drews (1995: 66) conducted a study at the Technikon Natal Chiropractic Clinic comparing the types of conditions seen at this teaching clinic and those seen at 17 private chiropractic clinics in South Africa. It was concluded that 54,4% of patients (N = 162) presenting to the teaching clinic and 57,4% of patients (N = 162) presenting to private practitioners, complained of neck pain.

From the above mentioned literature sources, it can be noted that neck pain is a significant problem seen by chiropractors and that there is a great need for continuing research into this problem.

2.3 CAUSATIVE FACTORS AND WORKPLACE ERGONOMICS ASSOCIATED WITH NECK PAIN.

One of the most common causes of neck pain is mechanical dysfunction of the cervical spine, however the exact nature of this pathology remains obscure (Pikula, 1999: 112). Although basically all spinal structures are capable of producing pain, it appears that the cervical zygapophyseal joints as well as the discs are the most frequent contributors (Jordan et al. 1998: 311).

According to Grieve (1994: 392), the two main predisposing factors in causing mechanical neck pain are prolonged poor postural habits and the frequency with which spinal flexion occurs with daily living. Bland (1994: 114) claims that the patient's age, occupation, previous injury, the use of bifocal eyeglasses and specific physical characteristics are all causative factors in patients with neck pain.

Neck pain has been associated with occupations in which flexed cervical postures occur, static work postures and repetitious work involving lifting of objects (Jordan et al. 1997: 468). The authors further state that all of these factors involve the musculature and other connective tissues of the cervical spine, as such, they have been implicated in mechanical neck pain syndromes as well as cervicogenic headache.

A study reviewed by Grieve (1988: 190) showed that 5% of industrial workers were unable to work because of neck pain. Stock (1991: 87) states that the relationship between workplace factors and the development of disorders of muscles, tendons and peripheral nerves in the neck and upper limbs has become the subject of growing interest in the past 10 years. They are believed to be a major cause of time lost from work and long-term disability, and payments for workers' compensation claims for these disorders have risen rapidly over the past 10 years in most industrialized countries (Stock, 1991: 88).

According to Wiesel et al. (1992: 11), an estimated 85% of all neck injuries seen in the United States result from automobile accidents. Barnsley et al. (1995: 20) performed a double-blinded, controlled study on the prevalence of chronic cervical zygapophyseal joint pain after whiplash in which diagnostic blocks of either Lignocaine or Bupivacaine were used. Painful zygapophyseal joints were identified in 54% of patients (95% confidence interval) with chronic neck pain after whiplash (N = 50). Thus, motor vehicle accidents are a common cause of neck pain in the modern world, and more often than not the facets joints are the source of the pain.

2.4 FACET SYNDROME

2.4.1 Definition

Facet syndrome may be broadly defined as pain or dysfunction arising primarily from the zygapophyseal joints and their immediately adjacent soft tissues resulting in an aggregate of signs and symptoms (Gatterman, 1995:11; Panzer, 1995: 415).

2.4.2 Synonyms

Gatterman (1995: 7) lists some synonyms of facet syndrome as: cervical joint block, cervical joint or facet joint dysfunction, articular derangement or dyskinesia, chiropractic subluxation complex, facilitated segment, fixation, functional spinal lesion, intervertebral blocking, locked facet, manipulable lesion, mechanical musculoskeletal dysfunction, misalignment, neurobiomechanical lesion, posterior facet dysfunction, spinal irritation and vertebral locking.

2.4.3 Aetiology

Bergmann et al. (1993: 60) states that 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. The inflammatory component of facet syndrome may be initiated by joint injury, mechanical joint derangement or joint immobilization. Lippit (1984: 747) adds that segmental instability, degenerative

arthritis and inflammation or synovitis, whether traumatic or rheumatologic, are also contributing factors.

According to Peters (1984: 85), the term facet syndrome pertains to the condition characterized by an overriding of the facets of adjacent vertebrae, whereby the intervertebral foramina are narrowed from the superior to the inferior. However, he claims that the term also relates to a state of subluxation with tension, pressure, stretching or irritation of the vertebral joint capsule, as a result of postural strain or trauma, but without any narrowing of the related foramina (Peters, 1984: 85).

The opinion of Kirkaldy-Willis and Burton (1992: 248) is that the facet syndrome is caused by rotational strain to both facet joints and annulus fibrosis, with dysfunctions of the facet joints producing most of the symptoms. Zohn (1988: 22) claims that impairment of movement of the joint is associated with the sensation of pain which in turn increases loss of function.

According to Panzer (1995: 425), the occurrence of facet syndrome has been correlated to an increase in facet weight-bearing. Peters (1984: 89) supports this by stating that any degenerative thinning of the intervertebral disc results in the superior apophyseal facet being forced down on the corresponding inferior apophyseal joint surface resulting possibly in the inflammatory reaction and stretching of the joint capsule that is seen in the facet syndrome. A history of

activity involving flexion with rotatory strain on the facets is common in a typical victim of facet syndrome (Peters, 1984: 89).

Foreman and Croft (1995: 313) refer to the following chain of events as being the cause of facet syndrome. Stretched and torn ligaments from repeated microtrauma or from a single traumatic event such as a whiplash injury can cause an abnormal range of motion in the zygapophyseal joints. This results in inflammation and overstretching of the joint capsules, causing the zygapophyseal joints to become an ongoing source of pain. Reflexly, this may result in muscle hypertonicity to stabilize and splint the abnormal motion. This in turn may cause further abnormal cervical motion with fine intersegmental movement being affected. Hypertonicity of the intersegmental muscles, which function to coordinate fine intersegmental movement, occurs first, however it is the spasm of the longer postural neck muscles that is normally clinically visible. The above-mentioned changes may initiate nociceptive stimuli.

In a study conducted by Dwyer et al. (1990: 453) in which normal zygapophyseal joints were stimulated by distending the joint capsule with injections of fluoroscopic contrast medium, each joint produced a clinically distinguishable, characteristic pattern of pain. These patterns were similar to those of patients with facet syndrome, and thus it could be deduced that this neck pain was likely to be caused by the facet joints.

2.4.4 Clinical Features and Diagnostic Criteria

Pain from an irritable facet joint may be detected by local tenderness, which is relatively circumscribed, over a facet, with confirmation by manoeuvres to pinch or compress the facet joint as in Kemp's Test (Meyer et al. 1991: 127).

According to Aprill and Bogduk (1992: 744), noninvasive imaging techniques do not provide a basis for the diagnosis of neck pain, and structure-specific diagnosis can at best only be made using invasive needle techniques such as provocation discography and zygapophyseal joint blocks. This is supported by Panzer (1995: 420), who states that injection of local anaesthetic or a cortisone derivative into a specific facet joint, followed by relief of pain, is generally considered diagnostic of facet syndrome. Ethical considerations, however, restrict the number of invasive tests that can be applied to a sample population (Aprill and Bogduk, 1992: 744).

Mootz (1995: 177) states that the facet syndrome often has referred pain distribution patterns that may provide diagnostic clues. Facet syndrome produces local and radiating pain and according to Roy et al. (1988: 118), there are two main cervical facet syndromes, depending on the level of the involved joints. The cervical headache syndrome corresponds with involvement of C2 – C3, and C3 – C4 levels and consists of a hemi-occipital headache with or without supra-orbital radiation. The second syndrome, cervical dorsalgia, involves the C5 – C6 and C6

– C7 levels. It is characterized by interscapular thoracic pain with or without brachial pain (Roy et al. 1988: 118).

Facet pain patterns were found to be consistent enough in the cervical spine that examiners could predict the level of facet involvement based on pain distribution alone (Aprill and Bogduk, 1990: 458). To test the predictive value of segmental pain charts, Aprill and Bogduk (1990: 458) conducted a study on ten patients with suspected cervical zygapophyseal joint pain. Before investigation, the involved radiologist interviewed each patient and recorded the distribution of their pain on a body diagram. Using pain charts derived from studies on normal volunteers, predictions were made by two observers of the spinal level of the symptomatic facet joint. Correct predictions were made in all nine patients who were shown to have symptomatic joints. Confirmation of this was achieved with diagnostic medial branch nerve blocks.

A study was performed by Fukui et al. (1996: 81) to determine the distribution of referred pain from cervical zygapophyseal joints and the cervical dorsal rami. The sample comprised of 61 patients who had occipital, neck, and shoulder pain of suspected zygapophyseal origin, and a total of 181 joints and 62 segments were studied. Under fluoroscopic control, the zygapophyseal joints from C0/C1 to C7/T1 were stimulated by the injection of contrast media. If this produced the patients' usual pain, the distribution of referred pain was mapped out, and the

sites of referred pain were divided into 10 areas. The main distribution of referred pain were as follows:

- C0/1, C1/2, C2/3 – upper posterolateral cervical region
- C2/3, C3 – occipital region
- C2/3, C3/4, C3 – upper posterior cervical region
- C3/4, C4/5, C4 – middle posterior cervical region
- C4/5, C5/6, C4, C5 – lower posterior cervical region
- C4/5, C5/6, C4 – suprascapular region
- C6/7, C6, C7 – superior angle of scapula
- C7/T1, C7 – mid-scapular region

Peters (1984: 88), outlines the following complaints that a typical victim of facet syndrome may suffer from. The patient may complain of sudden onset of unilateral or bilateral pain, with or without radiation, and often with referred pain. There may be marked muscle spasm, usually without neurological findings. Pain increases through movement and is relieved by rest. If the pain has a postural basis, sharp stabbing pain may be experienced in the morning on rising. Between attacks, the pain is exacerbated by hyperextension and eased by flexion, and it often follows a sclerotomal, rather than a dermatomal pattern.

Cervical pain of zygapophyseal origin has been described as having the following clinical features (Panzer, 1995: 424):

- Characteristic local and referred pain (occipital to interscapular, depending on vertebral level).
- Abnormal end feel of facet joint capsule.
- Abnormal quality of resistance to motion.
- Pain on palpation of segmental accessory movements.
- Confirmation possible with facet or medial branch nerve block.

Bergmann et al. (1993: 63) identifies the 5 diagnostic criteria for cervical joint dysfunction with the use of the acronym PARTS:

- Pain and tenderness – evaluated in terms of location, quality and intensity, and identified through observation, percussion, and palpation.
- Asymmetry – identified through posture and gait analysis, as well as static radiography and static palpation for misalignment of vertebral segments.
- Range of motion abnormality – identified through motion palpation and stress radiography, noting any changes in active, passive and accessory joint motion.
- Tone, texture and temperature abnormality – identified through observation, palpation, instrumentation, and tests for length and strength.

- Special tests – orthopaedic tests are used to identify and isolate the involved facet joint.

Confirmation of the diagnosis may be a favourable response of the patient to manipulation (Kirkaldy-willis and Burton, 1992: 203).

Roy et al. (1988: 118) and Gatterman (1990: 163) believe that the diagnosis of facet syndrome should be based mainly on clinical evaluation, since radiographs are most often negative.

2.4.5 Evidence of Inflammation

The literature that follows provides evidence that inflammation is an aspect of cervical facet syndrome and this is why it is postulated that anti-inflammatory agents could be used in its treatment. Inflammation is defined 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 connective tissue formation; it may be a continuation of an acute form or a prolonged low-grade form' (Anderson, 1989: 305).

Bergmann et al. (1993: 60) claim that inflammation is a component of the vertebral subluxation complex, which may result from joint injury, joint immobilization or chronic joint derangement. According to Bergmann et al. (1993: 60), all inflammatory reactions are accompanied by cellular and humoral

components which may act as intrinsic sources of pain and vasodilation. This pain often leads to local reflex muscle spasm, which may be followed by local ischaemia and more pain and muscle splinting. This eventually results in a self-perpetuating cycle of pain and muscle spasm. Thus, it is believed that there must be some degree of joint or soft tissue inflammation in patients where pain is a constant feature (Bergmann et al. 1993: 60). Lantz (1995: 163) believes that the inflammatory response is a combination of biochemical and cellular events, which is largely mediated by the vascular system, but is initiated by local events within the affected tissues.

According to Bourdillon et al. (1992: 283), inflammation is likely to be a factor in many spinal joint dysfunctions, and it is this inflammatory reaction around a nerve or nerve root that may cause persistent pain. They believe that local epidural injections of a mixture of local anaesthetic with a steroid close to the nerve root can be very helpful due to the anti-inflammatory action. However, they also state that if the mechanical aspect of the joint dysfunction is not altered, these injections may have very short-term benefit or none at all. To support the latter, Bogduk (1994: 433) believes that it is mechanical changes and not inflammatory changes that determines if the zygapophyseal joint becomes symptomatic or not.

According to Lantz (1995: 163), a feature of the neuro-biological component of the chronic facet syndrome, is an inflammatory spillover into the surrounding tissues from the facet joint, resulting in chemical radiculitis. The duration of

symptoms in painful neck conditions are a possible indicator of the severity of inflammation present in the joint (Gifford, 1994: 507). Farfan (1992: 160) hypothesizes that the acute inflammation in facet syndrome may recover rapidly, however the resulting synovitis which affects the annulus at that level, may take a long time to settle. Reid (1992: 829) proposes that flare-ups of synovitis and facet joint pain produce the facet joint syndrome.

Roy et al. (1988: 118) evaluated the effectiveness of cervical facet joint infiltration. Twenty-one patients with cervical facet syndrome underwent either an intra- or a peri-articular cervical facet joint infiltration with corticosteroids under fluoroscopic guidance. A total of 39 levels were infiltrated. There were 22 intra-articular and 17 peri-articular injections. This treatment relieved symptoms in 91% of patients with follow-up ranging from 1 week to 12 months. The local injection of corticosteroids is thought to act by reducing inflammation in the capsule and irritation of the nerve root. It must be noted, however, that symptoms usually recurred, specifically in 71% of patients with complete responses and in 42% of those with partial relief. From this relative success resulting from the introduction of an anti-inflammatory agent into the affected joints, it can be deduced that inflammation plays a role in cervical facet syndrome, and that anti-inflammatories can be used to treat those symptomatic joints. Following a review of studies by Panzer (1995: 420), he claims that the injection of local anaesthetic or cortisone into a specific facet joint, resulting in pain relief, is generally considered diagnostic of facet syndrome.

Dwyer et al. (1990: 453) conducted a study in which the pain patterns evoked by stimulation of normal zygapophyseal joints were determined in five volunteers. Under fluoroscopic control, joints at segments C2-3 to C6-7 were stimulated by distending the joint capsule with contrast medium. Each joint produced a clinically distinguishable, characteristic pattern of pain, which enabled the construction of pain charts that putatively could be of value in determining the segmental location of symptomatic joints in patients presenting with cervical zygapophyseal pain. This induced distention of the joint capsule could be comparable to inflammation of the joint capsule, and thus it can be deduced that inflammation plays a role in cervical zygapophyseal joint pain. As a result of the proximity of the posterior branches of the dorsal rami to the capsules of the facet joints, inflammation of these joints may irritate the nerve roots and cause pain (Bourdillon et al. 1992: 301).

According to Dishman (1988: 102), cervical spine injury results in the release of histamine or bradykinin, thromboxane, monohydroxy fatty acids, leucotrienes and prostaglandins. He goes on to describe the cycle as follows. The leucotrienes produce inflammation which often leads to trigger point formation. When these substances form interactions with histamine, bradykinin and other polypeptides, they stimulate the pain impulse. From this there ensues a number of secondary effects such as nerve root hyperalgesia, muscle contraction, referred pain, autonomic reflex change and anti-dromic impulses which may represent themselves as myosistis, tendonitis, synovitis, vasculitis or syndesmitis. This

inflammatory reaction and accompanying decreased muscle length produces the restricted range of joint movement, tendon and fascial shortening, resulting in functional disability. (Dishman, 1988: 102). This is supported by Lantz (1995: 166) who states that immobilization in the cervical spine can result in connective tissue degradation, causing a release of autocoids which initiate an inflammatory process resulting in tissue remodeling and subsequent limitation of joint movement.

According to Schafer and Faye (1990: 306), the normal resolution of inflammation is fibrosis, which progresses to the development of scar tissue with subsequent restriction of joint motion. This same effect of inflammation on restricting joint mobility is also pointed out by Plaughner (1993: 217). This can compromise the functioning of the joint complex by causing circulatory, biomechanical and neurological consequences (Schafer and Faye 1990: 306). Therefore, it is the opinion of the researcher that the inflammatory component of injury must be resolved, before mechanical changes set in, which may be achieved by the use of anti-inflammatory drugs.

