THE RELATIVE EFFECTIVENESS OF SPINAL MANIPULATIVE THERAPY VERSUS SPINAL MANIPULATIVE THERAPY IN CONJUNCTION WITH THE ADMINISTRATION OF NON-STERoidal ANTI-INFLAMMATORY DRUGS IN PATIENTS WITH FACET SYNDROME OF THE CERVICAL SPINE

BY

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

I, Andrew Roger Williamson do declare that this dissertation is representative of my own work.

Signed, Date: 4 March 1999

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DEDICATION

This work is dedicated to God who is my constant source of strength and wisdom, and my parents, Neville and Phyllis.
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ABSTRACT

The paucity of clinical research into the efficacy and effects of the different treatment protocols available for cervical facet syndrome has led to a continued variation in standard care for this condition. The aim of this study was to determine the relative effectiveness of spinal manipulative therapy in conjunction with the administration of a nonsteroidal anti-inflammatory drug (NSAID) versus spinal manipulative therapy in conjunction with the administration of a placebo medication in the treatment of cervical facet syndrome. It was hypothesised that treatment with spinal manipulative therapy and NSAIDs over a two week period, with a further four week follow-up period, would be more effective than spinal manipulative therapy and placebo medication in terms of the objective and subjective clinical findings.

The study design chosen was that of a double-blind, comparative, clinical trial. Thirty consecutive patients diagnosed with cervical facet syndrome were randomly assigned either to the manipulation and NSAID group or the manipulation and placebo group. The age range of the patients extended from nineteen to fifty-three years. Forty percent of patient occupations in both groups involved work on a computer. Each patient in the NSAID group received 139.5mg of diclofenac free acid a day over five days. The placebo group received the same dosage of similar appearance and taste over the same period. Each group of fifteen patients received treatment three times a week for two weeks. After a follow-up period of four weeks the patients were re-assessed.

The patients were assessed by means of obtaining subjective information consisting of three questionnaires: the McGill Short-Form Pain Questionnaire, the Numerical Pain
Rating Scale-101 and the CMCC Neck Disability Index. Objective data was gathered from
goniometric and pressure algometer measurements. The objective and subjective data
were collected before the commencement of the treatment, at the sixth consultation and
the one month follow-up consultation.

The data was transferred to spreadsheets and underwent statistical analysis. Wilcoxon
Signed Rank Tests were conducted in order to determine whether there was any
significant change within each respective treatment group (intra-group analysis). Mann-
Whitney Unpaired Tests were conducted in order to determine whether there was any
significant change between the two groups (inter-group analysis). The alpha value was set
at the 0.05 level of significance. Power tests related to the Mann-Whitney Unpaired Tests
were also performed to give an indication to the likelihood of a Type II error being made.

Intra-group comparison of the results showed that only the NSAID group showed
significant (p < 0.025) improvement between the first treatment and one-month follow up
with respect to the algometer and CMCC data. In the same period, only the NSAID group
did not show any significant (p < 0.025) improvement in left and right lateral flexion.

Inter-group comparison of the results showed that there was no statistically significant
differences in the efficacy of the two treatment protocols in terms of objective and
subjective clinical findings. The power tests for all readings was low, indicating that there
was a high possibility of a Type II error (incorrectly accepting the null hypothesis).
It is recommended that this study be repeated with a larger and more homogenous sample population. Different studies using different NSAIDs for a longer period of time are warranted as individual response may vary according to the type and duration of NSAID used.
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CHAPTER ONE
1. INTRODUCTION

Kelsey (1982: 146) concluded that neck pain affects 40% to 50% of the general population at some time during their lives. Cassidy et al (1992) too, state that neck pain is a common disorder, and in most cases the cause is attributed to mechanical dysfunction of the cervical spine, although the exact nature of the pathology is poorly understood, as evident from the many theories on spinal dysfunction. The facet joints are well recognised as a source of cervical pain, and the facet syndrome is a relatively common entity that is amenable to chiropractic manipulation (Panzer 1995: 426).

According to Roy et al (1988), the pathology behind the cervical facet syndrome is inflammation of the capsule and irritation of the nerve roots. Panzer (1995: 420) believes that a cortisone injection into a specific facet joint followed by relief of pain is generally considered diagnostic of facet syndrome. Dishman (1988) proposes that when stress is placed on the cervical spine, leucotrienes are released producing inflammation which can also lead to the development of trigger points. He also believes that it is this inflammatory reaction that produces restricted range of motion, and tendon and fascial shortening. However, Plaugher (1993) states that facet joint overriding, stretching of the articular capsule and bone to bone contact of the joints is primarily the causative factor in facet syndrome, with manipulation being the treatment of choice.
In pharmacological studies nonsteroidal anti-inflammatory drugs (NSAID’s) have shown anti-inflammatory, analgesic and antipyretic activity (Arky 1997 : 833). There is also evidence in experimental animals that NSAID’s may have a chondroprotective function by altering proteinase activity in articular cartilage (Ratcliffe et al 1993), although Gottlieb (1997) states that NSAID’s have a detrimental effect on articular cartilage.

The first line of treatment of allopathic physicians for the treatment of neck pain is usually NSAID’s, whereas the first line of treatment of chiropractic physicians is usually chiropractic manipulation (Dabbs and Lauretti 1995). The chiropractic adjustment and the efficacy of manipulative therapy for facet syndrome has been closely associated with chiropractic care, and in the past has delivered a higher degree of patient satisfaction when compared to standard medical care (Cherkin and MacCormack 1989). 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, when possible, prevents recurrence, becomes the treatment of choice (Vernon 1988 : 112). This study, then, endeavors to determine that 'treatment of choice' by combining the two most common treatments for neck pain, viz NSAID’s and manipulation.

Dabbs and Lauretti (1995) were unable to locate even a single randomised controlled trial examining NSAID use in the treatment of neck pain, compared to 26 randomised trials evaluating NSAID use for low back pain being identified by Koes et al (1997).
A Medline, Mantis, Sabinet and Grateful Med search from 1966-1998 resulted in no study being located involving NSAID’s and the treatment of neck pain.

Worldwide, NSAID’s seem to be the most commonly prescribed medications (Koes et al 1997), and are postulated by Jones (1997) to be equally effective as muscle relaxants and opioids for the control of lower back pain, but without the burden of dependence and potential for abuse. This, however still needs to be determined in a clinical trial.

Should this study demonstrate greater efficacy for the combined treatment, this may serve as an argument for chiropractors at some stage being able to prescribe low schedule medication. Parkin-Smith (1997) points out the social, political and the financial aspects the profession could benefit from if they choose this combined medical approach. Although, historically chiropractic has always advocated a drugless pathway to health, there is no harm done in endeavoring to determine better treatment protocols for our patient’s sake.

This double-blind, placebo controlled trial was designed to determine whether a course of NSAID’s combined with manipulation would result in enhanced recovery of patients with cervical facet syndrome compared to those receiving manipulation alone. The study design has attempted to overcome the methodologic flaws that according to (Koes et al 1992) in the past have plagued trials involving manipulation and neck pain.
The information obtained and deductions made from the outcome of this study will hopefully identify a more effective protocol for treating facet syndrome of the cervical spine.
CHAPTER TWO
2. REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

This chapter gives a comprehensive overview on the available information of the condition under investigation. It also outlines the current trends from the different schools of health care in treating cervical facet syndrome. The evidence for the efficacy of spinal manipulation and the effects it has on the cervical spine are presented. Nonsteroidal anti-inflammatory drugs, their safety and uses are also discussed.

2.2 FACET SYNDROME SYNONYMS

According to Gatterman (1995: 7), the word facet syndrome has many synonyms. These include cervical joint lock, articular derangement, dysfunctional joint, chiropractic subluxation complex, fixation, functional spinal lesion, facet joint dysfunction, neurobiomechanical lesion, spinal irritation and posterior facet dysfunction. Jaeger and Pate (1990: 88) refer to facet dysfunction or facet irritation, whereas Wyatt (1992: 155) refers to synovitis when discussing facet syndrome.
2.3. **EPIDEMIOLOGY, DEMOGRAPHY AND PHYSICAL CHARACTERISTICS OF NECK PAIN SUFFERERS**

Grieve (1988: 190) reported that the prevalence of neck pain among 2500 randomly selected men and women was 16% and 20% respectively. Neck pain is a costly entity in terms of treatment, individual suffering and time lost from work (Jordan et al 1998). One particular study showed that 5% of industrial workers were unable to work because of neck pain (Grieve 1988: 190). Lawrence (1969) found that at any one time 12% of adult females and 9% of adult males were suffering from neck pain and that 35% of the general population can remember having had neck pain at some stage.

In a study involving 1201 Canadian adults aged 20-69, it was found that the age-standardised prevalence of neck pain is 66.7% (95% confidence interval). The point prevalence is 22.2% with more women experiencing high-disability neck pain than men. (Cote et al 1998). Lau et al (1996) found the one year prevalence of neck pain in Hong Kong Chinese was 15% and 17% in men and women respectively (N=800, > 30 years of age). In a study conducted at the Technikon Natal Chiropractic Clinic comparing the types of conditions seen at this teaching clinic and those in private chiropractic clinics (N=17) in South Africa, it was found 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 (Drews 1995: 66).
Aprill and Bogduk (1992) did a study into the prevalence of zygapophyseal joint pain in 318 consecutive patients with neck pain who underwent provocation discography and cervical zygapophyseal joint blocks. They concluded that the zygapophyseal joints being the source in neck pain sufferers pain could be as high as 63%. However, there were no control injections to accurately determine this.

Neck injuries often result in chronic neck pain. An estimated 85% of all neck injuries seen in the United States result from automobile accidents. (Wiesel et al 1992.) No figures are currently available in South Africa. Barnsley et al (1995) confirms Wiesel et al’s statement by identifying painful zygapophyseal joints in 54% of patients with chronic neck pain after whiplash (N=50). This double-blind, controlled study used diagnostic blocks of either lignocaine or bupivacaine.

Finally, in a study by Jordan et al (1997) patients with chronic neck pain (N=119) were found to have a greater muscular deficiency in their cervical extensor muscle group when compared to age-matched healthy people. Active range of motion in extension was also decreased, which was more common in females. Extension being the close-pack position may well implicate the facets in terms hereof.

The above information reveals that in a wide spectrum of literature sources, neck pain is a significant problem. Women seem to be affected more by neck pain than men and geographical distribution has variations in the number of sufferers. It is clear, however,
that the need for continuing research into this problem is needed in order to determine more effective and cost-effective treatments.

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 (Panzer 1995: 415). Gatterman (1995: 11) defines it as an aggregate of signs and symptoms that relate to the pathophysiology or dysfunction of spinal motion segments. This she also refers to as the subluxation syndrome. The term facet syndrome, according to Peters (1984), also relates to a state of subluxation with tension, stretching and irritation of the vertebral joint capsule without narrowing of the related foramina.

2.4.2 Aetiology

The two main predisposing factors in causing mechanical neck pain according to Grieve, are prolonged poor postural habits and the frequency with which spinal flexion occurs with daily living (Grieve 1994: 392). Bland (1994: 114) cites the patient’s age, occupation, previous injury, the use of bifocal eyeglasses and specific physical characteristics as all being a causative factor in neck pain.
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 immobilisation. (Bergmann et al 1993 : 60). Lippit (1984) supports this and includes segmental instability as a causative factor.

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

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 (Peters 1984). Mooney and Robertson (1976) hypothesised that chronic capsular and synovial reactions to trauma result in entrapment of the highly innervated synovial villi between the facet surfaces resulting in irritation of adjacent nerve roots.
### 2.4.3 Diagnostic Criteria

According to Aprill and Bogduk (1992), cervical zygapophyseal pain cannot be definitively diagnosed without invasive techniques. Panzer (1995) supports this statement by stating that injection of local anaesthetic or a cortisone derivative into a specific facet joint, followed by relief, is generally considered diagnostic of facet syndrome.

However, in a study by Jull et al (1988) into the accuracy of manual diagnosis for cervical zygapophyseal joint pain syndromes, the presence of symptomatic joints (N=11) were correctly diagnosed by a trained manipulative therapist. These joints had previously been diagnosed by radiologically-controlled nerve block. Another nine patients were then first diagnosed by the manipulative therapist and then evaluated by diagnostic nerve block. The therapist correctly identified all the patients with symptomatic zygapophyseal joints including the correct segmental level in each patient. The manipulative therapist in this study had many years of experience, and perhaps different results would have been obtained if more than one therapist had been used. Future studies would have to establish intertherapist reliability. (Jull et al 1988).

- Pain and Tenderness: The patients perception of pain and tenderness is evaluated in terms of quality, intensity and location through patient questioning, observation, percussion and palpation.

- Asymmetry: This is determined on a sectional or segmental level. Misalignment of vertebral segments are identified through observation (posture and gait analysis), static radiography and static palpation.

- Range of Motion Abnormality: Changes in active, passive and accessory joint motions are identified through motion palpation and stress radiography. In joint dysfunction a decrease in motion is commonly found.

- Tone, Texture and Temperature Abnormality: Qualitative aspects of contiguous and associated soft tissues are identified through observation, palpation, instrumentation and strength testing.

- Special tests: Certain testing procedures are used to identify and isolate the involved zygopophyseal joint such as Kemp’s test (Peters 1984).

Lippit (1984) states that in order to diagnose a classic facet syndrome, there must be local paraspinal tenderness, pain on spine hyperextension, absence of neurologic deficit and absence of root tension signs.

Facet pain patterns are consistent enough in the cervical spine to the extent that it is possible to diagnose the level of joint involvement by characteristic pain distribution alone. Confirmation of the level of involvement can be aided by abnormal end-feel of the facet

2.4.5 Radiographic Evidence

The role of radiography in the practice of chiropractic is well established (Taylor 1995: 84), and although in the case of facet syndrome the diagnosis is not a radiographic one (Jaeger and Pate 1990: 87, Menell 1990), certain radiographic features may be helpful (Panzer 1995: 424). Bergmann et al (1993: 101) also point to x-ray changes as being helpful in diagnosing facet syndrome.

Peters (1984) proposes that a decrease in disc height combined with abnormal apophyseal motion, increased apophyseal space and faulty apposition of the facets (overriding) all point to facet syndrome. Mennel (1990) believes that a segmental loss of the normal cervical lordosis in the absence of other gross radiographic change is the only definite indicator of facet syndrome. Yochum and Rowe (1996: 163) however, implicate an increased lordosis as an indication that a facet subluxation may be present (Macnab’s Line), but the reliability and validity of this has not been documented.

Degenerative arthrosis, subchondral sclerosis, and tropism may also be significant radiographic features if they correspond to clinical findings (Panzer 1995: 424).
2.4.6 Anatomy

It is important to have a thorough knowledge of the anatomy of the zygapophyseal joint in order to understand the pathophysiological changes that occur in facet syndrome. These joints are of added interest to those who treat spinal conditions as a loss of motion or abnormal motion may be a primary source of pain (Cramer and Darby 1995 : 19).

The zygaophyseal joint is a true diarthrodial joint with hyaline articular cartilage, a joint capsule and a synovial lining (Giles 1992 : 198). These freely-movable joints are located between the inferior and superior articular facets of adjacent vertebrae. The superior and inferior facets are angled at 45° forward and downward and backward and upward respectively. (Bland 1987 : 53).

Articular Cartilage: Before the age of 20 years the articular cartilage is smooth and thick. This thins with age, and in the adult cervical zygaophyseal joint the cartilage is thin with irregularly thickened subchondral bone. (Cramer and Darby 1995 : 21). Normal adult hyaline articular cartilage is avascular and aneural. It is usually thicker at the periphery of the concave surfaces and thinner at the centre of the convex surfaces. (Giles 1992 : 198-199). The edges often have small indentations into which small fringes of the synovial membrane attach.
The function of articular cartilage is to transmit loads and allow repetitive joint motion without breaking down. Articular cartilage has the ability to deform under load, this therefore allows greater congruency between opposing surfaces thereby spreading the force over a larger surface area. (Giles 1992 : 199). These joints bear very little weight normally, the majority of the weight-bearing being borne by the intervertebral disc. However, this small amount of weight-bearing can result in spondylitic changes in the zygapophyseal joints. (Magee 1992 : 35). It stands to reason that any factor compromising the normal biomechanics of the cervical spine could result in greater dependency on the zygapophyseal joints, resulting in early degenerative changes.

Joint Capsule: The fibrous joint capsule is lax enough to permit free movement in all directions (Bland 1987 : 52). The capsules are longer and looser in the cervical region to compensate for the greater amount of movement that occurs in this region (Cramer and Darby 1995 : 19). The joint space is enclosed in the capsule with the ligamentum flavum attaching to its medial and superior aspect. This may prevent the capsule from being nipped between the two articulating surfaces during movement. (Lippit 1984).

Above and below the capsule are inferior and superior recesses which contain small synovial fat pads (Giles 1992 : 199). According to Mercer (1994 : 70) these intra-articular inclusions may play a role in movement dysfunction, although exactly how is uncertain.
The capsule also has a relatively poor blood supply which results in slow healing once the capsule is damaged (Giles 1992: 199).

**Synovial Membrane**: The synovial membrane of the facet joint is constructed of synovial villi which vary in size, shape and appearance and contain a rich supply of nerves and blood vessels (Mooney and Robertson 1976). It lines the articular capsule, the ligamentum flavum, the synovial joint folds, but not the articular cartilage of the joint surfaces (Cramer and Darby 1995: 19).

The function of the synovial membrane is to act as a transferor for the exchange of nutrients and waste products between blood and the joint tissues. It also contains numerous elastic fibres which permit elastic recoil during joint movement. (Giles 1992: 203)

**Synovial folds**: Zygapophyseal joint synovial folds or menisci project into the facet joints at all levels of the cervical spine (Cramer and Darby 1995: 21). Each meniscoid has a thick base which tapers into a thin fibrous end which projects into the joint cavity (Mecer 1994: 69). According to Giles (1992: 202), the function of these synovial folds is to fill the space between noncongruent parts of the joint surface, to secrete synovial fluid which acts as a lubricant, and to allow for the supply of nutrients to the joint cavity. Mecer (1994: 70-71) hypothesises that it is these folds that allow a site for adhesion formation between the articular cartilage, and that mechanical dysfunction of the cervical spine could be attributed to these folds becoming trapped between the facet surfaces.
Innervation: The cervical zygaophyseal joint capsule receives a rich supply of sensory and proprioceptive innervation, much more so than the thoracic and lumbar spines (Bland 1994 : 53). The sensory supply is derived from the medial branch of the posterior primary division at the level of the joint. Additionally, each joint also receives a branch from the posterior primary ramus from the level above. (Cramer and Darby 1995 : 21).

Very few nerve fibres are found in the disc (Peters 1984). This further points to the zygaphyseal joints as a more likely source of pain than the intervertebral disc in any painful mechanical neck condition.

2.4.7 Evidence of Inflammation

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

There is an inflammatory factor in many spinal joint dysfunctions (Bourdillon et al 1992 : 283). This factor is a combination of biochemical and cellular events that is mediated by the vascular system, but initiated by local events within the affected tissues (Lantz 1995 : 163). Bergmann et al (1993 : 53) include the inflammatory response as one of the
potential pathological effects of the facet syndrome. They believe that where pain is a constant feature there must be some degree of joint or soft tissue inflammation. Although this is purely a theoretical assumption, it stands to reason that there cannot be only one pathological component in facet syndrome. This they substantiate by including mechanical and neurobiologic components.

Roy et al (1988) deduced that inflammation of the joint capsule with subsequent irritation of the nerve roots was responsible for facet joint pain. Reid (1992 : 829) supports this by proposing that it is these inflammatory flare-ups of facet joint pain and synovitis that produce the facet joint syndrome. He also advocates the use of NSAID's for the treatment of these flare-ups. To counteract this, Bogduk (1994 : 433) believes that it is mechanical changes and not inflammatory changes that determines if the zygapophyseal joint becomes symptomatic or not. In a dysfunctional joint, an inflammatory reaction around a nerve or nerve root may cause persistent pain and often NSAID's are preferable to high velocity manipulation (Bourdillon et al 1992 : 301, 307). This statement they partially correct by blaming those who are inexperienced in manipulation in aggravating the condition, by being too slow, or moving the joint too far and compromising the surrounding soft tissue, causing further inflammation.