2.5 TREATMENT OF CERVICAL FACET SYNDROME

2.5.1 Manipulation

2.5.1.1 Definition

There is still disagreement as to the breadth of the meaning of the word manipulation. In Europe the term is used, in this context, almost solely for procedures involving a high velocity, low amplitude, thrusting movement. In North America, however, it is used in a much wider sense, to include any active or passive movement initiated, assisted or resisted by the operator. This includes treatments sometimes listed as articulation, mobilization, isometric and isotonic techniques, myofascial, functional or indirect and even craniosacral techniques. (Bourdillon et al. 1992: 121).

According to Gatterman (1995: 12), the following definition of manipulation has reached consensus: 'a manual procedure that involves a directed thrust to move a joint past the physiological range of motion without exceeding the anatomic limit.'

Peterson (1993: 123) states that joint manipulative procedures are physical manoeuvres designed to induce joint motion through either non-thrust techniques or thrust techniques. They are intended to treat disorders of the neuromusculoskeletal system by improving joint alignment, range of motion and quality of movement. He goes on to say that the chiropractic adjustment is a

specific form of articular manipulation in which either long- or short-leverage techniques with specific contacts are used, and it is characterized by a dynamic thrust of controlled velocity, amplitude, and direction (Peterson, 1993: 124).

The definition given by Kirkaldy-Willis et al. (1992: 283) is both clear and concise.

'A manipulation is a passive manual maneuver during which a synovial joint is carried suddenly beyond the normal physiological range of movement without exceeding the boundaries of anatomical integrity. The usual characteristic is a thrust – a brief, sudden, and carefully administered impulsion that is given at the end of the normal passive range of movement. It is usually accompanied by a cracking noise.'

The primary treatment modality used by the chiropractic profession since its inception is vertebral manipulation. This is employed to restore normal joint and muscle function (Fitz-Ritson, 1990: 17).

2.5.1.2 Effects of Manipulation

According to several authors, an adjustment results in an audible snap or joint cavitation, with the release of gas into the joint capsule from the fluid within, followed by an increase in range of motion of that joint (Haas, 1990: 305; Bourdillon et al. 1992: 297; Peterson, 1993: 140).

According to Zusman (1994:651), one of the most dramatic effects of manipulation is the rapid restoration of joint range of movement, combined with the decrease in severe pain experienced by patients with a fixated spinal joint. The assumption is (Zusman, 1994:651), that manipulation moves or frees the impediment to normal joint function, which may be a loose body, disc material, synovial fringe or meniscoid entrapment, permitting movement and halting nociceptive input and associated reflex muscle spasm.

Peterson (1993:142) adds that derangements of the posterior joints, intercapsular adhesions, and intradiscal derangement are proposed interarticular sources of joint fixation, with associated segmental muscle spasm, periarticular soft tissue fibrosis and shortening as extra-articular sources. Hence, prolonged joint immobilization may eventually lead to fibrous adhesion formation between the joint surfaces, and manipulative therapy is suggested as a procedure that may induce quick distraction and break the intra-articular adhesions (Peterson, 1993: 142).

Kirkaldy-Willis et al. (1992: 288) explains the therapeutic effects of manipulation as follows. Joint movement, which was previously restricted, is increased by spinal manipulation, and due to this breaking of the articular adhesions, there is an increase in passive and active range of motion. Increased movement causes an increase in proprioceptive input, which in turn has a reflex inhibition on the transmission of pain. Gross et al. (1996: 587), refer to the gate control theory for

modulation of pain, as described by Melzack and Wall (1965), as an explanation as to how large-diameter fiber stimulation can modulate pain. Type I, II or III mechanoreceptors are synovial joint receptors that give kinesthetic and positional information to the central nervous system. Large-diameter fibers, stimulated by type I, II or III mechanoreceptors, have a facilitative effect on inhibitory interneurons in the substantia gelatinosa, resulting in a decrease of nociceptive activity, thereby reducing pain perception.

Panzer (1995: 424) put forward a summary of the specific proposed effects that manipulation has on the facet articulations:

- Release of entrapped meniscoid.
- Reduction in articular cartilage displacement by chronically entrapped meniscoid.
- Pain relief by co-activation of various receptors.
- Reduced weight bearing.
- Reduction of intervertebral foramen stenosis caused by segmental hyperextension.
- Reduced intracapsular or extracapsular adhesions.
- Relief of abnormal tension on joint capsule.
- Reduction of postimmobilization collagen cross-linking.
- Reduction of local vascular stasis.
- Release of osseous mechanical locking.

2.5.1.3 Contra-Indications, Complications and Safety of Manipulation

Peterson (1993: 132-133) provides a comprehensive summary of the contra-indications to spinal manipulation:

- Vascular – vertebrobasilar insufficiency, aneurysm, atherosclerosis, and anticoagulant therapy.
- Articular – advanced osteoarthritis, inflammatory arthritis (rheumatoid, psoriatic), ankylosing spondylitis, joint instability and hypermobility.
- Trauma – fracture, dislocation and severe sprains and strains.
- Bone weakening disorders – bone tumours, bone infections (tuberculosis), osteomyelitis, osteoporosis, and osteomalacia.
- Neurologic – disc prolapse with neurologic deficit, severe sacral nerve root compression, vertigo, severe pain, patient intolerance and space-occupying lesion.
- Psychological – malingering, hysteria and hypochondriasis.
- Finally, adjustive therapy is contra-indicated when the therapy may produce an injury, worsen an associated disorder, or delay appropriate curative or life-saving treatment.

According to Bergmann et al. (1993: 53), hypermobility is one of the few contra-indications to manipulation, but only at that level, however there will often be a hypomobile joint nearby which can be treated. Mootz (1995:180) disagrees

however, and states that manipulation of an unstable segment is unlikely to promote greater instability, and may provide the patient with relief.

Michaeli (1993: 309-312) reported on the occurrence and nature of complications following manipulative physiotherapy in South Africa. The survey questionnaire was mailed to all 250 physiotherapists who had successfully completed the postgraduate course on manipulative therapy in South Africa between 1971 and 1989. One hundred and fifty three physiotherapists responded, of which 90 used cervical manipulation. It was estimated that an approximate total of 228 050 manipulative procedures were performed by physiotherapists in this time period of which twenty-five patients reported 48 complications following cervical manipulation, most of which were minor complications. These complications were categorized as follows:

- 12 dizziness
- 11 nausea
- 10 severe headache
- 3 nystagmus
- 3 blurring of vision
- 3 vomiting
- 3 brachialgia
- 1 brachialgia with neurological deficit
- 1 loss of consciousness
- 1 acute wry neck

It must be noted that all of these adjustments were performed by physiotherapists and not chiropractors.

In a review of the literature relating to the complications arising from manipulation of the cervical spine conducted by Jaskoviak (1980: 213), it was concluded that during the period 1947 to 1980, there were 46 published cases of neurological deficit in the United States, 11 of which resulted in fatalities. The manipulations were given for varying patient complaints by chiropractors (28 cases), allopathic physicians (9 cases), osteopathic physicians (2 cases), a physical therapist (1 case), a wife (1 case), and self-administered (1 case). In three cases the type of manipulator was not given, and one case occurred spontaneously when the individual turned around to back up her car. In view of the fact that more than 75-million such cervical spine manipulations are performed yearly in the United States alone, the incidence is very minimal.

In the event of complications, Jaskoviak (1980: 216) outlines the immediate sequelae following cervical manipulation as the following:

- Syncope, dizziness and vertigo.
- Nystagmus, diplopia and blurred vision.
- Vomiting and nausea.
- Ataxia, plegia, weakness and paralysis.
- Headache.
- Coma.

Vascular accidents are considered to be the most serious of all complications of cervical manipulation (Gatterman, 1990: 55). Ladermann (1990: 63) expresses his concern for cerebrovascular accidents, however states that the publicity about post-chiropractic iatrogenic brainstem syndromes is disproportionate to their actual frequency. He argues that, if such complications were a systemic adverse reaction to manual therapy and if manipulation was the decisive factor, then the 'earth would be littered with corpses of victims of chiropractic ill-treatment.' He believes that manipulation can be the precipitating factor, but not the fundamental cause (Ladermann, 1990: 66).

Peterson (1993: 136), advocate a number of screening tests for vertebrobasilar ischaemia, namely Maigne's, Hautent's, DeKleyn's and Underberger's tests, which include rotation and extension of the cervical spine, and may produce characteristic signs and symptoms of compromised vertebral artery flow. Rivett *et al.* (1999: 368) supports the reliability of these premanipulative screening tests. However, Bolton *et al.* (1989: 304) and Cote *et al.* (1996: 159), highlight the limited diagnostic value of these tests, concluding that the value of the neck extension-rotation tests for screening patients at risk of stroke after cervical manipulation is questionable.

In a risk assessment of cervical manipulation versus NSAIDs for the treatment of neck pain by Dabbs and Lauretti (1995: 530), in which a review of the medline literature from 1966 to 1994 was conducted, it was concluded that the best

evidence indicates that cervical manipulation for neck pain is much safer than the use of NSAIDs by as much a factor of several hundred times. Gross et al. (1996: 595) adds that the risk of increased symptoms, such as dizziness or vertigo, or increased pain or stiffness, resulting from manual therapy is low (in the range of 1% – 2%), with the risk of serious complications or death being extremely low (in the range of 0,0001%). Furthermore, Bourdillon et al. (1992: 129) and Peterson (1993: 132) state that accidents that have occurred in spinal manipulative therapy appear to have occurred because the diagnosis was wrong or because the manipulative technique used was not accurately localized.

2.5.1.4 Efficacy of Manipulation

Panzer (1995: 424) believes that spinal manipulation directed to the facet articulation is generally considered the treatment of choice for facet syndrome. Facet syndrome generally involves pain and joint dysfunction, and Panzer (1994: 424) states that it is logical to apply treatment that not only relieves the pain but also helps correct the underlying dysfunction.

Numerous authors support that manipulative therapy is an effective treatment for mechanical neck pain (Brunarski, 1984: 243; Gross et al. 1996: 595; Howe et al. 1983: 1574; Mennel, 1990: 7; Sloop et al. 1982: 532; Terrett and Vernon, 1984: 217; Williamson, 1998: 112). Brunarski (1984: 243), in fact, states that the literature which he reviewed, has produced sufficient evidence to suggest that spinal manipulation may be more effective than standard medical care, such as

the use of medication, prolonged rest and immobilization of joints by plaster casts, corsets and surgical fusion, in the management of painful musculoskeletal conditions. Cherkin and MacCormack (1989: 351) support this, stating that chiropractic provides a higher degree of patient satisfaction when compared to conventional medical care. They compared patients' evaluations of the care they received from family physicians and chiropractors for low back pain. The study included 215 patients treated by family physicians and 242 patients treated by chiropractors. The percentage of chiropractor patients who were 'very satisfied' with the care they received for low back pain was triple that for patients of family physicians (66% versus 22%, $p < 0.001$) (Cherkin and MacCormack, 1989: 352-353). It must be noted, however, that of the studies reviewed by Brunarski (1984: 244), crucial design flaws and untoward bias against manipulation, whether intentional or not, has cast serious doubt on the credibility of the conclusions made by many of these studies. Forty percent of the studies which he reviewed were descriptive studies, lacking a control group. Many of the studies were retrospective studies, which are often plagued by incomplete data, inconsistent eligibility criteria, undeterminable contamination, co-intervention and potential bias. Bias was also suspected when assessments were not performed blinded (Brunarski, 1984: 244-246).

Sloop et al. (1982: 533) performed the first reported controlled study of manipulation for chronic neck pain. Twenty-one patients with symptomatic cervical spondylosis or non-specific neck pain were given an amnesic dose of

Diazepam before manipulation of the cervical spine. Eighteen patients served as control and also received Diazepam but no manipulation. Results were obtained after three weeks in a randomized fashion by an outpatient physician who did not know which patients had received manipulation. The tests employed to demonstrate the therapeutic effect of the treatments slightly favoured manipulation. These results however, were not statistically significant, although, 57% of the patients receiving manipulation asserted that the treatment helped them, compared to 28% of the control group ($p=0.13$). It must be noted that all manipulations in this study were performed by a rheumatologist and not a chiropractor. They go on to highlight a report of cervical manipulation in migraine patients by Parks et al. (1978), in which patients who received manipulation by chiropractors improved significantly more than those who were manipulated by non-chiropractors. The migraine patients, when they were receiving manipulations by chiropractors, showed improved Visual Analogue Scale scores for intensity of pain but not frequency of attacks. Two comparison groups of migraine patients, having had manipulations by non-chiropractors, improved significantly less. Sloop et al. (1982: 534) point out the need for further study, and that further exploration is required to determine the value of a single manipulation of the cervical spine.

Howe et al. (1983: 574) carried out a randomized controlled trial on manipulation of the cervical spine on 52 patients in general practice, and the results were assessed symptomatically and goniometrically for three weeks. Pain in the neck

improved in 68% of the patients ($p < 0,001$), neck stiffness improved in 87% of the patients ($p < 0,001$), and pain or paraesthesia in the shoulder improved in 45% of the patients ($p < 0,02$), immediately after manipulation. Manipulation also produced a highly significant immediate improvement in rotation ($p < 0,05$) and lateral flexion ($p < 0,01$). According to Howe *et al.* (1983: 578), this disposes of the idea that "manipulation only appears to benefit patients by a psychological effect of being an 'active' treatment performed by smooth-talking operators."

Terrett and Vernon (1984: 217-224) conducted a controlled study on the effect of spinal manipulation on paraspinal cutaneous pain tolerance levels. A model of experimental pain induction was constructed for use in the study. The sample consisted of 50 male caucasian subjects all of whom had no spinal pain at the time. The group that received a spinal manipulation demonstrated a 140% increase in local cutaneous pain tolerance levels which was statistically significant ($p < 0,05$) as compared to the control group.

A survey was conducted, by Johnson *et al.* (1989: 335), in which the cost of care and number of workdays lost, because of sprains and strains of the back or neck, were analysed. Comparisons were made on the benefits and cost of care received by patients treated by chiropractic doctors, medical doctors and osteopathic doctors. For those who received care from chiropractors, the mean number of compensated days lost from work was at least 2,3 days less than for those who were treated by medical doctors, and at least 3,8 days less than for

those treated by osteopaths. Much less money in employment compensation was therefore paid, on average, to those who received chiropractic care.

A pilot study was conducted by Vernon et al. (1990: 13) in which the effect of spinal manipulation, in the treatment of chronic neck pain, was evaluated by means of pressure pain threshold measurements. Nine subjects were allocated randomly to either a control group ($n = 4$), receiving oscillatory mobilization of the cervical spine, or an experimental group ($n = 5$), receiving rotational manipulation of the cervical spine. An assessor-blinded evaluation of the pressure pain threshold levels was conducted before and again five minutes after treatment. There was a statistically significant ($p < 0,0001$) increase in pressure pain threshold in the experimental group with an average mean increase of 45%. In the control group no change in any of the pressure pain threshold measurements was found.

Cassidy et al. (1992: 497) did a pilot study on the effect of manipulation on pain and range of motion in the cervical spine. Fifty consecutive outpatients suffering from unilateral neck pain received a single rotational manipulation on the same side as the pain. Thirty-seven patients reported a decrease in pain, and all patients had an increase in range of motion in all directions with ipsilateral rotation being the greatest. Overall, the Numerical Pain Rating Scale – 101 pain scores decreased from a pre-treatment mean of 43,7 to a post-treatment value of

31,1 in the 50 patients, representing a mean improvement of over 12 points on the scale.

Skargren et al. (1997: 2167), conducted a prospective, randomized, clinical trial in which patients with low back pain or neck pain received treatment from either a chiropractor or physiotherapist. In total, 323 patients participated in the trial, 179 in the chiropractic group and 144 in the physiotherapy group. The effects of treatment strategies on different aspects of perceived pain, function, and general health were recorded. The patients with acute, uncomplicated problems seemed to benefit more from chiropractic in this study, whereas, physiotherapy seemed more beneficial to patients who had had their problems for one month or longer. Virtually all the patients treated by chiropractors received manipulation, with 80% of them receiving manipulation as the only form of treatment. Of note was that 41% of the patients in the chiropractic group estimated that their expectations were fulfilled after the treatment was completed compared to 24% of the patients in the physiotherapy group (Skargren et al. 1987: 2174).