Bland (1994 : 323) put forward the important role that substance P has in the inflammatory process by recruiting the cells needed for the healing process. He states that in cervical spine syndromes substance P may provide clues for pharmacological
intervention in the modulation of pain. When inflammation in the cervical spine caused by mechanical means is present, substance P is present which causes increased permeability of blood vessels and recruitment of leucocytes which results in adhesion formation. (Bland 1994 : 323).

The duration of symptoms in painful neck conditions are a possible indicator to the severity of inflammation present in the joint (Gifford 1994 : 507), although Lantz (1995 : 165) states that the evaluation of chronic inflammation in the vertebral subluxation complex is difficult especially in the zygapophyseal joints. This may be due to Farfan’s (1992 : 160) hypothesis that the acute inflammation in facet syndrome may recover rapidly, but the resulting synovitis affecting the corresponding level annulus takes a long time to settle.

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

Immobilization in the cervical spine can result in connective tissue degradation. This causes a release of autocoids which initiate an inflammatory process resulting in tissue remodeling and subsequent limitation of joint movement (Lantz 1995 : 166), which is a
prominent feature of facet syndrome. When the cervical spine is injured, the injury results in the release of leukotrienes producing inflammation which often leads to the development of trigger points. It is thought that it is this inflammatory reaction that produces restricted range of joint movement, tendon and fascial shortening. Presumably, it is this kind of reaction that can be inhibited by anti-inflammatory drugs. (Dishman 1988.) Plaugher (1993 : 217) also points out the effects of inflammation on restricting joint mobility of an articulation.

When there is chronic inflammation in the cervical spine the clinical picture changes. According to Lantz (1995 : 163), inflammatory spillover into the surrounding tissues from the joint can result in chemical radiculitis, a feature of the neurobiologic component of the facet syndrome. It appears that this spillover of inflammation is mainly a feature of chronic facet syndrome.

For those in the chiropractic profession, of major concern in the management of facet syndrome is that the normal resolution of inflammation is fibrosis, which progresses to the development of scar tissue with subsequent restriction of joint motion. Scar tissue can compromise the functioning of the joint complex by causing circulatory, biomechanical and neurological consequences. It is therefore important not only to eradicate all signs and symptoms of inflammation, but to restore joint mobility by abolishing fibrotic adhesions. (Schafer and Faye 1990 : 306.)
From the above it is plausible to presume that NSAID's combined with cervical manipulation may render the patient with better short and long term relief than manipulation alone.

2.4.8 Clinical Features

The cervical facet syndrome produces both local and radiating pain (Roy et al 1988). The patient with facet syndrome may complain of a sudden onset of unilateral neck pain, often with referred pain. Muscle spasm is usually present causing restricted movement. Pain increases through this movement and is relieved by rest. If the pain has a postural basis, then a sharp stabbing pain may be present first thing in the morning that improves as the day progresses. The pain is aggravated by hyperextension and eased by flexion and often follows a sclerotomal rather than a dermatomal pattern. (Peters 1984.)

Mootz (1995 : 177) states that the facet syndrome is usually devoid of neurological signs, however pain distribution patterns from referred pain may provide diagnostic clues. This statement was supported by Fukui et al (1996) who mapped out the referred pain patterns of the cervical zygapophyseal joints. Sixty-one patients with occipital, neck and shoulder pain of suspected zygapophyseal origin were studied. The joints from C0/1 to C7/T1 were injected with contrast media, if the patient's usual pain was reproduced, then this area of pain that corresponded to a specific level was mapped out. The following referred pain distribution patterns were determined.
C2/3, C3 - occiptial region
C0/1, C1/2, C2/3 - upper posterolateral cervical 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-scapula region. (Fukui et al 1996.)

Abnormal quality on resistance to motion; abnormal end-feel, and reproduction of pain, either local or referred, when passive accessory movements are tested, are other clinical features of cervical facet syndrome. However, abnormal quality of resistance could occur in the presence of muscular spasm that braces the joint, the development of intra-articular adhesions, the loss of synovial fluid and erosion of articular cartilage. (Jull et al 1988.) It is therefore important to satisfy all the diagnostic criteria in order to be absolutely certain of one's diagnosis of facet syndrome.

Confirmation of the diagnosis may be a favourable response of the patient to manipulation (Cassidy et al 1992: 203).
2.5 MANIPULATION

2.5.1 Definition

Chiropractic is the principal proponent of spinal manipulative therapy (Brunarski 1984), and according to Fitz-Ritson (1990) it has been the primary treatment modality used by the chiropractic profession since its inception.

Outside of the chiropractic field, the word 'manipulation' still fails to have a firm definition. In Europe the term is used solely for a high velocity, low amplitude thrusting movement, whereas in North America the term includes treatments listed as mobilization, isometric and isotonic techniques, myofascial, functional, indirect and even craniosacral techniques. Bourdillon et al (1992: 121.)

In chiropractic the term 'manipulation' is called the 'chiropractic adjustment', and is defined by Mierau et al (1988) as an abrupt, quick, low-amplitude force skillfully applied to the apophyseal joints of a specific spinal segment to increase range of motion in that segment. The manipulative maneuver is usually associated with an audible cracking sound, and it is the joint crack that separates manipulation in general from mobilization. Haas (1990) however, believes that cavitation is not a necessary criteria to characterize the completion of an adjustment.
2.5.2 Contraindications

Accidents that have occurred in spinal manipulative therapy appear to have occurred because the diagnosis was in error or because the manipulative technique used was not accurately localized (Bourdillon et al. 1992: 129; Bergman et al. 1993: 132).

Patients who have the following conditions should not receive chiropractic manipulation: tumours, dislocation, fracture, infection, instability hematoma, myelopathy, radiculopathy, congenital anomalies (e.g., unstable os odontoideum), Arnold Chiari malformation, basilar invagination and cerebral ischemic syndromes (Wyatt 1992: 199-200). Bourdillon et al. (1992: 286) includes osteoporosis and hypermobility as contraindications to manipulation, but Mootz (1995: 180) believes that manipulation of an unstable segment is unlikely to promote greater instability and may provide the patient with relief. Both authors however, state that the presence of a hypermobile segment does indicate the presence of a hypomobile segment in the near vicinity.

It is clear that there are many conditions that are contraindicated to spinal manipulation and that even with all its benefits is not beneficial to all patients.

Of major concern in the cervical spine are cerebrovascular accidents related to chiropractic care (Laderman 1990). Bergman et al. (1993: 136) advocate a number of screening tests for vertebrobasilar ischemia including DeKleyn’s and Maigne’s test, which include rotation and extension of the cervical spine which compromise the vertebral artery and produce the characteristic symptoms and signs. Bolton et al. (1989) however, state that tests
routinely used to detect patients who are at risk to vertebrobasilar ischemia have shown to be unreliable and of little diagnostic value.

Caution should be exercised when adjusting an injured spine as it may aggravate already damaged tissues. In such cases, light mobilisation techniques are preferential. (Wyatt 1992: 193).

2.5.3 Effects of Manipulation

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

One of the most noticeable and dramatic effects of manipulation is the rapid restoration of the range of motion combined with a decrease in pain experienced by a patient with a fixated joint (Zusman 1994: 51). This is confirmed by Cassidy et al. (1992) who did a study into the effect of manipulation on pain and range of motion in the cervical spine. Fifty patients with ipsilateral neck pain received a single rotatory manipulation on the same side at the level of tenderness. 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. This study was not randomized, and the same adjustment procedure was
given to every patient. Perhaps a greater improvement in the range of motion would have
been achieved if the adjustment given was in the direction of the restriction for that
specific spinal segment.

In another study, Mierau et al (1988) demonstrated that after manipulation of the third
metacarpophalangeal joint (n=33) there was a significant increase in passive flexion when
compared to mobilization of the same joint. It is reasonable to assume the same would be
the case in the cervical spine, as both are synovial (diarthrodial) joints.

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

Bergman et al (1993 : 143-144) further point to intra-articular adhesions as a cause of
joint locking. Irritation to the cervical spine may lead to chronic inflammation, and joint
effusion may lead to synovial tissue hyperplasia, laying down of fibrous tissue and
subsequent intra-articular adhesions. Chiropractic adjustments are recommended to break
these adhesions and induce separation of the joint. (Bergman et al 1993 : 143-144.)

One of the profound effects of manipulation is the ability it has to overcome muscle
spasm. Leach (1983) proposes that trauma to the cervical spine may cause nerve irritation
that triggers protective muscle spasm and involuntary contraction of the muscles that straighten the neck. In a controlled clinical trial (n=20), it was demonstrated that chiropractic manipulative therapy was highly effective in the correction of cervical hypolordosis/kyphosis (Leach 1983). Although the sample size was small in Leach's study it could indicate that the hypothesis put forward by Bourdillon et al (1992 : 301) is true concerning the effect manipulation has on muscle spindles, by causing sudden lengthening followed by resulting muscle relaxation. Alternatively the cause of a cervical hypolordosis following trauma could be attributed to joint fixation.

In a study by Yeomans (1992) into the effect of spinal manipulative therapy on cervical intersegmental mobility, it was found that in all fifty-eight subjects spinal mobility increased significantly (p-value > 0.3) at each spinal level tested, with exception of C1 mobility. In the case of C1, there was no normal assessment value to compare the experimental results to. Although the study was non-randomised and un-blinded, the measurement of mobility was accurate (Brodeur 1994 : 18) and does give sufficient evidence that spinal manipulative therapy does have a positive effect on spinal immobility, a common finding in facet syndrome.

When concerned with the specific effects of manipulation on a patient suffering from facet syndrome, Panzer (1995 : 424) proposes the following:

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

The information presented has focused mainly on the mechanical effects of manipulation. Other proposed effects are sympathetic nervous system effects, adrenal catecholamine secretion, blood pressure and heart rate fluctuations (Zusman 1994 : 654), somatovisceral and viscerosomatic effects (Mootz 1995 : 182).

Stephens and Gorman (1996) did an investigation into the effect spinal manipulation has on normal vision. They concluded, using computerized static perimetry changes, that there was a measurable rise in visual sensitivity of both eyes. Only one subject was used so their results are far from conclusive. Interestingly, Donzis and Factor (1997) reported a case in which a presumably healthy 39-year-old woman developed sudden left peripheral field loss after chiropractic neck manipulation. The cause was a cerebral infarct post-manipulation.
2.5.5 Effectiveness of Manipulation

Although recent research has demonstrated the efficacy of spinal manipulation for patients with low back pain, little is known about its efficacy for neck pain and headache (Hurwitz et al 1996). Spinal manipulation directed to the facet articulation is generally the effective treatment of choice for facet syndrome (Panzer 1995: 424), and according to Sloop et al (1982), is also recommended for the symptomatic treatment of cervical spondylosis and nonspecific neck pain.

According to Cherkin and MacCormack (1989), chiropractic provides a higher degree of patient satisfaction when compared to conventional medical care, in this case general practitioners. According to Brunarski (1984), it is unclear whether this higher degree of satisfaction is due to the chiropractic treatment or to the caring attitude and hands-on treatment of the chiropractor towards the patient. Perhaps this greater patient satisfaction can be attributed to the prompt pain relief the chiropractic patient experiences. Haldeman (1992a: 437) states that spinal manipulative therapy offers more immediate pain relief to patients with spine related disorders than other forms of conservative therapy.

Brunarski (1984) analysed fifty clinical trials on manipulation and concluded that there is sufficient evidence to suggest that spinal manipulative therapy may be more effective than standard medical care in the management of painful musculoskeletal conditions. It must be noted however, that only fifteen of the fifty trials reviewed were randomised, and that
even these were fraught with design flaws such as examiner bias, lack of control groups, lack of specific adjustments, non-blinding and non-standardized inclusion and exclusion criteria.

One of the major symptoms of the cervical facet syndrome is headaches (Schafer 1987: 349). In a study conducted by Boline et al (1995), spinal manipulation was compared to pharmaceutical treatment (amitriptyline) for chronic tension-type headache. One hundred and twenty-six patients completed the randomized controlled trial. The results showed that spinal manipulative therapy is an effective treatment for tension headaches. Eighty-two percent of the patients in the amitriptyline group reported side-effects compared to 4.3% of the patients in the manipulative group. Although amitriptyline therapy was slightly more effective in reducing pain at the end of the treatment period, patients who received spinal manipulative therapy experienced a sustained therapeutic benefit in contrast to the amitriptyline group who regressed to their initial pain and disability levels. It is also interesting to note that the sustained therapeutic benefit associated with spinal manipulation seemed to result in a decreased need for over-the-counter medication. The authors recommended future studies to compare manipulation to an appropriate placebo in order to gain a more accurate view into the effectiveness of chiropractic treatment for headache.

In a randomized clinical trial of manual therapy (n=65), physiotherapy (n=66), placebo (n=64) and treatment by the general practitioner (n=61) for chronic back and neck pain,
the need for a placebo group is further emphasized (Koes et al 1992). At the three and six week follow-up the placebo group showed more favourable mean scores than the general practitioner group. Although at a 90% confidence level, manual therapy and physiotherapy did not show a significant difference for the mean improvement in the main complaint, manipulation showed favourable results. (Table 2.1.) Jordan et al (1998) criticized this study because the results for patients with neck pain were not presented separately from those for low back pain patients, and dropout and contamination rates appeared to be high.

Perhaps a significant difference would have been found if chiropractors had performed the adjusting. According to Brunarski (1984), a typical chiropractor receives a minimum of 1880 hours of training in manual medicine whereas medical manipulators and osteopaths receive less than 200 and 700 hours respectively. Sloop et al (1982) reports that in a study of manipulation in migraine, patients who received manipulation by chiropractors improved significantly more than patients who were manipulated by non-chiropractors.
TABLE 2.1 A Comparison of Manual Therapy, Physiotherapy, Placebo and Treatment by the General Practitioner (Koes et al 1992):

<table>
<thead>
<tr>
<th></th>
<th>Mean Improvement</th>
<th>3 weeks</th>
<th>6 weeks</th>
<th>12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual Therapy</td>
<td></td>
<td>2.3</td>
<td>3.4</td>
<td>4.0</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td></td>
<td>2.0</td>
<td>3.4</td>
<td>3.8</td>
</tr>
<tr>
<td>Placebo</td>
<td></td>
<td>1.7</td>
<td>2.7</td>
<td>3.8</td>
</tr>
<tr>
<td>General Practitioner</td>
<td></td>
<td>1.3</td>
<td>2.0</td>
<td>3.9</td>
</tr>
</tbody>
</table>

One year later manipulation still achieved a better mean improvement than physiotherapy; 4.5 to 4.1 (Koes et al 1993).

A study was undertaken by Jordan et al (1998) that compared the effectiveness of three commonly used treatment interventions, viz. intensive training of the cervical musculature, physiotherapy, and spinal manipulation on 119 patients with chronic neck pain. All three interventions were associated with a similar degree of improvement (95% confidence interval) regarding self-reported pain, disability, and medication use. Pain did, however, appear to have decreased more rapidly in the chiropractic group. Improvements were sustained at the 4 and 12 month follow-up consultations. Unfortunately, there was no
control group so it is uncertain if these improvements were a result of the treatment, or other reasons. (Jordan et al 1998) (natural history, co-intervention, etc).

Table 2.2 Pain Level Comparison of Intensive Training, Physiotherapy and Chiropractic Treatment (Jordan et al 1998):

<table>
<thead>
<tr>
<th>Median Pain Improvement</th>
<th>Baseline</th>
<th>Completion</th>
<th>4 month</th>
<th>12 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiropractic</td>
<td>13</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>12</td>
<td>6</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Intensive Training</td>
<td>12</td>
<td>6</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>

A randomized clinical trial of chiropractic (n=179) and physiotherapy (n=144) for neck and back pain suggested that chiropractic was more favourable for patients with an acute episode, and physiotherapy for patients with a chronic episode of pain of greater than one month. Also of note was that the mean number of treatment sessions during the treatment period was lower in the chiropractic group than in the physiotherapy group (Skargren et al 1998) (Table 2.3).
Table 2.3  
**Chiropractic versus Physiotherapy in Terms of Mean Number of Treatments (Skargren et al 1998):**

<table>
<thead>
<tr>
<th></th>
<th>Chiropractic</th>
<th>Physiotherapy</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Number of Treatments</td>
<td>4.9</td>
<td>6.4</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>95% CI = -1.53</td>
</tr>
</tbody>
</table>

Abbreviations: CI - Confidence Interval

In a double-blind, controlled study of manipulation for chronic neck pain by Sloop et al (1982), manipulation was shown to be more effective compared to the control group. This was the first reported controlled study of manipulation for chronic neck pain. Patients in both groups were given an amnesic dose of diazepam prior to manipulation of the cervical spine. Twenty-one subjects received manipulation, and eighteen controls received diazepam only. Improvements with regard to the Visual Analogue Scale (VAS) and statements of outcome by patients are shown in Table 2.4.

Table 2.4  
**Comparison of Manipulation to Diazepam Control**: (Sloop et al 1982)

<table>
<thead>
<tr>
<th></th>
<th>Manipulation Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean VAS Improvement</td>
<td>18mm</td>
<td>5mm</td>
</tr>
<tr>
<td>Percentage of Patients Favoring Treatment</td>
<td>57%</td>
<td>28%</td>
</tr>
</tbody>
</table>
All manipulations were performed by a rheumatologist. The sample size was not large enough to give conclusive results and the manipulative techniques used were not standardized. (Sloop et al 1982.) Objective data, such as range of motion and pressure threshold levels were not taken. Patients with symptomatic cervical spondylosis and non-specific neck pain were used for this study. Perhaps if a more specific selection criteria had been set out to exclude conditions such as myofascial syndromes, the outcome would have been different.

Overall, it would seem that there is sufficient evidence to suggest that spinal manipulative therapy may be more effective than standard medical care in the management of painful musculoskeletal conditions of the cervical spine. With regard to research, it is possible that bias against manipulation may have missed important differences in treatment effectiveness. (Brunarski 1984.) However, the opposite may also be true when chiropractors are performing studies into the effectiveness of spinal manipulation.
2.6 NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

2.6.1 Introduction

Worldwide, NSAIDs seem to be the most commonly prescribed medications (Koes et al 1997). Bellamy (1996) states that NSAIDs are the mainstay of treatment for most musculoskeletal disorders in the western world. They are prescribed extensively for their anti-inflammatory, analgesic, and antipyretic properties (Goodman and Simon 1994, Dabbs and Lauretti 1995).

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

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

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

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

2.6.2.1 Pharmacological Properties


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

All NSAIDs appear to be absorbed completely, are highly protein bound to albumin (>90%, 99.7% for diclofenac), and have low volumes of distribution. Only 5% of the unchanged drug is excreted in the urine and the bile. This may vary as the free
concentration of diclofenac may be higher in patients with low serum albumin levels, e.g., due to cirrhosis or rheumatoid arthritis. (DiPiro 1989: 908.)

The half-lives after single doses vary greatly and is the most variable property of the various NSAIDs (Table 2.5). Diclofenac compares favourably with aspirin and tolmetin. The antiinflammatory effect generally peaks after 2 to 3 weeks, irrespective of the half-life. However, once a steady state is achieved, saturation of the metabolic pathways increases the half-life. (DiPiro 1989: 908-909, Arky 1995: 834, Goodman Gilman et al 1990: 669, Goodman and Simon 1994.)

Table 2.5  Mean Plasma Half-Lives of some NSAIDs  (Goodman and Simon 1994)

<table>
<thead>
<tr>
<th>DRUG</th>
<th>HALF-LIFE (HOURS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>0.25 ± 0.03</td>
</tr>
<tr>
<td>Diclofenac Sodium</td>
<td>1.1 ± 0.2</td>
</tr>
<tr>
<td>Diclofenac Free Acid</td>
<td>1 ± 0.5</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>2.1 ± 0.3</td>
</tr>
<tr>
<td>Ketoprofen</td>
<td>1.8 ± 0.4</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>57 ± 22</td>
</tr>
<tr>
<td>Salicyclate</td>
<td>2 - 15</td>
</tr>
</tbody>
</table>

All NSAIDs appear to be as effective as aspirin in terms of analgesia and antiinflammatory properties, but cause fewer side-effects than aspirin, although diclofenac does provide a longer period of analgesia (DiPiro 1989: 908, Arky 1997: 834). NSAIDs penetrate the
joint fluid in concentrations generally half those found in the blood. (DiPiro 1989: 908.) It has been suggested that the anti-nociceptive and anti-inflammatory effects of diclofenac depend on the NSAID levels at the injured site, which may not be in equilibrium with the circulation (Torres-Lopez 1997). Diclofenac accumulates in synovial fluid after administration, which may explain the duration of the therapeutic effect that is considerably longer than the plasma half-life (Goodman Gilman et al. 1990: 669). This makes it an excellent choice for the treatment of facet syndrome.