Jordan et al. (1998: 311) conducted a prospective, single-blinded, randomized clinical trial to compare the relative effectiveness of intensive training of the cervical musculature, a physiotherapy treatment regimen, and chiropractic treatment. The study included 119 patients with chronic neck pain of more than 3 months duration. Intensive training was carried out in groups of four to five patients under the guidance of a physiotherapists, with all patients in this

treatment group undergoing the same training. Patients in the physiotherapy and chiropractic group were treated according to an individual treatment plan structured by the physiotherapist or chiropractor respectively, after a functional examination. There was no clinical difference between the three treatments, with patients from all three groups demonstrating significant improvement regarding self-reported pain and disability. These improvements were maintained at 4 and 12 month follow-ups. It is of note that pain appeared to decrease more rapidly in the chiropractic group. This information was obtained by measuring the patients pain halfway through the treatment period. The patient filled out a pain scale of 0-10 with 0 representing 'no pain at all' and 10 representing 'worst imaginable pain', prompted by the phrase 'neck pain at the present time'. Results were as follows: intensive training, median 3,7; physiotherapy, median 3,9; and chiropractic, median 3,3. There was no statistical significance between the groups ($p = 0.14$). Due to the fact that there was no control group in this study, the authors were unable to conclude whether the improvements were as a result of the treatments or simply a result of time.

In a systematic review and meta-analysis on the conservative management of mechanical neck pain (Aker et al. 1996: 1291), it was concluded that there was little information available from clinical trials to support many of the treatments for mechanical neck pain, and in general, conservative interventions had not been studied in enough detail to assess efficacy or effectiveness adequately. Gross et al. (1996: 595) supports this and adds that no one treatment protocol has been

shown to be optimal as specific types of manual therapies have not yet been investigated in detail, although, when used in combination with other treatments, manual therapies have been demonstrated to be effective for mechanical neck pain in the short term.

2.5.2 Non-Steroidal Anti-Inflammatory Drugs

2.5.2.1 Introduction

Worldwide, non-steroidal anti-inflammatory drugs (NSAIDs) appear to be the most commonly prescribed medication (Koes et al. 1997: 214).

The NSAID used in this study was Piroxicam 20 mg, under the propriety name Adco-Piroxicam.

2.5.2.2 Piroxicam

Piroxicam is one of the oxicam derivatives, a class of enolic acids that possesses anti-inflammatory, analgesic and anti-pyretic activity. In recommended doses, piroxicam appears to be the equivalent of aspirin, however, it may be tolerated better than aspirin. The principal advantage of piroxicam is its long half-life, which permits the administration of a single daily dose. (Insel, 1990: 668).

Piroxicam is chemically designated as:

4 – Hydroxy – 2 – methyl – N – 2 – pyridinyl – 2H – 1,2 – benzothiazine – 3 – carboxamide 1,1 – dioxide (Arky, 1997: 2008).

2.5.2.3 Pharmacological Properties

Piroxicam is an effective anti-inflammatory agent (Arky, 1997:2008, Insel, 1990:668). The exact mechanism of action is not yet fully established, however it is proposed that the effects may be due to the ability of piroxicam to inhibit the biosynthesis of prostaglandins, known as the mediators of inflammation. According to Insel (1990: 668), piroxicam can also inhibit activation of neutrophils even when products of cyclogenase are present, hence additional modes of anti-inflammatory action have been proposed. Piroxicam does not act by stimulating the pituitary-adrenal axis (Arky, 1997: 2008).

2.5.2.4 Pharmacokinetics and Metabolism

Piroxicam is well absorbed following oral administration, with peak concentrations occurring in plasma within 2 to 4 hours, subsequently declining with a mean plasma half-life of about 50 hours (Arky, 1997:2008; Insel, 1990: 668). Neither food nor antacids alter the rate or extent of absorption (Insel, 1990: 668).

After absorption, piroxicam is extensively (99%) bound to plasma proteins (Insel, 1990: 668). After 7 to 12 days, a steady state is attained at which plasma

concentrations in plasma and synovial fluid are approximately equal (Arky, 1997: 2008; Insel, 1990:668). Metabolism of piroxicam occurs in the liver by hydroxylation of the pyridyl side chain and conjugation of this product (Arky, 1997: 2008; Insel, 1990: 668).

Piroxicam and its biotransformation products are excreted in the urine and the faeces, with about twice as much appearing in the urine (Arky, 1997: 2008). Less than 5% of the unchanged drug is excreted in the urine (Insel, 1990: 668).

2.5.2.5 Toxic Effects and Contra-Indications

Insel (1990: 668) reported that the incidence of adverse effects in patients taking piroxicam is about 20%, with gastrointestinal reaction being the most common, and the incidence of peptic ulceration being less than 1%. Besides gastrointestinal bleeding, other reported side effects include, oedema, increased serum transaminase levels, raised blood urea nitrogen levels, decreased platelet aggregation and prolonged bleeding time, skin rash, Stevens-Johnson syndrome, decrease in haemoglobin and haematocrit, thrombocytopenia and non-thrombocytopenic purpura, aplastic anaemia, leucopenia, eosinophilia, bronchoconstriction, dizziness, headache, somnolence and vertigo [Adco-Piroxicam package insert (Appendix G)].

Aoki et al. (1983: 250) conducted a multi-centre double-blinded comparison of piroxicam and indomethacin in the treatment of lumbar diseases. Out of the 116

patients who received piroxicam, 11,2% of them experienced side-effects, compared to 13,2% of the 114 patients receiving indomethacin. None of the side-effects were considered serious. They included abdominal pain (5 patients), anorexia (2 patients), diarrhoea (2 patients), dizziness (1 patient), edema (5 patients), dry mouth (1 patient) and rash (1 patient).

Complications or side-effects of NSAIDs were reported in most of the 26 trials reviewed by Koes et al. (1997: 217). The number of patients reporting side effects varied from 0% to 31%. The side effects usually concerned mild to moderately severe events, such as abdominal pain and diarrhoea, and other side effects such as oedema, dry mouth, rash, dizziness, headache and tiredness.

The most common and most serious adverse effects associated with NSAIDs are gastro-intestinal ulcers and haemorrhage, and it has been 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 to 10 times greater than that on non-users (Dabbs and Lauretti, 1995: 532).

According to Brunarski (1984: 243), the pharmacological relief of pain alone has not been shown to enhance the healing of spinal tissues. He believes, in fact, that this may result in the patient returning to strenuous activity before adequate healing has been achieved, placing the patient at risk of repeated trauma and

progressive degeneration of spinal tissues. This process of wear and tear may ultimately result in an overwhelming event of pain and disability.

According to Arky (1997: 2008), piroxicam should not be used in patients who have previously exhibited hypersensitivity to it, or in individuals with the syndrome comprised of bronchospasm, nasal polyps, and angiodema precipitated by aspirin or other NSAIDs. Piroxicam should also not be used in patients who have hepatic dysfunction or who are pregnant [Adco-Piroxicam package insert (Appendix G)].

2.5.2.6 Indications

Adco-Piroxicam is indicated for a variety of conditions requiring anti-inflammatory and analgesic activity [Adco-Piroxicam package insert (Appendix G)]. It has been useful in the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhea, postoperative pain and acute gout (Insel, 1990: 669).

2.5.2.7 Safety

According to Dabbs and Lauretti (1995: 532), NSAIDs are generally considered safe. However, despite their widespread use and perceived safety, NSAIDs have a significant risk of serious complications. It has been estimated that the chance of a patient on NSAID therapy having a gastric ulcer is 10% to 20%, which is a rate 5 to 10 times greater than that of non-users. Gastrointestinal ulcers can be

serious and frequently lead to complications such as haemorrhage, perforation and even death (Dabbs and Lauretti, 1995: 534).

In a study by Allison et al. (1992: 749) in which they examined the stomach, duodenum and small intestine of 713 patients post mortem, nonspecific small-intestinal ulceration was found in 8,4% of the users of NSAIDs and 0,6% of the non-users. Three patients who had used NSAIDs over a long term, died from perforated nonspecific small-intestinal ulcers. Ulcers of the stomach or duodenum occurred in 21,7% of NSAID users and 12,3% of patients who had not used NSAIDs. It was concluded that patients who take NSAIDs have an increased risk of non-specific ulceration of the small-intestinal mucosa, which may be life threatening (Allison et al. 1992: 753).

In a double-blinded study to compare the efficacy and safety of meloxicam 15mg with piroxicam 20mg in patients suffering from osteoarthritis of the hip (Linden et al. 1996: 35), it was noted that the most frequent side effects reported were gastrointestinal disorders, occurring in 21% and 23% of meloxicam and piroxicam patients respectively. This incidence of gastrointestinal side effects is therefore a limiting factor in the prescription of NSAIDs (Linden et al. 1996: 38).

2.5.2.8 Efficacy

There is very limited literature on the use of NSAIDs for neck pain. Dabbs and Lauretti (1995: 530) reviewed the related literature to evaluate the risk of serious

injury or death from cervical manipulation and NSAID use, and also evaluated the effectiveness of cervical manipulation and NSAID use for mechanical neck pain. A series of Medicine literature searches were performed, and materials were reviewed from 1966 to 1994. It was concluded that there was no evidence that indicates that NSAID use is any more effective than cervical manipulation for neck pain.

A meta-analysis of randomized clinical trials was performed by Koes et al. (1997: 215), to determine the efficacy of NSAIDs for the treatment of low back pain. Once again, a Medline literature search was carried out for the period 1966 to 1994. It was concluded that there were flaws in the design of most of the studies which were reviewed. The results of the 26 randomised trials that had been carried out, did however suggest that NSAIDs are effective for the short-term symptomatic relief in patients with uncomplicated low back pain. Each trial reviewed was given a score in relation to favourable research methods used. The trial by Amlie et al. (1987), in which they compared the use of Piroxicam to placebo in the treatment of low back pain, received the second highest methods score. Pain was measured by means of the visual analogue scale on days 3 and 7. The patients progress was measured on these same days in this study on neck pain. Piroxicam was superior to placebo after 3 days but there were no significant differences after 7 days, thus showing that it is a fast acting and effective treatment for low back pain. Due to the similarities in the

pathophysiology of low back pain and neck pain, it can be assumed that Piroxicam should be effective for the treatment of neck pain.

In a two week, double-blinded, parallel, multi-center study conducted by Aoki et al. (1983: 247), Piroxicam (20mg once daily) and Indomethacin (25mg three times daily) were compared in the treatment of painful lumbar disorders. A total of 230 patients were evaluated, 116 who received Piroxicam and 114 who received Indomethacin. While both drugs were highly effective in relieving symptoms, the difference between the treatments was most obvious at the end of the first week, when 21,6% of the patients receiving piroxicam were rated as 'very much improved' compared to 11,4% of the patients receiving indomethacin.

Linden et al. (1996: 35) performed a double-blinded study to compare the efficacy and safety of Meloxicam 15mg with Piroxicam 20mg in patients with osteoarthritis of the hip. Both treatment groups showed a continuous reduction in pain during the six weeks of treatment, with a particularly large decrease in the first week. These improvements were significant when compared to baseline, proving their efficacy, however there was no significant difference between Meloxicam 15mg and Piroxicam 20mg.

Moran (1990: 268) conducted an observer-blinded comparison of Diclofenac Potassium, Piroxicam and placebo in the treatment of ankle sprains (N = 108). The measures of efficacy were assessed by the investigator on days 1,3 and 7,

which is the same as the design of this study. In terms of overall reduction in pain and inflammation, both active treatments were significantly superior to placebo. In the affected ankles of patients, inflammation was notably reduced by both active treatments, particularly on Day 3 when there was a significant difference between Diclofenac Potassium or Piroxicam to placebo ($p=0,0001$). This demonstrates that Piroxicam significantly reduces inflammation in a symptomatic joint. Diclofenac Potassium was, however, significantly better than Piroxicam with respect to improvement of pain on walking and overall reduction of pain, which suggests that it may have been a better choice than Piroxicam for this study. However, in light of the fact that Moran's study involved the ankle joint and not the spine, and in reviewing the studies by Amlie et al. (1987) and Aoki et al. (1983), it was decided that Piroxicam was a better option.

Williamson (1998: 112) compared manipulation in conjunction with NSAIDs to manipulation in conjunction with placebo for the treatment of cervical facet syndrome. The NSAID used in this study was Diclofenac free acid 46,5mg (equivalent to 50mg Diclofenac Sodium). Both treatment protocols proved to be effective for the treatment of cervical facet syndrome, with neither group showing a statistically significant advantage over the other in treatment effect. The data did, however, seem to indicate a trend towards more effective pain relief and disability in favour of the NSAIDs.

Hepburn (2000: 66) compared the relative effectiveness of non-steroidal anti-inflammatory medication (Adco Piroxicam) to a homoeopathic complex (Traumeel S) in the treatment of cervical facet syndrome. The same NSAID was used in this study. Measurements regarding the efficacy of the treatments were taken on days 1,3 and 7 which is also the same as the design of this study. Hepburn (2000: 66) found that both medications were effective in treating cervical facet syndrome, however, neither group was statistically better than the other in overall improvement, in terms of disability and pain perception.

2.6 CONCLUSION

For neck pain, the first-line treatment of allopathic physicians is usually prescription of NSAIDs, whereas the first-line treatment of chiropractic physicians is usually cervical manipulation (Dabbs and Lauretti, 1995: 530). According to Dabbs and Lauretti (1995: 530), annually, 'neck symptoms' account for more than eight million visits to allopathic physicians and millions of visits to chiropractors. Cervical manipulation for neck pain is much safer than the use of NSAIDs by as much a factor of a several hundred times, however there was no evidence that indicates that NSAID use is any more effective than cervical manipulation (Dabbs and Lauretti, 1995: 534). It is therefore logical, that a study directly comparing these two treatments should be conducted, so that even if they do prove to be equally effective, a safer treatment protocol, in terms of complications, for neck pain can be established.

CHAPTER THREE

3. MATERIALS AND METHODS

3.1 INTRODUCTION

This chapter deals with the methods employed in data collection, as well as the statistical methods used for the interpretation of the data.

3.2 THE DATA

The data consisted of primary and secondary data.

3.2.1 The Primary Data

The primary data was obtained directly from the patients and it consisted of the following:

- Information gathered from the Case History (Appendix A), Physical Examination (Appendix B), and Cervical Spine Regional Examination (Appendix C).
- The Short-Form McGill Pain Questionnaire (Appendix D) to measure the patients perception of the quality of the pain.
- The Numerical Pain Rating Scale – 101 (Appendix E) to measure the patients perceived level of pain intensity.
- The CMCC Neck Disability Index (Appendix F) to measure the extent to which the pain disrupts the patients lifestyle.

- The patients perceived improvement to measure how much they thought that they had improved, and was measured in a percentage, and recorded by the researcher.
- The Algometer which was used to measure the patients pressure pain threshold.

3.2.2 The Secondary Data

This consisted of a review of the relevant literature relating to cervical facet syndrome and the treatment interventions which were used in this study. Literature was obtained from various sources, including journal articles, published reports and textbooks, Medline, Mantis, the Internet and its relevant search engines.

3.3 RESEARCH METHODOLOGY

3.3.1 The Subjects

This study was limited to patients who attend the Chiropractic Clinic at Technikon Natal, who on examination were found to be suffering from facet syndrome of the cervical spine. Subjects were recruited via advertisements placed at local sports clubs, gyms, pharmacies, hospitals, computer colleges and tertiary institutions, as well as advertising placed in local newspapers. Forty patients were consecutively selected from those who responded. No bias was given to gender,

racial group, occupation or economic status of the patient, however no stratification of subjects took place.

The forty patients were randomly divided into groups A and B (20 patients in each group), by drawing a number between 1 and 40 out of a hat. Patients that drew even numbers were assigned to group A and patients that drew odd numbers were assigned to group B. Participants in group A were treated using spinal manipulation only, and those in group B received NSAID therapy alone. Adco Piroxicam was the NSAID of choice in this study.

3.3.2 Inclusion and Exclusion Criteria

Inclusion criteria included the following:

- Only patients between 18 and 65 years of age were accepted. Children and older adults were excluded to minimize the number of patients in the sample with congenital anomalies or neck pain associated with degenerative diseases such as arthritis.
- Only patients with chronic neck pain, defined by Gatterman (1990: 406), as long-standing (weeks, months or years) but not necessarily incurable with symptoms ranging from mild to severe, were included. For the purpose of this study, the patient must have had neck pain for at least 4 weeks prior to the first consultation. Chronic neck pain patients were chosen due to the sparsity of research in this field, and also to reduce the

chance that patients would have become asymptomatic due to the natural history of the condition.

- From the case history, physical examination and cervical spine regional examination, the patients had to meet the criteria necessary for a diagnosis of cervical facet syndrome as defined by Schafer and Faye (1990: 98-110) and Bergmann et al. (1993: 63):
 - Pain and tenderness over the involved osseous and soft tissue area.
 - Asymmetry or misalignment identified through static palpation.
 - Range of motion abnormality identified through motion palpation.
 - Tone, texture and temperature abnormalities identified through observation and palpation.
 - Special tests i.e. a positive Kemp's test.
- Any conditions associated with cervical facet syndrome (such as myofascial pain), were assessed and noted in the cervical spine regional examination, but no treatment for these conditions were administered.