2.6.2.2 Indications and Therapeutic Uses

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

Koes et al (1997), in their review of randomised clinical trials (n=26) on the efficacy of NSAIDs for low back pain, concluded that NSAIDs are effective for short-term symptomatic relief in patients with uncomplicated low back pain, but are less effective in patients who are suffering from back pain and nerve root symptoms. It is reasonable to assume that the same would apply to patients who are suffering from uncomplicated neck pain.
2.6.2.3 Toxic Effects

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

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

2.6.2.4 Efficacy of Diclofenac

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

In a pharmacy-based survey (n=82) of diclofenac, it was found that the majority of purchases were for musculoskeletal conditions and headache. Over two-thirds of the
respondents (71%) indicated receiving either moderate or complete relief of their symptoms after taking diclofenac. Sixteen percent of the respondents claimed to have experienced adverse reactions from diclofenac usage, however none of these reactions were severe enough to prompt the user to notify his or her pharmacist or doctor. Eighty-three percent of the respondents indicated their willingness to use diclofenac again in the future. (Emmerton et al 1995.) When using post-marketing surveillance research methods it would seem that larger sample sizes would be required (>1000), in order to accurately determine the information portrayed in this survey. Other factors influencing the outcome of surveys like this would depend on the quality of data obtained and the efficiency of administration.

In a study of the antinociceptive effect of diclofenac in the rat, it was found that acetaminophen and ketorolac exhibited a faster onset, and it was possible to relate it to the circulating drug concentration. The reason that diclofenac has a prolonged antinociceptive effect when compared to other NSAIDs is that there is evidence that this agent is transferred across the synovial membrane to the synovial fluid, from which it is eliminated more gradually than from plasma. It has been suggested that the clearance of diclofenac from synovial fluid to blood occurs slowly because the drug binds with high affinity to the albumin that is expropriated into the synovial space in joint disease. Thus, the prolonged effect of diclofenac can be attributed to the notion that it is retained by the albumin-enriched synovial fluid. (Torres-Lopez et al 1997.)
Diclofenac (50mg) and tiaprofenac acid (100mg) were used in a double blind, randomised clinical trial to treat outpatients suffering from traumatic joint injuries. Sixty patients were studied, with thirty-one receiving diclofenac and twenty-nine receiving tiaprofenac acid. Pain intensity decreased from baseline values in both groups, when measured by the 100mm Visual Analogue Scale (VAS) one hour, two hours, and four days after taking the first dose of the medication (Table 2.6). Both medications were effective in reducing swelling, tenderness, pain at rest and pain on movement. (Karam 1992.)

2.6 Diclofenac versus Tiaprofenac Acid in terms of Average Pain Intensity (Karam 1992):

<table>
<thead>
<tr>
<th></th>
<th>Diclofenac</th>
<th>Tiaprofenac Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pretreatment</td>
<td>98.5</td>
<td>100</td>
</tr>
<tr>
<td>One hour</td>
<td>81.2</td>
<td>95.6</td>
</tr>
<tr>
<td>Two hours</td>
<td>65</td>
<td>80.4</td>
</tr>
<tr>
<td>Four days</td>
<td>20</td>
<td>33.2</td>
</tr>
</tbody>
</table>

It is however difficult to determine which NSAID is superior to the next, because patient response to the NSAIDs is typically variable and highly individual. A patient may respond well to one drug in a particular chemical class but have little or no benefit from another NSAID in the same class. It is sometimes necessary to try other NSAIDs, in a selective manner, after an adequate trial (2-3 weeks) at an adequate dose. (DiPiro 1989: 909.)
Deyo (1996) attempts to clarify why there is no uniquely successful drug therapy for spinal pain by suggesting that the uncertainty and slow progress in this area is due to the limited quality of the many clinical trials, with inadequate description of patients and outcomes being common deficits.

In a randomized clinical trial (p<0.05) comparing the effectiveness of diclofenac, chiropractic manipulation, physiotherapy, bed rest, back school and placebo on low back pain it was found that in acute patients, chiropractic was the superior treatment regime (Table 2.7). In patients with chronic low back pain it was found that physiotherapy and back school were the treatments that scored the highest on the mean improvement scale. (Postacchini et al 1988.)

Table 2.7  **Mean Improvement on Combined Pain, Disability, and Spinal Mobility Score** (Postacchini et al 1988):

<table>
<thead>
<tr>
<th>Treatment</th>
<th>3 Weeks</th>
<th>2 Months</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac</td>
<td>3.0</td>
<td>10.7</td>
<td>14.0</td>
</tr>
<tr>
<td>Manipulation</td>
<td>7.5</td>
<td>9.7</td>
<td>12.3</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>5.0</td>
<td>8.4</td>
<td>10.2</td>
</tr>
<tr>
<td>Bed Rest</td>
<td>5.4</td>
<td>7.5</td>
<td>7.3</td>
</tr>
<tr>
<td>Placebo</td>
<td>1.8</td>
<td>7.3</td>
<td>11.0</td>
</tr>
</tbody>
</table>
It seems logical that by combining the treatment that offers the greatest short term relief (Chiropractic) with the treatment that offers the greatest long term relief (diclofenac) a very effective treatment regime can be offered to those suffering from low back pain. It also seems logical that the same would apply to treatment of the cervical spine.

A randomized clinical trial (n=48, p=0.05) was conducted to compare the efficacy and tolerability of single doses of diclofenac dispersible and naproxen granular in patients with acute, painful, minor sports injuries. Diclofenac was significantly superior to naproxen with respect to pain on pressure and pain relief at 15 minutes. After 4 hours, diclofenac was significantly superior to naproxen with respect to pain on movement and pain relief scores. (Colombo et al 1997.) Although, in all probability, these results cannot give a long term indication on the superior effectiveness of diclofenac in chronic cervical facet syndrome, it does suggest that it will give the patient faster short term relief.

2.6.2.5 Safety

The use of NSAIDs is associated with a 2% to 4% annual incidence of serious gastrointestinal complications (Goldstein et al 1997). Although this incidence is low, the widespread use of these drugs and the fact that patients may suffer major morbidity or mortality means that the possibility of side-effects must be taken seriously and looked for (Goodman and Simon 1994). Case control studies suggest that a fifth of all admissions to hospitals in patients over the age of 60 with bleeding gastric or duodenal ulcers is directly
attributable to taking NSAIDs (Edwards and Bouchier 1992: 773). It is estimated that, at any given time, the chance of a patient on NSAID therapy having a gastric ulcer is 10% to 20%, a rate 5 to 10 times greater than non-users (Dabbs and Lauretti 1995). It is therefore imperative that patients undergo an intensive screening process to rule out risks to NSAIDs. Goodman and Simon (1994) suggest that with the risk that NSAIDs pose, it is not worth using them on patients with mechanical joint pain and that acetaminophen or nonacetylated salicylates are often adequate substitutes.

The risk of a serious neurovascular complication from cervical manipulation is approximately 1 per 100,000 patients receiving a course of treatment per year, or 0.001%. It is estimated that 1 in 400,000 patients receiving a course of treatments will die as a result of cervical manipulation, or 0.00025%. The risk of a serious gastrointestinal complication requiring hospital admission because of NSAID use for similar conditions (i.e., a diagnosis of cervical arthritis or spondylosis) is 0.4% per year. The risk of death due to peptic ulcer perforation and hemorrhage due to NSAID use for osteoarthritis is 0.04% (Dabbs and Lauretti 1995). They concluded that the risk of serious complications or death is 100-400 times greater for NSAID use than for treatment by cervical manipulation for similar conditions.
Figure 2.1  Risk of Serious Ulcers and Death from NSAIDs versus Risk of Stroke and Death from Neck Manipulation (Dabbs and Lauretti 1995):

2.7 Conclusion

It may well be argued that patients will be put at unnecessary risk when receiving both NSAIDs and cervical manipulation for the treatment of cervical facet syndrome. This is certainly true. Emmerton et al (1995) report that only 24% of diclofenac taking patients were taking diclofenac medication as a result of prescription from their doctor. Goodman and Simon (1994) suggest that of major importance is to be on alert for patients who are on non-prescription NSAIDs, who often have not informed their physicians. Emmerton et
al (1995), in their findings report that of the people surveyed who purchased diclofenac, 58.4% were using it for the relief of musculoskeletal pain. Chiropractic has become synonymous with the treatment of musculoskeletal pain (Haldeman (b) 1992). It seems logical that those who primarily treat musculoskeletal conditions should have some control over NSAID administration to patients. This could ensure proper screening of potential users, and thereby decreasing the possibility of NSAID abuse by nonprescription users (Goodman and Simon 1994).

There is at present a new class of anti-inflammatory and analgesic drugs undergoing clinical trial known as the selective cyclooxygenase inhibitors, which promise to be without the types of toxicity associated with NSAIDs. These are however unlikely to be available for routine clinical use before the end of the decade. Lately, there has been a new development in the NSAID class with the introduction of diclofenac/misoprostol (Arthrotec®). Misoprostol is an active compound that helps prevent NSAID induced gastrointestinal damage. There is evidence that the diclofenac/misoprostol combination provides an improved therapeutic ratio over diclofenac alone, not only by improving gastrointestinal safety but also by enhancing analgesic/anti-inflammatory effects. (Shield 1998.) With this in mind it would seem more feasible to use this drug on cervical facet syndrome sufferers, who are already at risk to stroke.