Due to the fact that the contra-indications and side effects of the two treatment interventions were very different, there were differences in the exclusion criteria for group A and B.

The exclusion criteria for group A included the following:

- If any conditions which contra-indicated spinal manipulation were present or suspected, those patients were rejected from the study. These conditions were outlined by Peterson (1993: 132-133):
 - Vascular – vertebrobasilar insufficiency, aneurysm, atherosclerosis, and anti-coagulant therapy.
 - Articular – advanced osteoarthritis, inflammatory arthritis ((rheumatoid, psoriatic), ankylosing spondylitis, joint instability and hypermobility.
 - Trauma – fracture, dislocation and severe sprains and strains.
 - Bone weakening disorders – bone tumours, bone infections (tuberculosis), osteomyelitis, osteoporosis and osteomalacia.
 - Neurologic – disc prolapse with neurological deficit, vertigo, severe pain, pain intolerance and space-occupying lesion.
 - Psychological – malingering, hysteria and hypochondriasis.
- If radiographic examination of the cervical spine was clinically indicated to rule out contra-indications to spinal manipulation, those patients were rejected from the study.
- Any other treatment received or taken for the neck pain during the duration of the study resulted in the exclusion of the subject.

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The exclusion criteria for group B included the following:

- If any conditions which contra-indicated NSAID administration were present, those patients were excluded from the study. This included patients who had previously exhibited hypersensitivity to it, individuals with the syndrome comprised of bronchospasm, nasal polyps and angiodema precipitated by aspirin or other NSAIDs, patients with hepatic dysfunction or patients who were pregnant (Arky, 1997: 2008, Adco Piroxicam package insert).
- Patients that had or developed contra-indications to Adco Piroxicam in accordance with the Adco Piroxicam package insert (Appendix G), were excluded. These included gastro-intestinal symptoms, oedema, increased serum transaminase levels, raised blood urea nitrogen levels, decreased platelet aggregation and prolonged bleeding time, skin rash, Stevens-Johnson syndrome, decrease in haemoglobin and haematocrit, thrombocytopenia and non-thrombocytopenic purpura, aplastic anaemia, leucopenia, eosinophilia, bronchoconstriction, dizziness, headache, somnolence and vertigo.
- Patients that were taking any medication which has a known interaction with Adco Piroxicam were excluded from the study. This included coumarin-type anticoagulants (Adco Piroxicam package insert).
- The medical practitioners opinion on whether it was safe for that patient to be administered with NSAIDs, was the final determinant for exclusion or inclusion into the study. His decision was based on the case history,

physical examination, cervical spine regional examination and screening questionnaire (Appendix I), as well as his medical expertise.

- Any other treatment received or taken for the neck pain during the duration of the study resulted in the exclusion of the subject.

3.3.3 Ethics

Each patient that was considered for the study initially had the nature and the reasons of the study explained to them, as well as the possible side-effects of manipulation and the NSAID used. Patients were also informed that they had a 50% chance of either receiving chiropractic manipulative therapy alone or NSAID therapy alone. Patients who satisfied the criteria set out for the study then had to fill in and sign an informed consent form (Appendix H), explaining the terms and conditions of the study. Patients in both groups were also given a patient information letter (Appendix M), which explained the exact nature of the study in lay-man's language, to ensure all patients understood.

The following ethical considerations were abided to (Pak and Adams, 1994: 37):

- The rights and welfare of the patients were protected.
- The patients were not coerced into participating in the study.
- Information was given to the patient in an understandable language.
- The research involved no more than minimal risk.
- Confidentiality was maintained.
- Participation was voluntary and did not involve financial benefit.

- The patient was free to withdraw from the study at any stage.

3.3.4 Initial Consultation

All patients underwent an initial consultation consisting of a full case history (Appendix A), physical examination (Appendix B), and cervical spine regional examination (Appendix C). The patients in group B had to fill in and sign a screening questionnaire (Appendix I), a declaration (Appendix J), and indemnity (Appendix K), as required by the involved medical practitioner. The case history, physical examination, cervical regional examination and screening questionnaire results were then discussed telephonically by the researcher with the involved general practitioner, to determine whether that patient was a suitable candidate for NSAID administration. If they were deemed suitable, the patient was then admitted to the study.

3.3.5 Intervention

Patients in group A received spinal manipulative therapy of the affected area which was performed by the researcher. Kemp's test, static palpation and motion palpation (Schafer and Faye, 1990: 98-110) were used by the researcher as objective tests in the cervical spine to determine the spinal level and direction of restricted motion. Hubka and Phelan (1994: 591) conducted a study to assess the interexaminer reliability of manual palpation for cervical spine tenderness in thirty patients with unilateral mechanical neck pain. The results showed that there was good interexaminer reliability ($p < 0.001$), and they concluded that palpation

for cervical spine tenderness is a highly reliable examination tool (Hubka and Phelan, 1994: 591).

The levels, direction of restriction and techniques carried out were recorded at every treatment. The involved cervical facet area was manipulated by the researcher according to the diversified technique (Szaraz, 1990: 190), using a low amplitude, high velocity thrust delivered at the point of restriction, into the direction of lost motion for the cervical facet. No other treatment was given to these patients. Each patient in group A received three treatments in three consecutive days. These patients were also required to attend a follow-up consultation on the seventh day, to be assessed of their progress. Twenty-four hours lee-way were given to patients who could not make it within the allocated time.

The patients in group B received 40 mg Adco Piroxicam daily for the first 2 days, and then for the remainder of the 7 day treatment period, they received 20 mg daily. This is in accordance with the Adco Piroxicam package insert (Appendix G). These patients were required to record the times each dose of medication was taken in the table provided on the Medication Diary (Appendix L), to improve patient compliance. After the initial consultation, the patients were required to attend follow-up consultations on day 3 and day 7 to be assessed of their progress. Twenty-four hours lee-way was given to patients who could not make it on these days.

The severity of the patients neck pain was measured at the consultations on days 1, 3 and 7. Before each consultation, the subjective and objective readings were obtained and recorded using the following:

- Short Form McGill Pain Questionnaire was completed by the patients.
- NRS-101 was completed by the patients.
- CMCC Neck Disability Index was completed by the patients.
- Pressure-pain threshold by a pressure algometer over the involved facet was determined by the researcher.

The following assessment occurred at the consultation on day 3 and day 7:

- The patients perceived improvement which was given as a percentage verbally by the patient and recorded by the researcher.

3.4 METHODS OF MEASUREMENT

3.4.1 Subjective Measurements

Pain is defined as 'an unpleasant sensory and emotional experience that is always subjective' (Bolton and Wilkinson, 1998: 1).

3.4.1.1 The Short-Form McGill Pain Questionnaire (Appendix D)

This questionnaire provides valuable information on the sensory, affective and evaluative dimensions of pain experience and is capable of discriminating among

different pain problems (Melzack, 1987: 191). According to Melzack (1987: 191), it has become one of the most widely used tests for the measurement of pain.

This questionnaire was derived from the McGill Long-Form Questionnaire. A small, representative set of 15 descriptive words from the sensory and affective categories of the standard form were chosen. Each descriptor is ranked on an intensity scale of 0 = none, 1 = mild, 2 = moderate, and 3 = severe (Melzack, 1987: 192; Melzack and Katz, 1992: 162).

Two studies were performed comparing the sensitivity of the standard long-form and short-form McGill Pain Questionnaires (Melzack, 1987: 192). In the first study, seventy patients suffering from post-surgical, obstetrical and musculoskeletal pain, were presented forms in a single order, long form followed by short form. The patients were tested before and thirty minutes after medication or other therapy for pain. Because the order of presentation of the long and short forms may have influenced the correlations obtained, a second study was carried out with patients suffering post-surgical (N = 31) and dental (N = 31) pain. In both groups in the second study, patients were assigned an order – long form followed by short form or visa versa – on the basis of a computer-generated list of random orders. Both studies showed that the sensory, affective and total scores of the short and long forms of the McGill Pain Questionnaires significantly correlated.

The short form McGill Pain Questionnaire is therefore a useful instrument, specifically in studies where time to obtain information from patients is limited (Melzack, 1987: 197).

3.4.1.2 The Numerical Pain Rating Scale – 101 (NRS-101, Appendix E)

The NRS-101 is used to measure the patients perceived level of pain intensity. The patient is prompted to rate his or her pain intensity on a numerical scale from 0 to 100, with 0 representing 'no pain', and 100 representing 'pain as bad as it could be'. The patients were required to give two ratings, the first for pain when it is at its worst and the second for pain when it is at its least. The average between these two figures was then used as an indication of the average pain intensity experienced by the patient.

In a study by Jensen et al. (1986: 117-126) in which they compared 6 pain intensity scales, it was concluded that the NRS-101 had certain practical advantages over the others because, it was more simple and practical to administer and score, it could be administered in written or verbal form, and it did not appear to be associated with age.

Bolton and Wilkinson (1998: 1) compared the responsiveness of three pain scales: the visual analogue scale, the verbal rating scale and the NRS-101. The study involved seventy-nine new patients attending an outpatient clinic. The most

common site of pain was in the back (39.0%), followed by the neck (19.0%), the head (14.7%) and the arm or shoulder/s (8.3%). In conclusion, they suggested that the NRS-101 was the preferred method of measuring treatment outcome in terms of pain levels due to the relative ease of use, and the advantages of using responsive evaluative measures (Bolton and Wilkinson, 1998: 5).

3.4.1.3 The CMCC Neck Disability Index (NDI, Appendix F)

The NDI was designed to assess disability of activities of daily living which are most affected by neck pain (Vernon and Mior, 1991: 409). It is a revised form of the Oswestry Low Back Pain Index and gives the doctor information as to how the patients neck pain has affected their ability to manage in everyday life (Vernon and Mior, 1991: 411). The NDI consists of a ten item questionnaire, with each question having a maximum score of 5 and a minimum score of 0. The score is calculated out of 50 and converted to a percentage.

Vernon and Mior (1991: 415) conducted a study on the reliability and validity of the NDI, and concluded that it has been shown to demonstrate a high degree of test-retest reliability and internal consistency, is applicable to a wide age range, is unaffected by gender, and has an acceptable level of validity, being sensitive to severity levels and to changes in severity over time.

According to Hains et al. (1998: 75), the NDI possesses stable psychometric properties and provides an objective means of assessing the disability of patients suffering from neck pain.

3.4.1.4 The patients perceived improvement

The patients were asked on day 3 and day 7 to give a percentage of how much improvement they believe that they had experienced since the first consultation. This was given verbally by the patients and recorded at the beginning of the consultations on day 3 and day 7 by the researcher.

3.4.2 Objective Measurements

3.4.2.3 The Algometer

An algometer (The Wagner FX2 Model) was used to determine the pain sensitivity over the articular pillar of the cervical spine at the affected level. The algometer measures pressure threshold which is the minimum pressure that induces pain or discomfort (Fischer, 1986: 836).

In this study the algometer was applied over the articular pillar of the most tender or painful facet joint in the area of dysfunction. This area was determined by Kemp's test, static palpation and motion palpation to locate fixations. The algometer was applied over the identified articular pillar at an angle perpendicular to the skin surface. The patient was instructed to say 'now' at the point they first

experienced pain, and the pressure was manually increased at a rate of 1 kg/second. Pressure was then released at the moment pain was first experienced and readings were taken.

Nussbaum and Downes (1998: 160-169) conducted a study on the reliability of clinical pressure-pain algometric measurements obtained on consecutive days. The purpose of their study was fourfold. It was to investigate (1) 'normal' pressure-pain threshold (PPT) in the biceps brachii muscle, (2) the reliability of repeated measurements of PPT in subjects without pain over three consecutive days, (3) the reliability of measurements of PPT between examiners, and (4) the number of measurements required to obtain a best estimate of PPT. They found intra-class correlation coefficients between two examiners to be 0,74 – 0,89 at a significance of $p < 0,001$. In conclusion they stated that PPT is a reliable measure and can be used to evaluate the development and decline of experimentally induced muscle tenderness. Reliability is enhanced when all measurements are taken by one examiner (Nussbaum and Downes, 1998: 169).

3.5 SPECIFIC TREATMENT OF THE SUBPROBLEMS

3.5.1 The First Subproblem

The first subproblem was to determine the relative short-term effectiveness of cervical spine manipulative therapy compared to Adco Piroxicam administration, in patients with chronic facet syndrome of the cervical spine, in terms of subjective clinical findings.

3.5.2 The Second Subproblem

The second subproblem was to determine the relative short-term effectiveness of cervical spine manipulative therapy compared to Adco Piroxicam administration, in patients with chronic facet syndrome of the cervical spine, in term of objective clinical findings.

3.6 STATISTICAL PROCEDURE

3.6.1 Treatment of the Data

3.6.1.1 Subjective Data

The questionnaires that the patients completed were screened to ensure that they had been filled out correctly. The raw data from the questionnaires were collected, and recorded separately for each group. Statistical analysis of the data, at 5% significance level was performed.

3.6.1.2 Objective Data

The algometer readings, in Kg/cm², were recorded separately for the two groups. Statistical analysis of the data, at 5% significance level was performed.

3.6.2 Statistical Analysis Of The Data

The data was analysed using the computer statistical package SPSS version 9.0 (SPSS Inc. 44N. Michigan Avenue, Chicago, Illinois, 60611, USA).

Non-parametric tests were used to analyse the data because the sample sizes were less than 30 (i.e. $n = 20$). The non-parametric tests included, the Wilcoxin Signed Rank test and the Mann-Whitney U-test. These tests were used to analyse the data obtained from the algometer readings, the Short-Form McGill Pain Questionnaire, the NRS – 101, the CMCC Neck Disability Index, and the patients perceived improvement.

3.6.2.1 Procedure 1: Wilcoxin Signed Rank Test (Intra-group)

The Wilcoxin Signed Rank Test was used at the 5% level of significance. It was used to determine whether any statistically significant improvement occurred within group A and group B between day 1 and day 3; between day 3 and day 7; and between day 1 and day 7.

The null hypothesis (H_0) stated that there would be no improvement between each of these days. Therefore, the null hypothesis is either rejected or accepted depending on the p-value being less than α or greater than α .

The alternative hypothesis (H_1) stated that there was an improvement between each of these days (Fisher and Van Belle, 1993: 315-319).

H_0 : There is no improvement between the consultations.

H_1 : There is an improvement between the consultations.

($\alpha = 0.05$)

Decision rule:

If $p < \alpha$, reject H_0 .

If $p \geq \alpha$, accept H_0 .

$$(i) \quad p = \frac{\text{reported p-value}}{2} \quad \begin{array}{l} \text{if } H_1 \text{ is of form } > \text{ and } z \text{ is positive} \\ \text{if } H_1 \text{ is of form } < \text{ and } z \text{ is negative} \end{array}$$

$$(ii) \quad p = 1 - \frac{\text{reported p-value}}{2} \quad \begin{array}{l} \text{if } H_1 \text{ is of form } > \text{ and } z \text{ is negative} \\ \text{if } H_1 \text{ is of form } < \text{ and } z \text{ is positive} \end{array}$$

(z is a value determined by the SPSS computer statistical package)
(The reported p-value is the SPSS print out value of p).

3.6.2.1 Procedure 2: Mann Whitney U-test (Inter-group)

The Mann-Whitney U-Test was used at the 5% level of significance. It was used to determine whether any significant difference existed between group A and group B on days 1, 3 and 7.

The null hypothesis (H_0) stated that there would be no difference between each group. Therefore, the null hypothesis is either rejected or accepted depending on the p-value being greater or less than α or greater than α .

The alternative hypothesis (H_1) stated that there was a difference between each group (Fisher and Van Belle, 1993: 315-319) on days 1,3 or 7.

H_0 : There is no difference between the two groups.

H1: There is a difference between the two groups.

($\alpha = 0.05$)

Decision rule:

If $p < \alpha$, reject H_0 .

If $p \geq \alpha$, accept H_0 .

Where p is the reported p -value.

CHAPTER FOUR

4. THE RESULTS

4.1 INTRODUCTION

This chapter covers the results from the statistical analysis of the data obtained from both groups.

Group A – Spinal Manipulative Therapy.

Group B – Adco Piroxicam Therapy.

Included in this chapter are tables of reasons for exclusion or dropout of patients from the study, as well as tables of demographic data.