Alternatively, of interest to those who have strong reservations about the use of allopathic medicine in chiropractic, is chondroitin sulphate. In a randomized double blind, double
dummy study (n=146) diclofenac, chondroitin sulphate, and placebo were tested in patients with osteoarthritis of the knee. Patients who were treated with diclofenac demonstrated a fast reduction in symptoms, that reappeared after the medication was discontinued. In the chondroitin sulphate group, the patients symptoms disappeared later in time, but lasted for up to six months after treatment was discontinued. It has also been demonstrated that chondroitin sulphate is able to cause an increase in RNA synthesis which appears to correlate with an increase in the synthesis of proteoglycans and collagens. (Morreale et al 1996.) Klee (1998) however states that even with these so-called chondroprotective drugs, NSAIDs are still the effective drugs of first choice, provided that there is careful dosing and surveillance of possible gastrointestinal effects.

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

However, according to Haldeman (b)(1992), medical and chiropractic researchers should no longer work in isolation. Controlled trials of various medical and chiropractic treatment approaches are going to have to increase so that decisions can be reached as to when medical intervention is appropriate and when it is not. Research into the effect of manipulation on the cervical spine is still in its infancy, with formal chiropractic research only spanning fifteen years (Haldeman(b) 1992).
Dabbs and Lauretti (1995) recognize the need for further clinical trials concerning NSAIDs and manipulation for neck pain. By undertaking a randomized clinical trial and keeping to as many of the ideal research principles (Brunarski 1984) as possible, evidence can be put forward as to the effectiveness of these two treatment regimes.

Chiropractic care has been suggested to be more cost-effective than conventional care for musculoskeletal conditions (Stano 1993). By combining a low-priced NSAID (eg. aspirin) with chiropractic care this cost-effectiveness may be even better by decreasing the number of treatment sessions.

The fact that chiropractic science has survived despite the overwhelming dominance of the field of spinal research by medical scientists, which is of worldwide acceptance is a tribute to the chiropractic profession (Haldeman 1992).
CHAPTER THREE
3.0 MATERIALS AND METHODS

3.1 INTRODUCTION

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

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

3.2 THE DATA

The data consisted of primary and secondary data.

3.2.1 The Primary Data

- The case history, physical examination, cervical regional examination and radiographic findings of the patients used in this study.
- The patient’s perception of their disability (CMCC Neck Disability Index).
- The patient’s perception of their pain level (Numerical Pain Rating Scale-101).
- The patient’s perception of the sensory dimension of their pain (McGill Short-Form Pain Questionnaire).

- The patient’s cervical spine range of motion (CROM Goniometer).

- The patient’s pressure threshold in terms of pain (Wagner Algometer).

- The reaction of the experimental group to manipulation and NSAID’s in terms of pain and disability aggregates and range of motion.

- The reaction of the control group to manipulation and placebo medication in terms of pain and disability aggregates, and range of motion.

3.2.2 The Secondary Data

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

3.3 THE SUBJECTS

Patients were attracted to this research study by means of advertisements placed on noticeboards in gyms, corporate offices, tertiary institution campuses and on two local radiostations. Thirty 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.
Each research patient who presented at the Technikon Natal Chiropractic Clinic with neck pain was given a brief assessment to determine if they would be a suitable candidate for the study. This assessment consisted of questions pertaining to the nature and progression of the pain, the presence of any hard neurological signs and symptoms and a range-of-motion test.

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

3.4 INCLUSION AND EXCLUSION CRITERIA

The criteria were as follows:

1. Only patients between the ages of eighteen and sixty-five were to be accepted.

2. Any conditions associated with cervical facet syndrome (e.g. myofasciitis) were to be assessed and noted, but no treatment for these conditions was to be administered.

3. If any conditions which contraindicated NSAID administration were present, such patients were to be rejected from the study (Arky 1997: 835).

4. Patients taking aspirin, anticoagulants, digoxin, methotrexate, cyclosporin, lithium, oral hypoglycemics, diuretics, or phenobarbital were not to be included in the study, due to the varied interactions these drugs have with the medication used, viz diclofenac (Arky 1997: 835-6).
5. Any other treatment received or taken during the duration of the study would result in the exclusion of the subject.

6. The patients had to follow the researcher's instructions during the course of the study. This included instructing the patient not to change their normal everyday lifestyle. Compliance was to be ensured by careful questioning of the patient at each consultation.

7. If any patient developed side effects (Arky 1997: 836) that could be related to the medication given, such a patient was to be excluded from the study.

8. Radiographic examination of the cervical spine was to be used only where clinically indicated, to rule out contraindications to spinal manipulation. If any such condition was present, such patients were excluded from the study (Haldeman 1992: 352; Gatterman 1990: 57-62).

9. From the case history, physical examination, cervical regional and radiographic examination the patients had to meet the criteria necessary for a diagnosis of cervical facet syndrome as advocated by Schafer and Faye (1990: 98-110) and Bergmann et al (1993: 41-42).

- pain or tenderness over the involved osseous and soft tissue area,
- asymmetry/misalignment qualities identified through observation and static palpation,
- range of motion abnormality identified actively and through motion palpation,
- palpable tissue tone differences over the area of dysfunction,
'special tests that include Kemps and facet joint challenge, done at the level of
dysfunction.

Pain and restriction of movement greater in extension than flexion was also
used as one of the diagnostic criteria for cervical facet syndrome. Although
Kirkaldy-Willis (1992: 106) includes this as one of the diagnostic criteria for
posterior facet syndrome in the lumbar spine, it is reasonable to assume that the
same would occur in the cervical spine, if not more so due to the orientation of the
cervical zygapophyseal joints. These joints in the upper cervical spine lie at
approximately a 35° angle to the horizontal plane, and the lower joints form a 65°
angle to the horizontal plane (Cramer and Darby 1995: 21). As the cervical spine
has a greater range of motion than the lumbar, it is likely that inflamed synovial
joint folds may become compressed and entrapped between the two joint surfaces,
resulting in pain. Biomechanically, this is more likely to occur in the closed-
packed position (extension), than flexion of the neck. (Magee 1992: 34).

Although Mior et al (1990) and Nansel et al (1989) found the interexaminer
reliability of identifying end-feel restriction at specific segmental levels to be poor
(0.00 to 0.15), Haas and Panzer (1995: 65) argue that future research should
include the correlation of palpatory findings with patient symptomatology, other
diagnostic findings, adjustive intervention and treatments outcomes for a more
accurate stand on the validity of motion palpation to be developed. Motion
palpation was included in this context.
3.5 ETHICS

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

3.6 THE SAMPLE GROUP

The sample size consisted of thirty consecutively selected patients that conformed to the admission criteria governing the study, and were randomly divided into two groups of fifteen each. An objective observer was appointed by the researcher who then conducted the randomisation procedure, as this study was of a double-blind nature. Groups A and B were identified by placing numbers one to thirty in one box and an equal number of A’s and B’s in another box. Prior to this, A and B were deemed by the objective observer either the experimental (NSAID), or control placebo medication group. As each number was drawn from Box One a corresponding letter was drawn from Box Two. The sequence was then given to the researcher prior to the commencement of the study. This allowed the researcher to know which sachet (labelled A or B) to give to each patient. The letter A or B, indicating either the NSAID or placebo medication, was inscribed on each set of
fifteen sachets. The nature of group A and B was withheld from the researcher by the objective observer until the study was completed.

The group receiving NSAID’s was the experimental group and the group receiving placebo medication was the control group. Both the experimental and control group received chiropractic spinal manipulation of the cervical spine as well.

3.7 ASSESSMENTS

Those patients who were eligible for the study were required, at the initial consultation, to complete the Numerical Pain Rating Scale-101 (Jensen et al 1986), the Short-Form McGill Pain Questionnaire (Melzack 1987) and the CMCC Neck Disability Index (Vernon and Mior 1991). Cervical spine range of motion, by way of a goniometer (CROM Performance Attainment Associates Model) and pressure readings over the affected level using an algometer (Wagner FX2 model), were also performed on the initial consultation.

This sequence of measurements was repeated at the sixth consultation and the one month follow-up visit. Measurements were taken prior to the commencement of the treatment at each data collecting consultation.
3.8 INTERVENTIONS

Each patient who qualified to participate in the study received six treatments over a period of two weeks. A follow-up consultation was conducted a month after the final treatment. If the patient became asymptomatic before the final treatment, the patient continued to be assessed for the remainder of the treatment period.

As it transpired, patients in group A were treated using spinal manipulative therapy and received NSAID's. Patients in group B were treated using spinal manipulative therapy and received placebo medication.

3.8.1 Spinal Manipulative Therapy

The involved facet/s were adjusted using a high velocity, low amplitude manipulation as described by Szaraz (1990). The direction of the thrust was according to motion palpation findings, where a specific manipulation is used to restore the desired movement (Schafer and Faye 1990: 100-110). Depending in which position the affected level could best be tractioned to tension, the patient was adjusted either supine or seated (Bartol 1995: 98). The patients age, gender, body build, general physical condition, flexibility and location of the area of dysfunction also influenced the nature of the osseus thrust. In all the adjutive procedures administered, an index finger or thumb contact was used.

Where motion palpation findings indicated a rotatory restriction, the head was rotated no more than approximately 45° during the adjustment procedure.
3.8.2 Medication

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

- Measurable plasma levels are observed within 10 minutes of dosing with peak plasma levels occurring in one hour.
- Cataflam diffuses into and out of synovial fluid.
- Cataflam comes in convenient blister packs and can be taken on an empty stomach or with food which can improve patient compliance.
- In one study of chronic pain, in patients with osteoarthritis (N=196), Cataflam was comparable in efficacy to ibuprofen 800mg and diclofenac delayed-release tablets 50mg.
- In another study of chronic lower back pain, chiropractic manipulation (N=87) was found to be no better than full dosage (150mg per day) diclofenac (N=81). Mean improvement was based on combined pain, disability and spinal mobility scores. Postacchini et al (1988).
- Novartis, the pharmaceutical company that manufactures the product, kindly agreed to sponsor the medication for this trial.
- It is classed as a NSAID and is a freely-available over-the-counter drug.
The NSAID tablets were individually crushed using a pestle and mortar and placed in identical empty paper sachets. The placebo medication consisted of lactose powder with a pinch of salt added to make the taste somewhat similar to the NSAID being used. The placebo medication was then also placed in the same type of sachets the NSAID medication was contained in.