4.2 RECRUITMENT AND EXCLUSIONS

Forty people were accepted into and completed the study. Many patients who were screened were not accepted into the study. After being accepted into the study, some patients were unable to complete the study and dropped out.

Table 4.1: Reasons for patient dropout / exclusion.

Age (over 65 or under 18 years of age)	4
Not arriving for initial consultation	5
Not arriving for follow-up consultations	4
Headache (primary source of pain)	1
Shoulder pain (primary source of pain)	3
Acute myofasciitis (primary source of pain)	2

Pregnant	1
Gastric ulcer	3
Hiatus hernia	1
Assymptomatic at time of initial consultation	2
Pain for less than 4 weeks	2
Significant head or neck trauma	7
Hard neurological signs and symptoms	6
<u>TOTAL</u>	<u>41</u>

4.3 DEMOGRAPHIC DATA

Table 4.2: Gender distribution.

GENDER	GROUP A	GROUP B
MALES	9 (45%)	12 (60%)
FEMALES	11 (55%)	8 (40%)

The overall male : female ratio was 21: 19.

Table 4.3: Age prevalence.

AGE INTERVALS	GROUP A	GROUP B
18 – 25	10 (50%)	6 (30%)
26 – 35	3 (15%)	6 (30%)

36 – 45	4 (20%)	5 (25%)
46 – 55	3 (15%)	2 (10%)
56 – 65	0 (0%)	1 (5%)
MEAN AGE	31.65 yrs.	34.15 yrs.

The mean age for the entire sample was 32.9 years.

Table 4.4: Patients' occupations.

	GROUP A	GROUP B
STUDENTS	6 (30%)	7 (35%)
DRIVING RELATED OCCUPATIONS	3 (15%)	1 (5%)
COMPUTER RELATED OCCUPATIONS	4 (20%)	2 (10%)
DESK WORK	3 (15%)	3 (15%)
OTHER	4 (20%)	7 (35%)

Table 4.5: History of trauma affecting the cervical spine.

	GROUP A	GROUP B
MOTOR VEHICLE ACCIDENT	4 (20%)	6 (30%)
MOTOR BOAT ACCIDENT	0 (0%)	1 (5%)
SURFING INJURY	1 (5%)	0 (0%)
<u>TOTAL</u>	5 (25%)	7 (35%)

Table 4.6: Onset of neck pain.

	GROUP A	GROUP B
RAPID ONSET*	5 (25%)	2 (10%)
GRADUAL ONSET*	15 (75%)	18 (90%)

* The above categories were purely the patients perception of whether their neck pain came on rapidly over a few hours or less, or if it was more gradual in onset. No specific time categories were set.

Table 4.7: Duration of neck pain prior to the initial consultation.

TIME INTERVALS	GROUP A	GROUP B
4 weeks – 2 months	3 (15%)	2 (10%)
3 months – 6 months	6 (30%)	4 (20%)
7 months – 1 year	1 (5%)	5 (25%)
2 years – 5 years	5 (25%)	5 (25%)
6 years – 10 years	2 (10%)	3 (15%)
> 10 years	3 (15%)	1 (5%)

4.4 THE ANALYSED DATA

The sample size was less than 30 (i.e. $N = 20$), therefore non-parametric tests were utilized for statistical analysis of the data. The Wilcoxin Signed Rank test and the Mann-Whitney U-test were the two tests utilized. The level of significance for these two tests was set at $\alpha = 0,05$ (5%).

The Wilcoxin Signed Rank test was used for intra-group comparison. Each group was analysed individually to determine if there was any significant improvement within the group between the following days:

- The 1st and the 3rd day.
- The 1st and the 7th day.
- The 3rd and the 7th day.

The Mann-Whitney U-test was used for inter-group comparison. The test was used to determine whether any significant difference existed between Group A and Group B on each of the following days:

- Day 1.
- Day 3.
- Day 7.

4.4.1 Intra-group comparison: Wilcoxin Signed Rank test

Table 4.8: Algometer results for groupA (p-values)

	Day1 & Day 3	Day 1 & Day 7	Day 3 & Day 7
Algometer	0.0005 *	0.000 *	0.006 *

Key: * = statistically significant improvement (i.e. $p < 0.05$)

The null hypothesis was rejected according to the defined decision rule, indicating that there was a statistically significant improvement between all consultations for all algometer readings in group A.

Table 4.9: Subjective results for group A (p-values).

	Day 1 & Day 3	Day 1 & Day 7	Day 3 & Day 7
McGill	0.000 *	0.000 *	0.013 *
CMCC	0.000 *	0.000 *	0.003 *
NRS-101	0.000 *	0.000 *	0.0295 *
Perc. Improv.	-	-	0.0005 *

Key: * = statistically significant improvement (i.e. $p < 0.05$)

The null hypothesis was rejected according to the defined decision rule, indicating that there was a statistically significant improvement between all consultations for all subjective results in group A.

Table 4.10: Algometer results for group B (p-values).

	Day 1 & Day 3	Day 1 & Day 7	Day 3 & Day 7
Algometer	0.005 *	0.004 *	0.1375

Key: * = statistically significant improvement (i.e. $p < 0.05$)

The null hypothesis was rejected according to the defined decision rule, indicating a statistically significant improvement between days 1 and 3 and days 1 and 7 for algometer readings in group B. The null hypothesis was, however, accepted according to the defined decision rule, indicating no statistically significant improvement between days 3 and 7 for algometer readings in group B.

Table 4.11: Subjective results for group B (p-values).

	Day 1 & Day 3	Day 1 & Day 7	Day 3 & Day 7
McGill	0.000 *	0.000 *	0.029 *
CMCC	0.0005 *	0.001 *	0.104
NRS-101	0.0015 *	0.0085 *	0.0535
Perc. Improv.	-	-	0.016 *

Key: * = statistically significant improvement (i.e. $p < 0.05$)

The null hypothesis was rejected according to the defined decision rule, indicating a statistically significant improvement between all consultations for all subjective results in group B, except for the CMCC Neck Disability Index and the Numerical Pain Rating Scale – 101, where the null hypothesis was accepted, indicating no statistically significant improvement between Days 3 and 7 for these results.

4.4.2 Inter-group comparison: Mann-Whitney U-test

Table 4.12: Algometer results for group A and group B (p-values).

	Day 1	Day 3	Day 7
Algometer	0.989	0.892	0.524

Key: * = statistically significant difference (i.e. $p < 0.05$)

The null hypothesis was accepted according to the defined decision rule, indicating that there was no statistically significant difference between group A and group B at all consultations for all algometer readings.

Table 4.13: Subjective results for group A and group B (p-values).

	Day 1	Day 3	Day 7
McGill	0.569	0.377	0.312
CMCC	0.342	0.124	0.079
NRS-101	0.568	0.635	0.490
Perc. Improv.	-	0.011 *	0.014 *

Key: * = statistically significant difference (i.e. $p < 0.05$)

The null hypothesis was accepted according to the defined decision rule, indicating no statistically significant difference between group A and group B at all consultations for all subjective results, except for the patients perceived improvement on day 3 and day 7, where the null hypothesis was rejected, indicating a statistically significant difference between group A and group B.

4.5 GRAPHS OF MEAN VALUES FOR OBJECTIVE SUBJECTIVE READINGS IN GROUP A AND GROUP B.

**Figure 4.1: Algometer Readings
(kg/cm²)**

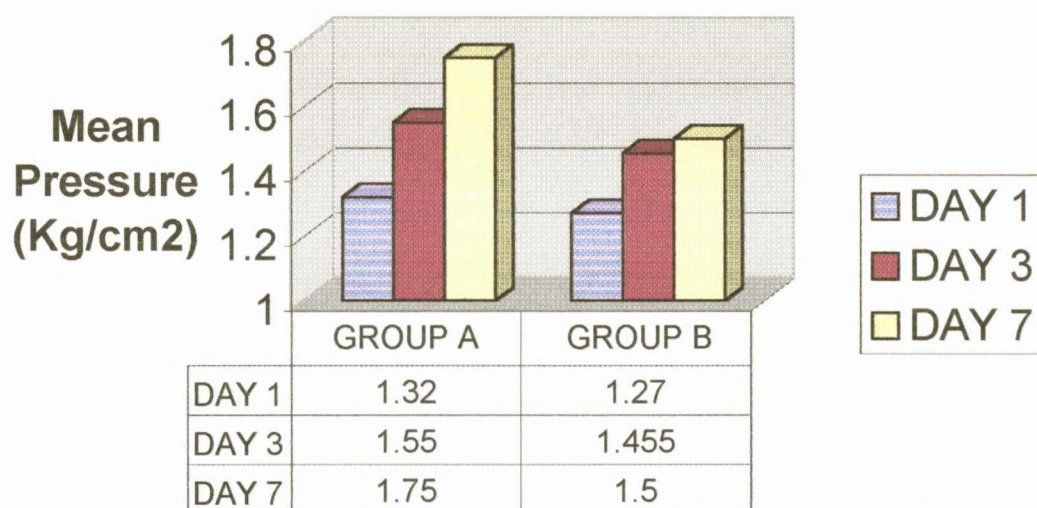


Figure 4.2: Short Form McGill Pain Questionnaire

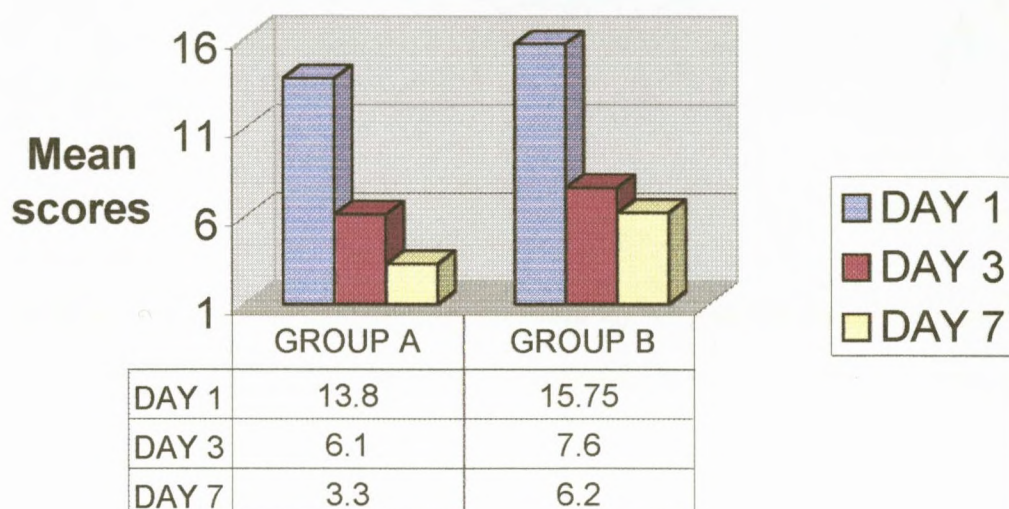


Figure 4.3: CMCC Neck Disability Index

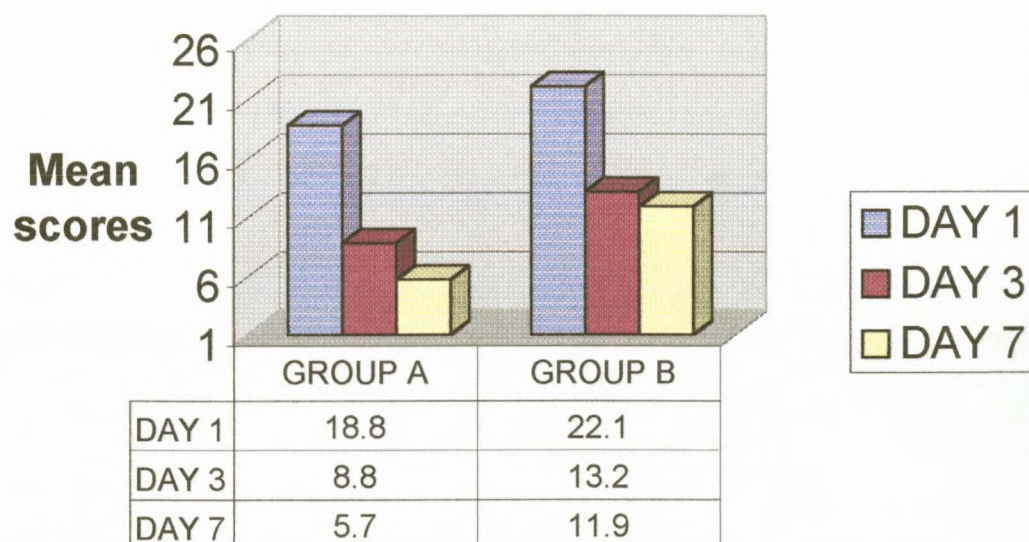
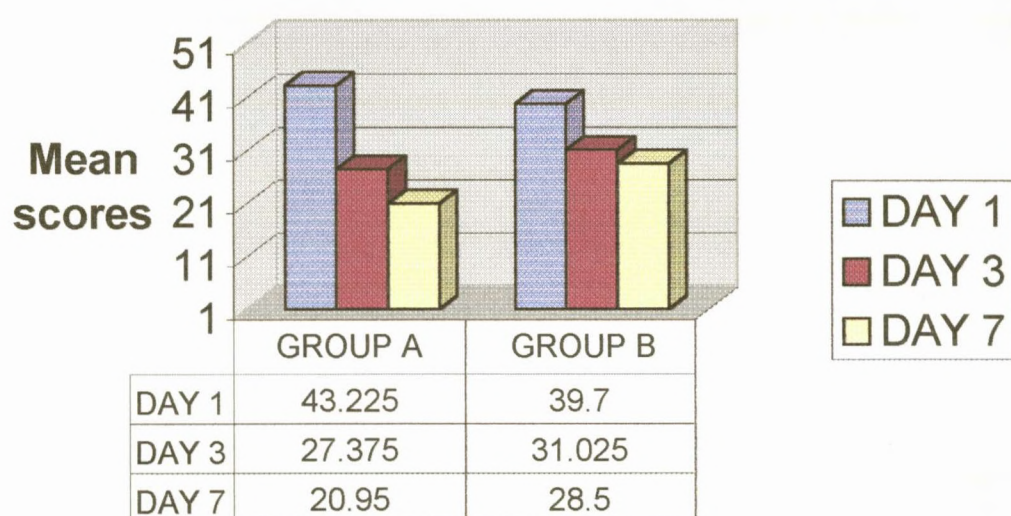


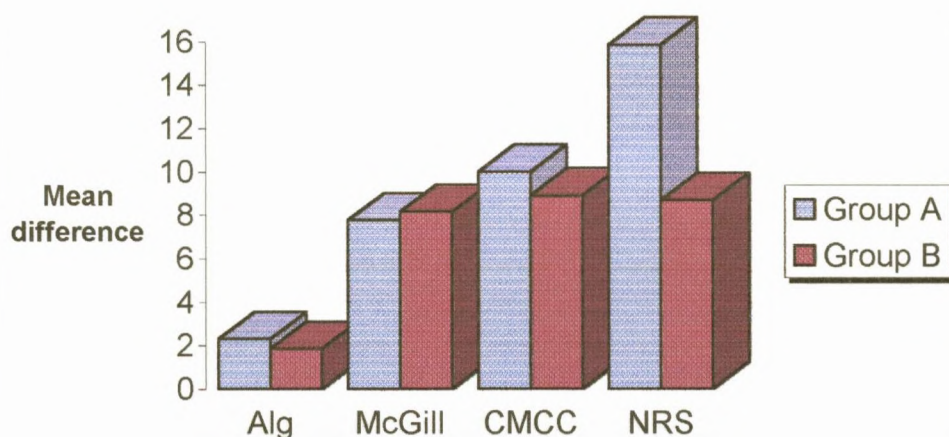
Figure 4.4: Numerical Pain Rating Scale



4.6 GRAPHS OF MEAN DIFFERENCES OF OUTCOME MEASURES

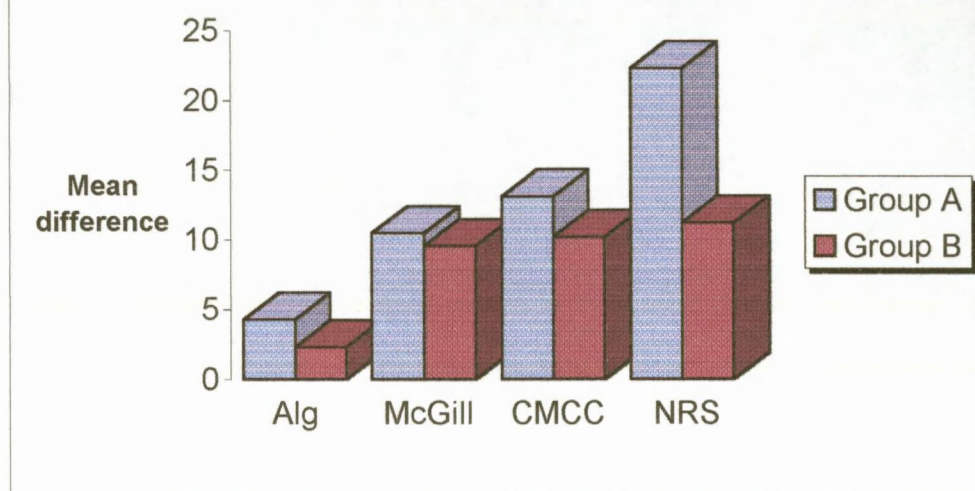
The values for these graphs were determined by calculating the differences in mean readings on the respective assessment days with regards to objective and subjective results obtained. In this manner it was possible to see graphically which treatment group improved to a greater extent, in spite of the lack of statistically significant differences.

Figure 4.5: Mean differences for outcome measures between Day 1 and Day 3.



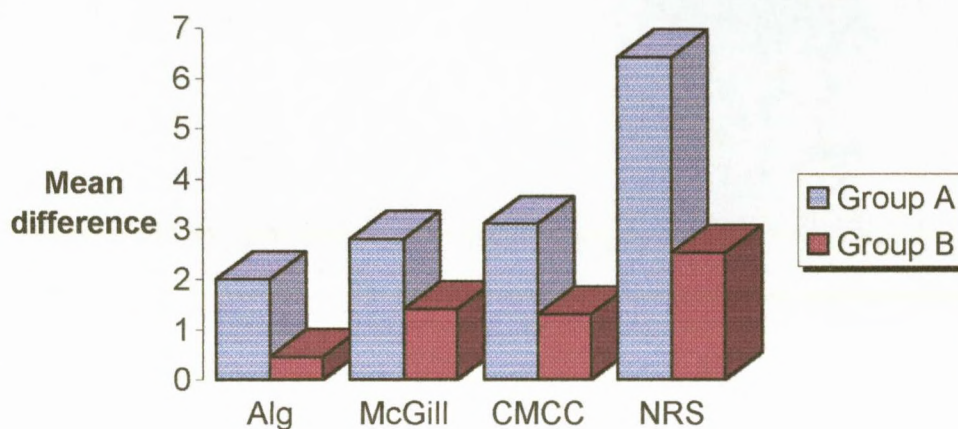
Mean differences between the readings on day 1 and day 3 for all algometer, CMCC Neck Disability Index and NRS-101 results suggest that there was a greater improvement in group A than in group B. McGill Short Form Questionnaire results suggest that there was a slightly greater improvement in group B between days 1 and 3. However, statistical analysis revealed that none of these differences were statistically significant.

Figure 4.6: Mean differences for outcome measures between Day 1 and Day 7.



Mean differences for all subjective and objective outcome measures suggest that a greater improvement occurred between day 1 and day 7 in group A than in group B. however, statistical analysis revealed that none of these differences were statistically significant.

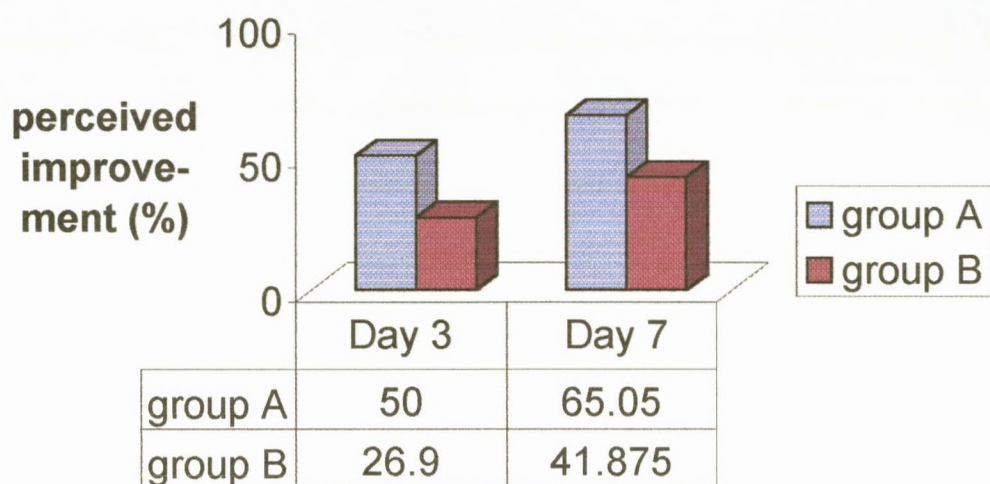
Figure 4.7: Mean differences for outcome measures between Day 3 and Day 7.



Mean differences for all subjective and objective outcome measures suggest that a greater improvement occurred between the day 3 and day 7 in group A than in group B. However, statistical analysis revealed that none of these differences were statistically significant.

4.7 GRAPH OF PATIENTS PERCEIVED IMPROVEMENT

Figure 4.8: Mean values of patients perceived improvements on Day 3 and Day 7.



CHAPTER FIVE

5. DISCUSSION

5.1 INTRODUCTION

This chapter is concerned with discussing the results of the statistical analysis of the data obtained from both groups, as well as a discussion of reasons for exclusion or dropout of patients from the study, and a discussion of the demographic data. The information which will be discussed in this chapter was presented in the previous chapter.

5.2 REASONS FOR EXCLUSION OR DROPOUT OF PATIENTS

No patients in this study were X-rayed, as it would have meant that the entire research population would have had to be X-rayed. This would have resulted in the budget being extremely high. For this reason, seven patients with significant head or neck trauma had to be excluded from the study, as they would have required a series of cervical spine X-rays to confirm the diagnosis and to rule out contra-indications to spinal manipulative therapy (table 4.1).

Furthermore, six patients with hard neurological signs and symptoms were excluded from the study (table 4.1). It is possible that some of these patients were suffering from chronic facet syndrome of the cervical spine, however, to continue to treat these patients without knowing the exact cause of their symptomology would not be regarded as proper clinical practice. These patients

would have also required a series of cervical spine X-rays to confirm the diagnosis and to rule out contra-indications to spinal manipulative therapy.

After explaining the nature of the research over the phone, six patients who said that they would get back to the researcher never did so. It was suspected that the reason for this was that they did not approve of taking anti-inflammatory medication. It was also suspected that this was the reason that five patients did not arrive for their initial consultation (table 4.1). Furthermore, of the four patients that did not arrive for their follow-up consultations, three of them were in the anti-inflammatory group. The fourth patient that did not arrive for her follow-up consultation developed bronchitis during the treatment period. It was suspected that the patients who replied to the advertisements hoped to receive traditional chiropractic treatment, since the research was being performed at a chiropractic clinic, and preferred not to take any medication, especially medication that had possible side-effects (i.e. Adco Piroxicam).

5.3 DEMOGRAPHIC DATA

With regard to gender distribution (table 4.2), there were two more females than males in group A, and four more males than females in group B. The overall male: female ratio was 21: 19. This was inconsistent with the conclusions drawn by Linton et al. (1998: 1457) and Cote et al. (1998: 1695), that the prevalence rate of neck pain for women was higher than that for men. With such a small

sample size, however, assumptions cannot be made on the prevalence rate with regard to gender distribution.

The majority of the patients in this study were between the ages of 18 and 35 years of age, with 65% of the patients from group A and 60% of the patients from group B fitting into this age group (table 4.3). In fact, 50% of the patients in group A were between the ages of 18 and 25, with 30% of the patients in group B fitting into this category. This may be due to the fact that 13 (32.5%) of the patients in this study were students (table 4.4), who would generally fit into this age group. Furthermore, the fact that this study was conducted at the Chiropractic Day Clinic on the campus of the Natal Technikon, probably meant that the awareness of the trial and the availability of the clinic was greater amongst students than non-students. Despite extensive advertising, people that spent a lot of time in the vicinity of the clinic would more readily participate in the study, than people who might have to travel some distance on several occasions to participate in the study. The age prevalence was similar for the two groups in this study, with the mean age for group A being 31.65 years and for group B 34.15 years. The mean age for the entire sample was 32.9 years.

Table 4.4 shows that there was no predominance of a specific type of occupation in this study, besides the large amount (32.5%) of student participants, the reasons for which has been discussed in the previous paragraph. From this, it can only be concluded that neck pain affects all people despite their occupation.

Twelve (30%) of the patients in total had experienced previous trauma involving the cervical spine, ten (25%) of which were involved in motor vehicle accidents (table 4.5). One patient in group A injured his neck whilst surfing, and one patient in group B was involved in a motor boat accident. Four of these patients were in group A and six were in group B. This lends weight to the beliefs of Wiesel *et al.* (1992: 11) and Barnsley *et al.* (1995: 20), that motor vehicle accidents are a common cause of neck pain in the modern world. There was only a small difference between the two groups with regard to history of trauma affecting the cervical spine, with 5 (25%) of the patients in group A and 7 (35%) of the patients in group B having experienced such trauma.

The majority of patients in this study (82.5%) had a gradual onset of neck pain, with only 7 patients (17.5%) having a sudden onset of neck pain (table 4.6). This may be due to the fact that most of the patients (87.5%) had neck pain for three months or longer prior to the first consultation (table 4.7), and were probably unable to recall an exact moment or day when the neck pain began. The duration of neck pain prior to the first consultation varied in both groups, with no specific time period predominating. The duration, in fact, was fairly evenly distributed in both groups, ranging from 4 weeks to more than 10 years.

5.4 INTRA-GROUP COMPARISONS

A comparison of the data obtained from day 1 to that obtained from day 3 was used to determine if a rapid improvement occurred in either of the treatment

groups. Comparing the data from day 3 with that of day 7 was used to detect any improvement that occurred after day 3. Results from comparing the data from day 1 to the data from day 7 represents the overall improvement.

5.4.1 Objective Data

5.4.1.1 Algometer Readings

Group A showed a statistically significant improvement in all algometer readings between all consultations (table 4.8, $p = 0.0005$ between days 1 and 3, $p = 0.000$ between days 1 and 7, and $p = 0.006$ between days 3 and 7). Group B, however, showed a statistically significant improvement in algometer readings between days 1 and 3 ($p = 0.005$), and days 1 and 7 ($p = 0.004$), but the improvement between days 3 and 7 ($p = 0.1375$) was not statistically significant (table 4.10).

The intra-group results suggest that, with regard to algometer readings, manipulation showed a steady improvement throughout the seven day period, whereas NSAIDs tended to show an improvement in the first three days, however this improvement was not maintained from the third to the seventh day. This statement, however, was not supported by the inter-group comparison which will be discussed later on. These results suggest that NSAIDs may be more effective for the short-term (a few days) relief of chronic cervical facet syndrome, than relief over a slightly longer period (a week).

5.4.2 Subjective Data

5.4.2.1 The Short-Form McGill Pain Questionnaire

Both groups showed a statistically significant improvement between days 1 and 3 ($p = 0.000$ for group A and group B), days 1 and 7 ($p = 0.000$ for group A and group B) and days 3 and 7 ($p = 0.013$ for group A, $p = 0.029$ for group B) (tables 4.9 and 4.11). This indicates that both treatment interventions were effective for the treatment of chronic cervical facet syndrome, in terms of quality of pain, with regards to the Short-Form McGill Pain Questionnaire scores between all days of assessment.

5.4.2.2 The CMCC Neck Disability Index

Group A showed a statistically significant improvement between all consultations ($p = 0.000$ between days 1 and 3, $p = 0.000$ between days 1 and 7, $p = 0.013$ between days 3 and 7), whereas group B showed a statistically significant improvement between days 1 and 3 ($p = 0.0005$), and days 1 and 7 ($p = 0.001$), however between days 3 and 7 ($p = 0.104$) the improvement was not significant (tables 4.9 and 4.11). This indicates that spinal manipulative therapy was effective for the treatment of chronic cervical facet syndrome between all days of assessment with regards to the CMCC Neck Disability Index scores, however NSAID therapy was only effective between days 1 and 3, and days 1 and 7, but the improvement between days 3 and 7 was not sufficient enough to conclude that NSAIDs were effective between these days in terms of disability.

5.4.2.3 The Numerical Pain Rating Scale – 101

Group A showed a statistically significant improvement between all consultations ($p = 0.000$ between days 1 and 3, $p = 0.000$ between days 1 and 7, $p = 0.0295$ between days 3 and 7), whereas group B showed a statistically significant improvement between days 1 and 3 ($p = 0.0015$), and days 1 and 7 ($p = 0.0085$), however between days 3 and 7 ($p = 0.0535$) the improvement was not significant (tables 4.9 and 4.11). This indicates that spinal manipulative therapy was effective for the treatment of chronic cervical facet syndrome between all days of assessment with regards to the Numerical Pain Rating Scale – 101 scores, however NSAID therapy was only effective between days 1 and 3, and days 1 and 7, but the improvement between days 3 and 7 was not sufficient enough to conclude that NSAIDs were effective between these days in terms of pain perception.

5.4.2.4 The Patients Perceived Improvement

Both groups showed a statistically significant improvement between days 3 and 7 ($p = 0.016$ for group A, $p = 0.014$ for group B)(tables 4.9 and 4.11). This indicates that both treatment interventions were effective for the treatment chronic cervical facet syndrome with regards to the patients' perception of improvement between days 3 and 7. No reading was taken for this subjective assessment on day 1 for obvious reasons, therefore no comparisons were made between days 1 and 3 and days 1 and 7.

5.5 INTER-GROUP COMPARISON

The data from the first consultation from both groups was assessed to determine if there was any difference between the two groups in terms of the severity of the presenting condition. A comparison of the data obtained from day 3 and day 7 indicates which treatment regime was more effective.

5.5.1 Objective Data

5.5.1.1 Algometer Readings

Inter-group comparison of the algometer readings showed no statistically significant differences between any of the three days on which assessments occurred ($p = 0.989$ for day 1, $p = 0.892$ for day 3, $p = 0.524$ for day 7). This suggests that the means for both groups started off on day 1 at similar levels and improved to similar levels on day 3 and day 7. Although figure 4.1 shows that there were differences in these readings on the three days, these differences were not statistically significant. These differences do, however, suggest that there was a slightly greater improvement in group A than group B between days 1 and 3, days 1 and 7, and days 3 and 7 with regards to algometer readings (figures 4.4, 4.5 and 4.6).

5.5.2 Subjective Data

5.5.2.1 The Short-Form McGill Pain Questionnaire

There was no statistically significant difference between group A and group B on any of the three days on which assessments occurred with regard to Short-Form McGill Pain Questionnaire scores ($p = 0.569$ for day 1, $p = 0.377$ for day 3, $p = 0.312$ for day 7). This suggests that the means for both groups started off on day 1 at similar levels and improved to similar levels on day 3 and day 7. Although figure 4.2 shows that there were differences in these readings on the three days, these differences were not statistically significant. These differences do however suggest that there was a slightly greater improvement in group A than group B between days 1 and 7, and days 3 and 7, however between days 1 and 3 there was a slightly greater improvement in group B (figures 4.5, 4.6 and 4.7). This indicates that NSAIDs may have been slightly more effective for the short-term (3 days) relief of pain with regards to the Short-Form McGill Pain Questionnaire which is a measure of the quality of the pain.

5.5.2.2 The CMCC Neck Disability Index

There was no statistically significant difference between group A and group B on any of the three days on which assessments occurred with regard to CMCC Neck Disability scores ($p = 0.342$ for day 1, $p = 0.124$ for day 3, $p = 0.079$ for day 7). This suggests that the means for both groups started off on day 1 at similar levels and improved to similar levels on day 3 and day 7. Although figure 4.3

shows that there were differences in these readings on the three days, these differences were not statistically significant. These differences do however suggest that there was a slightly greater improvement in the manipulation group than the NSAID group between all days of assessment with regard to the CMCC Neck Disability Index scores (figures 4.5, 4.6 and 4.7), which is a measure of neck disability.

5.5.2.3 The Numerical Pain Rating Scale – 101

There was no statistically significant difference between group A and group B on any of the three days on which assessments occurred with regard to Numerical Pain Rating scores ($p = 0.568$ for day 1, $p = 0.635$ for day 3, $p = 0.490$ for day 7). This suggests that the means for both groups started off on day 1 at similar levels and improved to similar levels on day 3 and day 7. Although figure 4.4 shows that there were differences in these readings on the three days, these differences were not statistically significant. These differences do however suggest that there was a slightly greater improvement in the manipulation group than the NSAID group between all days of assessment, in terms of pain perception, with regard to the Numerical Pain Rating scores (figures 4.5, 4.6 and 4.7).