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

3.9 MEASUREMENTS

3.9.1 Objective Measurements

The objective data was obtained by means of an algometer and a goniometer. Both types of readings were taken on the initial, sixth and one month follow-up consultation and recorded on the form provided (Appendix I).
3.9.1.1 The Goniometer

Brodeur (1994:18) believes that the most important factor in evaluating and monitoring cervical function in a non-invasive manner is the cervical range of motion. Spinal articular dysfunction can result in hypomobility of joint movement (Blunt et al. 1995:208). Youdas et al. (1991) concludes that cervical spine disorders may alter the normal active range of motion of the cervical spine.

Active ranges of motion in the cervical spine were measured by means of the Cervical Range of Motion Instrument (CROM), a Performance Attainment Associates product. The ranges of motion, measured in degrees, were: forward flexion, extension, left and right rotation, and left and right lateral flexion.

This instrument was used for the following reasons (Youdas et al. 1991):

- the measurement procedure did not seem to alter the progression of the patient's condition,
- it has been shown to demonstrate good intra-examiner and inter-examiner reliability,
- it has been shown to have a high degree of reliability when compared to two other types of goniometers.

Although, in the past, the CROM goniometer has been used successfully in a number of clinical trials (Jones 1995:43, Parkin-Smith 1996:51, Ritchie 1997:39), there are possibly a number of factors that are often overlooked when using active range of motion measurements as objective data in the cervical spine. Blunt et al. (1995:209) state that a
manipulable subluxation may occur in a motion segment in which the holding elements have been stretched, causing hypermobility with a joint block that is reversible by manipulation. Gatterman (1990: 170) defines segmental hypermobility as a reversible physiological joint dysfunction. Compensatory hypermobility is a common finding with fixations of the spine (Gatterman 1990: 33). Manipulation of the adjacent hypomobile segments would theoretically decrease the range of motion in the hypermobile segments (Gatterman 1990: 171). It is therefore possible that the cervical spine may demonstrate normal range of motion before and after the riddance of the manipulative lesion.

Haldeman (1992: 275) states that testing passive range of motion is possibly a better indicator of joint pathology (facet syndrome in this clinical trial) than active range of motion. Supporting this was Bland (1994: 293) who advocates the use of a goniometer in measuring passive range of motion. However, this measurement as suggested by Brodeur (1994: 19) was excluded from the study due to the risk of aggravating the patients condition by causing further injury to the various components of the joint in question. By passively moving an injured joint to its end range of motion, the already damaged tissue may be further aggravated.

In general, radiographic measurements are more accurate than goniometric readings for cervical range of motion, however, it is invasive and difficult to measure rotation and lateral flexion on radiographs (Brodeur 1994: 18).
The procedure for using the CROM was as follows:

- The patients sat in a chair with their thoracic and lumbar spines making contact with the back of the chair. The patients' feet were flat on the floor with their arms hanging freely at their side.

- The plastic frame was then placed over the patient's head with the anterior portion of the device resting on the nose and the side portions placed over the ears. Velcro straps posteriorly then secured the device.

- The three orthogonally arranged dials on the frame were then set to zero.

- Rotation movements were assessed with a compass goniometer in conjunction with a magnetic yoke, while flexion, extension and lateral flexion movements were assessed by gravity dependant goniometers.

- Extension was measured by asking the patient to "put your head back as far as you can".

- Flexion was measured by asking the patient to make a double chin and then further flex until no more movement could be obtained.

- Lateral flexion was measured by asking the patient to put their left or right ear to their respective shoulder without turning their head or lifting their shoulders.

Rotation was measured by placing the magnetic yoke around the patient's neck and setting the compass to zero. The patient was asked to turn their head as far as they could to the left and right without moving their shoulders.
3.9.1.2 The Algometer

The algometer used in this clinical trial was the FDK20 Force Dial, a product of Wagner Instruments (P.O. Box 1217, Greenwich, CT, 06836 USA, Tel. 2038699861).

Measurements were taken over the most tender/painful facet joint in the area of dysfunction. The area was determined by means of positive:

- Kemp's test,

- joint challenge,

- motion and static palpation for fixations and subluxations.

Force readings were measured in kilograms per square centimeter.

Fisher (1987) defines pressure threshold as the minimum pressure inducing pain or discomfort. The algometer can be used to quantify different types of treatment such as manipulation in order to establish any improvement in the patient's condition (Fisher 1986: 837).

Vernon et al (1990) evaluated pressure pain threshold over tender points surrounding a manipulable spinal lesion in nine patients with chronic mechanical neck pain. Their study confirms that manipulation can increase local paraspinal pain thresholds. Although their sample size was small, there was a significant statistical difference (p < 0.0001).

The algometer had a one square centimeter square rubber disc attached to it which according to Fisher (1986) is suitable for measuring tenderness in joint capsules. He also states that the effect of painkillers and anti-inflammatory medication can be quantified using an algometer.
In a study done by Antonaci et al. (1998), pain perception thresholds were assessed with a mechanical pressure allogometer in twenty one healthy individuals. Thresholds were assessed at thirteen symmetrical points on each side of the neck. Inter-examiner reliability was good (0.75) and intra-examiner reliability was excellent (0.84).

The disc was placed over the identified facet at an angle perpendicular to the surface. Pressure was applied at a rate of one kilogram per second until the patient indicated discomfort. This was done over the most involved facet as judged by the researcher using the diagnostic criteria set out above.

The algometer was used as follows:

- The dial was set to zero by depressing the reset button.
- The 1cm squared rubber disc was placed over the most involved facet.
- The patient was instructed to say “now” at the point they first perceived pain and the pressure was then released by the researcher.
- The pressure was gradually increased at a rate of 1kg/second (Fisher 1986).

The algometer used is recalibrated every year, however this was not done immediately before the commencement of this study.

3.9.2 Subjective Measurements

Subjective measurements were taken from questionnaires the patients had to complete in writing. This was done on the initial, sixth and one-month follow-up consultation. The questionnaires used were the CMCC Neck Disability Index (Appendix F), the Numerical
Pain Rating Scale-101 (Appendix G) and the Short-Form McGill Pain Questionnaire (Appendix H).

3.9.2.1 CMCC Neck Disability Index (Appendix F)

The Neck Disability Index (NDI) is a ten item paper-and-pencil measure of disability resulting from neck pain. Each question has a maximum score of five and a minimum of zero. The score is calculated out of fifty and represented as a percentage.

According to Hains et al (1998) the NDI possesses stable psychometric properties and provides an objective means of assessing the disability of patients suffering from neck pain. The NDI is a revised form of the Oswestry Low Back Pain Index which was developed by Fairbank et al (1980). The NDI has been shown to demonstrate a high degree of test-retest reliability and internal consistency applicable to all ages and gender. It has an acceptable level of validity which is sensitive to severity levels and to changes in severity over time. (Vernon and Mior 1991.)
3.9.2.2 Short-Form McGill Pain Questionnaire (Appendix H)

The questionnaire is designed to provide information to the researcher on the sensory, affective and overall intensity of the patient’s pain (Melzack 1987). The questionnaire is successful in measuring the sensory dimension of pain.

It is derived from the McGill Long-Form Questionnaire and consists of fifteen descriptive words all pertaining to pain. Each descriptive word is assigned a score depending on the intensity of the sensation related to that word; 0 = none, 1 = mild, 2 = moderate and 3 = severe. (Melzack and Katz 1992: 162.)

Melzack (1987) has also shown that the Short-Form McGill Pain Questionnaire is sufficiently sensitive to demonstrate differences due to treatment at statistical levels comparable to those taken from the McGill Long-Form Questionnaire. Both questionnaires were given to seventy patients suffering from post-surgical, obstetrical and musculoskeletal pain. The long-form, followed by the short-form, were given to the patients before and thirty minutes after medication or other therapy for pain was administered. A second study was carried out on sixty-two post-surgical and dental patients with the short-form being given first. High correlation levels were see in both studies. (Melzack 1987.)

It is therefore a useful tool in the clinical setting where time is often limited.
3.9.2.3 Numerical Pain Rating Scale (101 Scale) (Appendix G)

Subjective pain intensity remains one of the most important measurements to both researchers and clinicians (Jensen et al. 1986). The 101-point Numerical Pain Rating Scale (NRS-101) is a questionnaire used to measure the intensity of pain a patient is experiencing. It consists of asking the patient to rate his or her perceived level of 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 number stated by the patient represents his or her level of pain intensity. The number was required to be written twice; firstly, when the pain intensity was at its worst, and secondly, when the pain intensity was at its least. The average between these two figures was then taken as the percentage intensity of the pain they were experiencing prior to each data collecting treatment.

In a recent study carried out by Bolton and Wilkinson (1998) on seventy-nine chiropractic patients to compare the responsiveness of three pain scales, they found the NRS to be the most responsive of the measures (effect size = 0.86, as opposed to 0.77 for the Visual Analogue Scale, and 0.76 for the Verbal Rating Scale). The authors, based on their findings, recommend the NRS for pain intensity measurement in most types of outcome studies.
3.10 SPECIFIC TREATMENT OF THE SUBPROBLEMS

3.10.1 The First Subproblem

The first subproblem was to evaluate the relative effectiveness of spinal manipulative therapy in conjunction with the administration of placebo medication, compared to spinal manipulative therapy in conjunction with the administration of NSAID’s, in patients with facet syndrome of the cervical spine, in terms of subjective clinical findings.

3.10.2 The Second Subproblem

The second subproblem was to evaluate the relative effectiveness of spinal manipulative therapy in conjunction with the administration of placebo medication, compared to spinal manipulative therapy in conjunction with the administration of NSAID’s, in patients with facet syndrome of the cervical spine, in terms of objective clinical findings.

3.10.3 The Third Subproblem

The third subproblem was to integrate, analyse and interpret the subjective and objective data collected in this study, in order to determine which of the two treatment approaches is more effective in alleviating the signs and symptoms associated with patients who are suffering from facet syndrome of the cervical spine.
3.11 STATISTICAL ANALYSIS

3.11.1 TREATMENT OF THE DATA

3.11.1.1 Subjective Data

The subjective data were treated as follows:

- The questionnaires that the patients had to complete were screened to ensure that they had been filled in correctly.
- The raw data from the three questionnaires were converted to percentages and recorded separately for each group.
- The data were then statistically analysed using a 95% level of confidence.