5.5.2.4 The Patients Perceived Improvement

The only inter-group comparison in which there was a statistically significant difference between group A and group B was the patients perception of

improvement, for which there was a difference on day 3 and day 7. This means that the patients in group A believed that they had improved to a significantly larger extent than the patients in group B believed that they had improved on both days 3 and 7 (figure 4.8).

5.6 SUMMARY DISCUSSION

According to the inter-group statistics, neither of the spinal manipulative therapy or NSAIDs were better than the other in the treatment of chronic cervical facet syndrome at any of the assessment intervals. It is of note, however, that the patients in the manipulation group believed that they had improved to a greater extent than the patients in the NSAID group. This could be likened with patient satisfaction, and it could be said that the patients that received chiropractic manipulation were more satisfied than the patients that received NSAIDs.

The intra-group statistical tests show significant improvement for both groups between all consultations, in terms of quality of the pain (Short-Form McGill Pain Questionnaire), disability (CMCC Neck Disability Index), and pain perception (Numerical Pain Rating Scale – 101), with the exception of disability and pain perception in group B between days 3 and 7. This suggests that there was a slightly better improvement in the spinal manipulation group for subjective results, although the inter-group statistical tests do not show this. The intra-group statistical tests for the patients pressure pain threshold (algometer readings), show that there was a significant improvement in both groups between all

consultations, except between days 3 and 7 for group B. This also suggests that there was a slightly better improvement in the spinal manipulation group for objective results, although the inter-group statistical tests do not show this. These results suggest that clinically, but not statistically, spinal manipulative therapy is a better form of treatment for chronic cervical facet syndrome. NSAIDs do however provide effective short-term (3 days) relief of pain.

5.7 STUDY LIMITATIONS

There were differences in the exclusion criteria for group A and group B. This was due to the fact that the contra-indications for the two treatment interventions were different. In an ideal study the contra-indications should be combined for the entire research population to ensure that the two groups are homogeneous.

When comparing the baseline characteristics of the patients in both groups, it becomes apparent that, although they are not identical, they are comparable. There were however more females in group A and more males in group B, however this should not affect the results as there is no reason that the treatment interventions should work any differently for males than for females. The age prevalence was similar with most of the patients from both groups being between the ages of 18 and 35 years. This is significant as it is usually the younger patients that respond better to treatment as tissue repair occurs more readily. Although not exact, the patients occupations, history of trauma, onset and duration of neck pain were similar in each group. Although the duration of neck

pain prior to the initial consultation was comparable between the two groups, the fact that this time period ranged from 4 weeks to more than ten years may have been a draw back in this study. Furthermore, with such a small sample size, even small differences between the groups, such as the two more patients in group B than in group A having a history of trauma affecting the cervical spine, can have an impact on the results of the study. Thus, the small sample size of 20 patients was a limitation of the study.

The reliability of the subjective measurements is questionable, with the only real reliable measurement being the objective readings of the algometer. It may have been a better option to use more than just one objective measure, such as the use a goniometer to measure changes in cervical spine range of motion. With regard to the subjective questionnaires, after having had the trial explained to them, the patients, who would have deduced that the questionnaires were a measure of their progress, may not have been entirely honest with their responses in order to please the researcher.

Human error with respect to the use of the algometer may have also played a role. In some cases there may have been slight differences in exact placement of the instrument on the respective consultations. The tenderness of overlying musculature may also interfere with the direct measurement of tenderness over the facet joint itself. Research needs to be done to determine how reliable

algometer readings are for testing pressure pain threshold over facet joints specifically (Hepburn, 2000: 62).

When treating chronic cervical facet syndrome, it is not normal for chiropractors to treat on three successive days. Usually a patient with such a condition will be treated three or four times over a week or two, with breaks of at least a day or two between successive treatments. Thus, it may have been a better option for the patients in group A to receive manipulative therapy on days 1, 3 and 5.

The patients stress levels was also something that was not taken into account. The patients may have returned from the treatment, to adopt a stressful position related to their work, family life, relationships or financial situation, which may have masked or impeded any improvement occurring as a result of the treatment. This however may not be an entirely valid point, as stress is so unpredictable and in ordinary life there is no ways that it can be controlled.

Every effort was made to ensure that the patients in group B took their medication as prescribed. Each patient was instructed to complete a medication diary (Appendix L), to improve patient compliance, however there was no guarantee that the medication diaries were representative of the truth. Patients may have falsely filled in medication times in order not to disappoint the researcher.

The patients in group B took medication for 7 days. In light of the fact that a 24 hour window period was given for the consultation on day 7 for patients who could not make it on the allocated day, some patients received their final assessment on the same day as they took their last dose of medication, whereas some patients received their final assessment a day after they took their last dose of medication. Therefore, some of these patients may have been assessed while the medication was still in effect, whereas others may have been assessed while the effect of the medication was declining. This may have had an effect on the results.

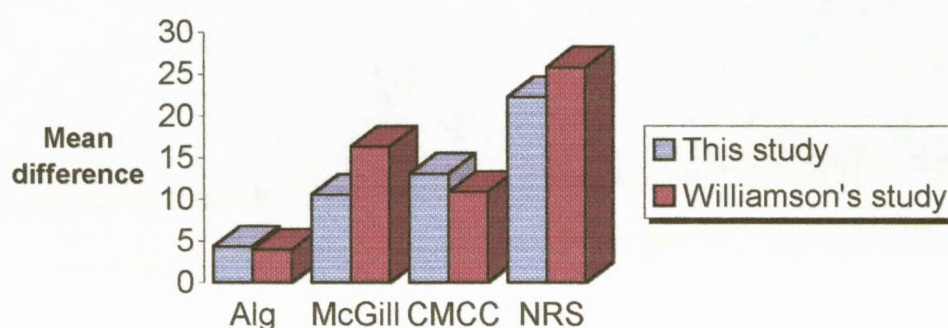
Another problem in this study was that the examiner was also the treating practitioner and bias may have been created. This bias may be represented by examiner expectations of superior results of one intervention over another. Furthermore, it may be criticized that the manipulative procedures were performed by a student, and not a therapist who had many years of experience.

There was no placebo group in this study. If a third group of patients had been used, which under the same conditions as the other two groups, received placebo treatment, such as placebo medication or placebo manual therapy in the form of detuned ultrasound, stronger deductions may have been drawn from this study.

5.8 COMPARISON WITH OTHER STUDIES

Group A's results can be compared to those of Williamson (1998), who conducted a double-blinded clinical trial in which he compared spinal manipulative therapy in conjunction with placebo to spinal manipulative therapy in conjunction with NSAIDs in the treatment of cervical facet syndrome. The NSAID used in his study was Diclofenac free acid 46.5 mg and it was combined with manipulative therapy. Thus, comparisons will only be made with the manipulation group in which only placebo medication was given. Patients received six treatments over two weeks and comparisons will be made between the data obtained from the first and sixth consultations with the data obtained on day 1 and day 7 in this study. The sample size of Williamson's (1998) study was 15 patients compared to 20 in this study. The objective and subjective data used were identical in the two studies with the exception of the goniometer for measuring range of motion not being used in this study. Although the baseline values differed in the two studies, the improvements obtained in all the data were similar in the two studies.

Figure 5.1: Mean differences for outcome measures between Day 1 and 7 for this study and Day 1 and 14 for Williamson's study.



One must remember that the data in Williamson's (1998) study was taken from day 1 and 14 compared to day 1 and 7 in this study.

Group B's results can be compared to those of Hepburn (2000), who conducted a double-blinded clinical trial in which he compared the use of NSAID's to a homoeopathic complex for the treatment of cervical facet syndrome. The NSAID used in his study was also Adco Piroxicam and the assessments were taken on exactly the same days as this study. The sample size of Hepburn's (2000) study was 25 patients compared to 20 patients in this study. The objective and subjective data that the two studies had in common were the algometer readings, the CMCC Neck Disability Index, and the Numeric Pain Rating Scale – 101. The improvements between all days of assessment in algometer readings were

greater for Hepburn's (2000: 48-49) study than for this study. The CMCC Neck Disability Index and Numerical Pain Rating Scale – 101 data was similar in the two studies for the NSAID group, however the improvement between days 1 and 7, and days 3 and 7 was greater in Hepburn's (2000: 48-49) study. This may be due to the fact that his study only involved patients suffering from acute or sub-acute cervical facet syndrome compared to chronic cervical facet syndrome in this study. The natural history of the condition may have played a role in the greater improvement experienced by the patients in his study. Hepburn (2000: 66) supported the findings of this study that Adco Piroxicam was effective in treating cervical facet syndrome.

The results from both the above mentioned studies also showed no significant difference between the two treatment groups. They did, however both show a statistically significant improvement within the treatment groups mentioned, supporting that NSAIDs alone and manipulation alone are effective for the treatment of cervical facet syndrome.

Cassidy et al. (1992: 497) conducted a pilot study in which fifty consecutive outpatients with unilateral neck pain were given a single rotational manipulation on the side of the pain. Prior to and immediately after the treatment, cervical range of motion was recorded on a goniometer, and pain intensity was rated on the Numerical Pain Rating Scale – 101. The results were compared with days 1 and 3 of this study. In the study by Cassidy et al. (1992: 497), overall, the

Numerical Pain Rating Scale – 101 pain scores decreased from a pre-treatment mean of 43.7 to a post-treatment mean of 31.1, compared to 43.225 and 27.375 consecutively in this study. As can be seen, the results of these scores in the two studies is almost identical. This correlation supports the findings of this study, that manipulation is effective for the relief of pain in the cervical spine.

CHAPTER SIX

6. RECOMMENDATIONS AND CONCLUSIONS

6.1 RECOMMENDATIONS

A large sample size is recommended as it would increase the validity of the results, and allow for the use of both paired and unpaired t-tests for the statistical analysis of the results. This would allow for the recognition of subtle changes in the data obtained.

The patients for the study should be selected in such a way, so as to ensure homogeneity between the two groups. To achieve this, the exclusion criteria should be identical for the two groups, despite the differences in contra-indications for the two treatment interventions. Furthermore, stratification of the two groups should occur, by matching the patients gender, age, occupations, history of trauma, onset and duration of neck pain, and stress levels between the two groups. The duration of neck pain for the entire study population should be reduced to a much smaller time period as some patients had had neck pain for 4 weeks, whereas others had had neck pain for more than ten years. The way people who have had neck pain for many years react to treatment in a week is very different from the way people react if they have had neck pain for a few months.

In this study, the examiner was also the treating practitioner and bias may have been created. To increase the validity of future studies, it is recommended that the objective reading taking is blinded. Thus, the algometer readings should have

been taken by an additional objective consultant, instead of the researcher, as objective results give a much clearer picture of the outcome of the study than subjective results, especially if they are blinded. Since this study had only one set of objective results (i.e. algometer readings), it may have been a better option to include another objective measurement, such as the use of a goniometer to assess the patients cervical spine ranges of motion.

For the final assessment in the NSAID group, some of the patients were assessed on the same day as they took their last dose of medication, whereas others were assessed a day later. In future studies of this nature it is recommended that all the patients are assessed, either, while still on the medication, or a certain time period after the last dose of medication.

When treating chronic cervical facet syndrome of the cervical spine, it is not normal for chiropractors to administer manipulative therapy on three consecutive days. It is suggested, that at least a day or two gap between successive treatments should be allowed for. Thus, it may have been a better option for the patients in group A to receive manipulative therapy on days 1, 3 and 5.

Lastly, it is recommended that a third group of patients who receive placebo treatment, be included into this study. This would give an indication of the natural progression of chronic cervical facet syndrome, allowing stronger deductions to be drawn from this study.

6.2 CONCLUSION

The results of this study indicate that both spinal manipulative therapy and Adco Piroxicam therapy are effective in the treatment of chronic facet syndrome of the cervical spine. At a 95% confidence level, neither group showed any advantage over the other in treatment efficacy. The only data that did show a statistically significant difference between the two treatment groups, was the patients perceived improvement, in which the manipulation group rating was higher on day 3 and day 7 than the Adco Piroxicam group. This is of note, as it can be equated to patient satisfaction, thus supporting Peterson's (1993: 137) claim that, in the past, chiropractic adjustment and the efficacy of manipulative therapy for facet syndrome has delivered a higher degree of patient satisfaction, when compared to standard medical care, which in this case was the use of Adco Piroxicam.

Furthermore, the mean data taken from the objective and subjective results, did in fact, favour cervical spine manipulation to NSAIDs, in terms of being more effective in the relief of pain and disability. This was determined by calculating the differences between the mean values of the objective and subjective results for the two treatment groups on the respective assessment days, to determine in which group the improvements were greater. This, however, is not conclusive as it does not fit into the statistical confidence parameter this trial employed, and will only be clarified by future trials of this nature.

The fact that spinal manipulative therapy was as effective as NSAID therapy, for the treatment of chronic facet syndrome of the cervical spine, offers a safer alternative for the treatment of this condition. Thus, this conservative form of treatment may be a better option in the future, than the traditional allopathic approach. Furthermore, clinically, spinal manipulative therapy showed continued improvement over the seven day period, whereas the effectiveness of NSAID therapy decreased after the first three days of treatment, however these differences were not statistically significant. This may indicate that spinal manipulative therapy provides better long term benefit.

In conclusion, this study has filled a gap in the research, by being the first study, to the knowledge of the researcher that directly compared these two treatments, with no co-intervention, for chronic cervical facet syndrome. Further studies of this nature are required for the results to be conclusive.

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APPENDIX A

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 B

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:
- Hemias:

Palpation - Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
 - Ascites:
 - Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
 Hernias:
 Masses:
 Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

I Any loss of smell/taste:
 Nose examination:

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

- Pupillary light reflexes = Direct:
= Consensual:

- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

- V
- a. Sensory
 - Ophthalmic:
 - Maxillary:
 - Mandibular:
 - b. Motor
 - Masseter:
 - Jaw lateral movement:
 - c. Reflexes
 - Corneal reflex
 - Jaw jerk

VI Lateral movement of eyes

- VII
- a. Motor
 - Raise eyebrows:
 - Frown:
 - Close eyes against resistance:
 - Show teeth:
 - Blow out cheeks:
 - b. Taste - Anterior two-thirds of tongue:

VIII General Hearing:
Rinnes = L: R:
Webers lateralisation:
Vestibular function

- Nystagmus:
- Rombergs:
- Wallenbergs:

Otoscope examination:

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

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

XII Inspection of tongue (deviation):

Motor System:

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

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

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

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

Sensory System:

- a. Dermatomes
 - Light touch:
 - Crude touch:
 - Pain:
 - Temperature:
 - Two point discrimination:
- b. Joint position sense
 - Finger:
 - Toe:
- c. Vibration:
 - Big toe:
 - Tibial tuberosity:
 - ASIS:
 - Interphalangeal Joint:
 - Sternum:

Cerebellar function:

Obvious signs of cerebellar dysfunction:

- = Intention Tremor:
- = Nystagmus:
- = Truncal Ataxia:

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

8. **SPINAL EXAMINATION:**(See Regional examination)

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

9. **BREAST EXAMINATION:**

Summon female chaperon.

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

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

APPENDIX C

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

Patient: _____ File: _____

Date: _____ Intern/Resident: _____

Clinician: _____ Sign: _____

OBSERVATION:

Posture
Swellings
Scars
Discolouration
Hair Line
Bony & Soft Tissue Contours

Shoulder position:

Left:

Right:

Muscle spasm
Facial expression

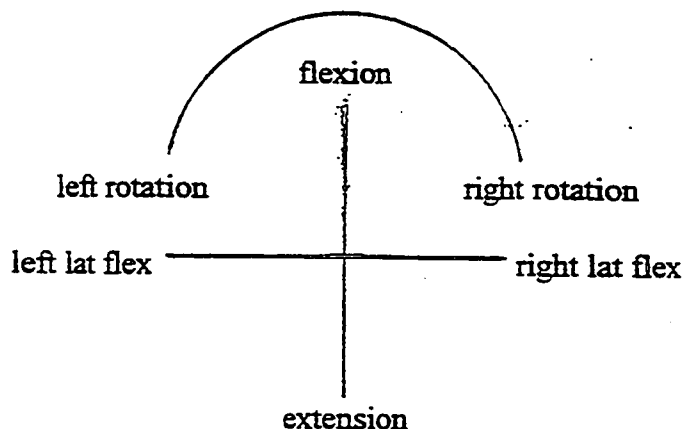
RANGE OF MOTION:

Flexion (45°):

L/R Rotation (70°):

Extension (70°):

L/R Lat Flex (45°):



PALPATION:

Lymph Nodes
Thyroid Gland

Trachea

ORTHOPAEDIC EXAMINATION:

Tenderness

Trigger Points:

SCM

Scalenii

Post Cervicals

Trapezius

Lev Scap

Doorbell sign

Kemp's test

Cervical distraction

Halstead's test

Hyperabduction test

Shoulder abduction test

Cervical compression

Lateral compression

Adson's test

Costoclavicular test

Eden's test

Shoulder depression test

Dizziness rotation test
Brachial plexus tension

Lhermitte's sign

NEUROLOGICAL EXAMINATION:

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

VASCULAR:

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

MOTION PALPATION & JOINT PLAY:

Left: Motion Palpation:
Joint Play:

Right: Motion palpation:
Joint Play:

Basic Exam: Shoulder:
Case History:

ROM: Active:
Passive:
RIM:

Orthopaedic/Neuro/
Vascular:
Observ/Palpation:

Upper T horacics:
Motion Palpation:
Joint Play:

Basic Exam: Thoracic Spine:
Case History:

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

APPENDIX D

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				

Adapted from the Short-form McGill Pain Questionnaire. Copyright 1984 Ronald Melzack

APPENDIX E

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.

APPENDIX F

CMCC NECK DISABILITY INDEX

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.

<p>Section 1 - Pain Intensity</p> <p><input type="checkbox"/> I have no pain at the moment.</p> <p><input type="checkbox"/> The pain is very mild at the moment.</p> <p><input type="checkbox"/> The pain is moderate at the moment.</p> <p><input type="checkbox"/> The pain is fairly severe at the moment.</p> <p><input type="checkbox"/> The pain is very severe at the moment.</p> <p><input type="checkbox"/> The pain is the worst imaginable at the moment.</p>	<p>Section 6 - Concentration</p> <p><input type="checkbox"/> I can concentrate fully when I want to with no difficulty.</p> <p><input type="checkbox"/> I can concentrate fully when I want to with slight difficulty.</p> <p><input type="checkbox"/> I have fair degree of difficulty in concentrating when I want to.</p> <p><input type="checkbox"/> I have a lot of difficulty in concentrating when I want to.</p> <p><input type="checkbox"/> I have a great deal of difficulty in concentrating when I want to.</p> <p><input type="checkbox"/> I cannot concentrate at all.</p>
<p>Section 2 - Personal Care (Washing, Dressing ...)</p> <p><input type="checkbox"/> I can look after myself normally without causing extra pain.</p> <p><input type="checkbox"/> I can look after myself normally but it causes extra pain..</p> <p><input type="checkbox"/> It is painful to look after myself and I am slow and careful.</p> <p><input type="checkbox"/> I need some help but manage most of my personal care.</p> <p><input type="checkbox"/> I need help every day in most aspects of self care.</p> <p><input type="checkbox"/> I do not get dressed, I wash with difficulty and stay in bed.</p>	<p>Section 7 - Work</p> <p><input type="checkbox"/> I can do as much work as I want to .</p> <p><input type="checkbox"/> I can do only my usual work, but no more.</p> <p><input type="checkbox"/> I can do most of my usual work, but no more.</p> <p><input type="checkbox"/> I cannot do my usual work.</p> <p><input type="checkbox"/> I can hardly do any work at all.</p> <p><input type="checkbox"/> I cannot do any work at all.</p>
<p>Section 3 - Lifting</p> <p><input type="checkbox"/> I can lift heavy weights without extra pain.</p> <p><input type="checkbox"/> I can lift heavy weights but it gives extra pain.</p> <p><input type="checkbox"/> Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table.</p> <p><input type="checkbox"/> Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.</p> <p><input type="checkbox"/> I can lift only very light weights.</p> <p><input type="checkbox"/> I cannot lift or carry anything at all.</p>	<p>Section 8 - Driving</p> <p><input type="checkbox"/> I can drive my car without any neck pain.</p> <p><input type="checkbox"/> I can drive my car as long as I want with slight pain in my neck.</p> <p><input type="checkbox"/> I can drive my car as long as I like with moderate pain in my neck.</p> <p><input type="checkbox"/> I cannot drive my car as long as I want because of moderate pain in my neck.</p> <p><input type="checkbox"/> I can hardly drive at all because of severe pain in my neck..</p> <p><input type="checkbox"/> I cannot drive at all.</p>
<p>Section 4 - Reading</p> <p><input type="checkbox"/> I can read as much as I want to without pain in my neck.</p> <p><input type="checkbox"/> I can read as much as I want to with slight pain in my neck.</p> <p><input type="checkbox"/> I can read as much as I want with moderate pain in my neck.</p> <p><input type="checkbox"/> I cannot read as much as I want because of moderate pain in my neck.</p> <p><input type="checkbox"/> I can hardly read at all because of severe pain in my neck.</p> <p><input type="checkbox"/> I cannot read at all.</p>	<p>Section 9 - Sleeping</p> <p><input type="checkbox"/> I have no trouble sleeping.</p> <p><input type="checkbox"/> My sleep is slightly disturbed (<1 hour sleep loss).</p> <p><input type="checkbox"/> My sleep is mildly disturbed (1-2 hours sleep loss).</p> <p><input type="checkbox"/> My sleep is moderately disturbed (2-3 hours sleep loss).</p> <p><input type="checkbox"/> My sleep is greatly disturbed (3-5 hours sleep loss).</p> <p><input type="checkbox"/> My sleep is completely disturbed (5-7 hours sleep loss).</p>
<p>Section 5 - Headaches</p> <p><input type="checkbox"/> I have no headaches at all.</p> <p><input type="checkbox"/> I have slight headaches which come infrequently.</p> <p><input type="checkbox"/> I have moderate headaches which come infrequently.</p> <p><input type="checkbox"/> I have moderate headaches which come frequently.</p> <p><input type="checkbox"/> I have severe headaches which come frequently.</p> <p><input type="checkbox"/> I have headaches almost all the time.</p>	<p>Section 10 - Recreation</p> <p><input type="checkbox"/> I am able to engage in all my recreation activities with no neck pain at all.</p> <p><input type="checkbox"/> I am able to engage in all my recreation activities, with some pain in my neck.</p> <p><input type="checkbox"/> I am able to engage in most, but not all of my usual recreation activities because of pain in my neck.</p> <p><input type="checkbox"/> I am able to engage in a few of my usual recreation activities because of pain in my neck.</p> <p><input type="checkbox"/> I can hardly do any recreation activities because of pain in my neck.</p> <p><input type="checkbox"/> I cannot do any recreation activities at all.</p>

APPENDIX G

SCHEDULING STATUS:

S3

PROPRIETARY NAME
(and dosage form):

ADCO-PIROXICAM 10 mg Capsules ADCO-PIROXICAM 20 mg Capsules

COMPOSITION:

Each ADCO-PIROXICAM 10 mg Capsule contains 10 mg piroxicam.
Each ADCO-PIROXICAM 20 mg Capsule contains 20 mg piroxicam.

PHARMACOLOGICAL CLASSIFICATION:

A. 3.1. Antirheumatics (Anti-inflammatory agents)

PHARMACOLOGICAL ACTION:

ADCO-PIROXICAM has analgesic, anti-inflammatory and antipyretic properties, and is used in the treatment of rheumatoid arthritis and other rheumatic disorders. Piroxicam acts as an inhibitor of prostaglandin biosynthesis.

ADCO-PIROXICAM is completely absorbed after oral administration; peak concentrations in plasma occur within two to four hours. Neither food nor antacids alter the rate or extent of absorption.

After absorption, piroxicam is extensively (99%) bound to plasma proteins, and has a long plasma half-life of approximately thirty-five to forty-five hours. At steady state, (eg. after seven to ten days) concentrations of piroxicam in plasma and synovial fluid are approximately equal.

Piroxicam is metabolised in the liver by hydroxylation of the pyridyl ring of the piroxicam side chain followed by conjugation with glucuronic acid and urinary elimination. Less than 10% of the drug is excreted in the urine unchanged.

INDICATIONS:

ADCO-PIROXICAM is indicated for a variety of conditions requiring anti-inflammatory and/or analgesic activity, such as rheumatoid arthritis, osteo-arthritis (arthrosis, degenerative joint disease), ankylosing spondylitis, acute musculoskeletal disorders and acute gout.

CONTRA-INDICATIONS:

ADCO-PIROXICAM should not be used in those patients who have previously shown a hypersensitivity to the drug; patients who have hepatic dysfunction; and patients who are pregnant. ADCO-PIROXICAM should be used with caution in patients with a history of gastrointestinal haemorrhage, ulcers or aspirin sensitivity.

WARNINGS:

Use during pregnancy:

The safety of ADCO-PIROXICAM use during pregnancy or during lactation has not yet been established. ADCO-PIROXICAM inhibits prostaglandin synthesis and release by an effect on prostaglandin biosynthetase. This effect has been associated with an increased incidence of dystocia and delayed parturition in pregnant animals when drug administration was continued into late pregnancy.

Use in children:

ADCO-PIROXICAM is not recommended for children.

USAGE AND DIRECTIONS FOR USE:

Rheumatoid arthritis, osteo-arthritis (arthrosis, degenerative joint disease), ankylosing spondylitis:

The usual daily dose for the relief of signs and symptoms of rheumatoid arthritis or osteoarthritis is 20 mg given in single or divided doses. Since steady state concentrations in plasma are not reached for seven to ten days, maximal therapeutic responses should not be expected for two weeks. Long-term administration of doses higher than 30 mg carries an increased risk of gastrointestinal side-effects.

Acute musculoskeletal disorders:

Therapy should be initiated with 40 mg daily for the first two days, given in single or divided doses. For the remainder of the seven to fourteen day treatment period, the dose should be reduced to 20 mg daily.

Acute Gout:

Therapy should be initiated by a single oral dose of 40 mg followed on the next four to six days by 20 mg given in a single or divided daily dosage. ADCO-PIROXICAM is not indicated for the long-term management of gout.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Gastrointestinal symptoms are the most commonly encountered side-effects. Long-term administration of doses higher than 30 mg daily carries an increased risk of gastrointestinal side-effects.

Peptic ulceration and gastrointestinal bleeding have been reported with ADCO-PIROXICAM. Drug administration should be closely supervised in patients with a history of upper gastrointestinal disease.

Other than the gastrointestinal symptoms, oedema, mainly ankle oedema, has been reported. Routine ophthalmoscopy and slit-lamp examination have revealed no evidence of ocular changes.

ADCO-PIROXICAM should not be used in patients on coumarin-type anticoagulants. Changes in different liver function parameters have been observed. Some patients may develop increased serum transaminase levels during treatment with ADCO-PIROXICAM.

Care should be exercised with the use of ADCO-PIROXICAM in patients with renal dysfunction. Blood urea nitrogen elevation has been observed in some patients. These elevations are not progressive over the course of treatment with ADCO-PIROXICAM, a plateau being reached which returns to or towards baseline levels if treatment is stopped. The rise in blood urea nitrogen is not associated with elevations in serum creatinine.

ADCO-PIROXICAM decreases platelet aggregation and prolongs bleeding time. This effect should be kept in mind.

Dermal hypersensitivity reactions, usually in the form of skin rash, have been reported. Stevens-Johnson syndrome may develop.

Decreases in haemoglobin and haematocrit, independent of gastrointestinal bleeding, have occurred. Thrombocytopenia and non-thrombocytopenic purpura (Henoch-Schönlein), aplastic anaemia, leucopenia and eosinophilia have been reported, and constitute indications for immediate withdrawal of ADCO-PIROXICAM.

It should be assumed that ADCO-PIROXICAM will precipitate bronchoconstriction in those patients who are hypersensitive to aspirin. Central nervous system effects such as dizziness, headache, somnolence and vertigo have been reported. ADCO-PIROXICAM increases plasma lithium levels.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the event of overdosage with ADCO-PIROXICAM, supportive and symptomatic therapy is indicated.

IDENTIFICATION:

ADCO-PIROXICAM 10 mg Capsules : Opaque maroon/opaque grey capsules.
ADCO-PIROXICAM 20 mg Capsules : Opaque maroon/opaque maroon capsules.

PRESENTATION:

ADCO-PIROXICAM 10 mg Capsules : Securitainers of 60 capsules.
ADCO-PIROXICAM 20 mg Capsules : Securitainers of 30 capsules.

STORAGE INSTRUCTIONS:

Store below 25 °C. Protect from light. Keep out of reach of children.

REGISTRATION NUMBERS:

ADCO-PIROXICAM 10 mg Capsules : U/3.1/195
ADCO-PIROXICAM 20 mg Capsules : U/3.1/196

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Adcock Ingram Limited

Adcock Ingram Park
17 Harrison Avenue, Bryanston Ext. 77
Private Bag X69, Bryanston, 2021

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

1 September 1987

252987 02/99

ZIMBABWE ONLY:
10 mg : 96/3.1/3081
PP 10

 Adcock Ingram

APPENDIX H

INFORMED CONSENT FORM

Research title: The Short term effectiveness of cervical spine manipulation versus Piroxicam administration in the treatment of chronic cervical facet syndrome.

Name of patient: _____

Supervisor: Dr. T Macdougall

Research student: Brendan O'Connor

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

9. Whom have you spoken to? _____

If your answer to any of the questions above is no, please seek clarity from the researcher before signing below.

Please print in block letters:

Patient/Subject Name: _____ Signature: _____

Parent/Guardian Name: _____ Signature: _____

Witness Name: _____ Signature: _____

Research Student Name: Brendan O'Connor Signature: _____

APPENDIX I

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

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, 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 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 J

DECLARATION :

I PARTAKE OF MY OWN FREE WILL IN THIS STUDY, HAVING BEEN DIAGNOSED WITH

AND MAY USE THE FOLLOWING DRUG

DOSAGE

PATIENT : _____

PARENT : _____

RESEARCH STUDENT : _____

CLINICAL SUPERVISOR : _____

MEDICAL DOCTOR : _____

DATE : _____

APPENDIX K

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 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. Transient hepatitis
4. Transient renal dysfunction
5. Skin and allergic reactions including urticaria and angioedema
6. Blood disorders e.g. anaemia, decreased platelets, decreased white blood cells
7. Wheeze related to broncho constriction
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 : _____

APPENDIX L

MEDICATION DIARY

NAME : _____ DATE : _____

		Time taken
<u>DAY 1</u>	1 tablet 1 tablet	<div><div></div><div></div></div>
<u>DAY 2</u>	1 tablet 1 tablet	<div><div></div><div></div></div>
<u>DAY 3</u>	1 tablet	<div><div></div></div>
<u>DAY 4</u>	1 tablet	<div><div></div></div>
<u>DAY 5</u>	1 tablet	<div><div></div></div>
<u>DAY 6</u>	1 tablet	<div><div></div></div>
<u>DAY 7</u>	1 tablet	<div><div></div></div>

APPENDIX M

PATIENT INFORMATION LETTER

Dear patient,

I am conducting a research study which will take the form of a clinical trial comparing the use of non-steroidal anti-inflammatory drugs (NSAID's) to the chiropractic adjustment for neck pain. The two treatments being compared have both been shown to be effective for the relief of pain in this condition.

The patients in this study will be randomly assigned to one of two groups containing 30 patients each. The patients in group A will receive chiropractic adjustments to the neck and the patients in group B will receive Adco Piroxicam (the NSAID to be used in this study). The patients in group A will be required to attend the Technikon Natal Chiropractic Day Clinic 3 times in the 3 day treatment period, and then again on the 7th day to be assessed of their progress. Patients in group B must take the medication daily for 7 days as will be explained to them, and will be required to attend the Technikon Natal Chiropractic Day Clinic 3 times in this 7 day treatment period to be assessed of their progress. These patients will also be required to fill in a medication diary while taking the medication.

During the study patients will not be able to receive any other form of treatment for their condition and they are further asked to refrain from any new or unaccustomed activities. Should there be any changes in their health during the study, they are asked to report them to me immediately as these may be side-effects of the medication. There is a small risk of developing side-effects to piroxicam which are listed in the attached copy of the Adco Piroxicam package insert. For the patients protection they will undergo a screening procedure in the form of a telephonic consultation with a medical doctor and a questionnaire which has been designed to detect if they are at risk of developing side-effects.

Treatment is free of charge and will be under the supervision of a qualified chiropractor. A medical doctor has been advised about the trial and may be called upon if the need arises. After reading this, patients are under no obligation to join the research. Patients are also free to withdraw from the study at any time. If patients have any questions please do not hesitate to ask me.

Thank you for your time.

Yours truly,

Brendan O'Connor.
(6th year chiropractic intern)