3.11.1.2 Objective Data

The objective data were treated as follows:

- The algometer readings, in Kg/cm², were recorded separately for the two groups.
- The cervical ranges of motion, recorded in degrees, were also recorded separately for the two groups.
- The data were then statistically analysed using a 95% level of confidence.

3.11.2 STATISTICAL ANALYSIS OF THE DATA
The Technikon Natal Statistician was consulted for advice on how to statistically analyse the data obtained from this research study. Due to the sample size of the study ($N_1$ and $N_2 < 25$), non-parametric tests were used to analyse the data. All data was transferred to a spreadsheet and statistical analysis was then conducted at a 95% confidence level.

### 3.11.2.1 Mann-Whitney Unpaired Tests

Mann-Whitney Unpaired tests were conducted in order to determine whether there was any significant change between the two groups (inter-group analysis), at the time of the first consultation, sixth consultation and the one month follow-up visit. Confidence intervals were constructed at a 95% confidence interval ($\alpha = 0.05$).

### 3.11.2.2 Wilcoxon Signed Rank Test

Wilcoxon Signed Rank Tests were conducted in order to determine whether there was any significant change within each respective treatment group (intra-group analysis), at the time of the first consultation, sixth consultation and one month follow-up visit. Confidence intervals were constructed at a 95% confidence interval ($\alpha = 0.05$).
3.11.2.3 Hypothesis Testing

The null hypothesis (H₀) for subproblem one and two stated that within each group there was no significant improvement of the patients in terms of objective and subjective clinical findings. The alternative hypothesis (H₁) for subproblem one and two stated that within each group there was a significant improvement of the patients in terms of subjective and objective clinical findings.

The null hypothesis (H₀) for subproblem three was that there was no statistically significant difference (alpha = 0.05) between group one and two in terms of subjective and objective clinical findings. The alternative hypothesis (H₁) for subproblem three was that NSAID's combined with manipulation would statistically be superior to manipulation combined with placebo for the treatment of cervical facet syndrome.

3.11.2.4 Summary Statistics

If the Mann Whitney U or Wilcoxon Signed Rank tests determined by way of calculation that there was a significant difference between the two groups in terms of objective and subjective clinical findings, the mean was used to identify the superior treatment group.

The standard deviation was then used to measure the reliability of the mean by measuring the spread of data around the mean. Both tests used the median within the calculations. The mean was therefore used to indicate possible trends within the two groups thereby increasing the reliability of the statistical analysis.
CHAPTER FOUR
4. THE RESULTS

4.1 INTRODUCTION

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

Experimental group - NSAIDs and manipulation (Group A).

Control group - Placebo and manipulation (Group B).

4.2 DISCUSSION OF RECRUITMENT

Forty-nine people were screened, of which thirty-five were accepted into the study. The fourteen who were not accepted did not meet the selection criteria (Table 4.1). Of the thirty-five patients accepted into the study, five dropped out during the course of the treatment period (Table 4.2).

Of the thirty patients receiving treatment, eleven reported a traumatic onset to their problem (motor vehicle accidents, falls, blows etc.), while twenty-one reported the onset as insidious.
Table 4.1  Reasons for research candidates not meeting selection criteria:

<table>
<thead>
<tr>
<th>Reason</th>
<th>No. (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache with no neck pain</td>
<td>3 (21%)</td>
</tr>
<tr>
<td>Allergy to NSAIDs</td>
<td>1 (7%)</td>
</tr>
<tr>
<td>Asthmatic</td>
<td>1 (7%)</td>
</tr>
<tr>
<td>History of gastric ulcer</td>
<td>2 (15%)</td>
</tr>
<tr>
<td>Nerve root entrapment signs and symptoms</td>
<td>2 (15%)</td>
</tr>
<tr>
<td>Impaired hepatic function</td>
<td>1 (7%)</td>
</tr>
<tr>
<td>Myofascitis only</td>
<td>1 (7%)</td>
</tr>
<tr>
<td>Upper thoracic pain only</td>
<td>3 (21%)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>14 (100%) out of 49 = 29%</strong></td>
</tr>
</tbody>
</table>

Table 4.2  Reasons for research candidates not completing treatment period:

<table>
<thead>
<tr>
<th>Reasons</th>
<th>No. (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of transport</td>
<td>1 (20%)</td>
</tr>
<tr>
<td>Motor vehicle accident</td>
<td>1 (20%)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>1 (20%)</td>
</tr>
<tr>
<td>Progression of neck pain</td>
<td>1 (20%)</td>
</tr>
<tr>
<td>Moved to another city</td>
<td>1 (20%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5 (100%) out of 35 = 14%</strong></td>
</tr>
</tbody>
</table>
4.3 DEMOGRAPHIC DATA

Table 4.3 Gender Distribution:

<table>
<thead>
<tr>
<th>GENDER</th>
<th>GROUP A</th>
<th>GROUP B</th>
</tr>
</thead>
<tbody>
<tr>
<td>MALES</td>
<td>5 (33%)</td>
<td>5 (20%)</td>
</tr>
<tr>
<td>FEMALES</td>
<td>10 (67%)</td>
<td>12 (80%)</td>
</tr>
</tbody>
</table>

The overall male: female ratio was 4:11. The two groups were similar with respect to gender distribution.

Table 4.4 Prevalence of Age:

<table>
<thead>
<tr>
<th>AGE INTERVALS</th>
<th>GROUP A</th>
<th>GROUP B</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-25</td>
<td>4 (27%)</td>
<td>4 (27%)</td>
</tr>
<tr>
<td>26-35</td>
<td>2 (13%)</td>
<td>3 (20%)</td>
</tr>
<tr>
<td>36-45</td>
<td>5 (33%)</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>46-55</td>
<td>4 (27%)</td>
<td>6 (40%)</td>
</tr>
</tbody>
</table>

The average age (mean) for group A was 37.7.
The average age (mean) for group B was 37.5.
The mean age for group A and B was 37.6.
Table 4.5  Occupation of patients:

<table>
<thead>
<tr>
<th>GROUP A</th>
<th>n</th>
<th>%</th>
<th>GROUP B</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin representative</td>
<td>1</td>
<td>7</td>
<td>Bookkeeper</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Student</td>
<td>2</td>
<td>13</td>
<td>Student</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Computer programmer</td>
<td>1</td>
<td>7</td>
<td>Librarian</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Secretary</td>
<td>4</td>
<td>27</td>
<td>Secretary</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Home executive</td>
<td>1</td>
<td>7</td>
<td>Home executive</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Switchboard operator</td>
<td>1</td>
<td>7</td>
<td>Administration officer</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Teacher</td>
<td>1</td>
<td>7</td>
<td>Psychologist</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Medical technologist</td>
<td>1</td>
<td>7</td>
<td>Clerk</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Managing director</td>
<td>1</td>
<td>7</td>
<td>Personnel officer</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Communications/superintendent</td>
<td>1</td>
<td>7</td>
<td>Communications representative</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Massage therapist</td>
<td>1</td>
<td>7</td>
<td>Nurse</td>
<td>1</td>
<td>7</td>
</tr>
</tbody>
</table>

40% of patients occupations involved work on a computer.

The mean duration of neck pain between the two groups was similar. The mean duration of neck pain in Group A was 22 months, and 28 months in Group B. All patients however, reported their neck problem to have worsened prior to the treatment period.
Table 4.6  

Average height and weight of the patients:

<table>
<thead>
<tr>
<th>HEIGHT AND WEIGHT</th>
<th>GROUP A</th>
<th>GROUP B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height (m)</td>
<td>172.26</td>
<td>172.46</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>64.73</td>
<td>67.46</td>
</tr>
</tbody>
</table>

The overall mean height and weight was 172.36m and 66.09Kg.

4.4 MANIPULATION DATA

Figure 4.1  

Comparison of the types and number of lateral adjustments given according to motion palpation findings:

![Comparison of lateral adjustments](image.png)
Figure 4.2  Comparison of the types and number of rotatory adjustments given according to motion palpation findings:

The atlanto-occipital joint was excluded, as it is unclear if this is a true zygapophyseal joint (facet joint). The literature describes a zygapophyseal joint as the junction between the inferior and superior articular facets of the articular process on one side of two adjacent vertebrae (Cramer and Darby 1995: 19, Yochum and Rowe 1996: 7).

Table 4.7  Total and average number of adjustments per patient:

<table>
<thead>
<tr>
<th></th>
<th>297</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of adjustments for 30 patients</td>
<td></td>
</tr>
<tr>
<td>Average number of adjustments over 6 treatments</td>
<td>9.9</td>
</tr>
</tbody>
</table>

Only one patient reported having an adverse effect to manipulation. This patient, who was in Group B, discontinued treatment after the second consultation. (Table 4.2).
4.5 NSAID DATA

Each patient, at the completion of their treatment period, was asked whether they thought they were on the real medication or the placebo medication irrespective of which group they were in. This was done to assess the quality of the blinding nature of the trial. The results are shown in Table 4.8.

Table 4.8 Perception of the patients as to which medication group they were assigned:

<table>
<thead>
<tr>
<th>NSAIDs</th>
<th>GROUP A</th>
<th>GROUP B</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>6 (40%)</td>
<td>7 (47%)</td>
</tr>
<tr>
<td>NO</td>
<td>9 (60%)</td>
<td>8 (53%)</td>
</tr>
</tbody>
</table>

Group A = Manipulations and NSAIDs

Group B = Manipulation and placebo

Interestingly, 4 patients in Group B reported gastro-intestinal disturbances which they related to the placebo medication they were taking. This, however did not cause them to discontinue the treatment. Only one patient in Group A discontinued the treatment as a result of dyspepsia (Table 4.2), with no others in Group A reporting any disturbances.
4.6 THE ANALYSED DATA

P - Value  \( \alpha = 0.05 \)

Reject Ho if \( P \leq \alpha / 2 \)

Accept Ho if \( P > \alpha / 2 \)

\( P \) was the observed level of significance

As \( \alpha / 2 = 0.025 \), the \( P \) - Value must be equal or less than 0.025 in order to reject Ho (there is a significant difference).

Power Test  The power of a statistical test is a measure of how sensitive a test is. The power of a test depends on the size of the sample, the accuracy of measurements involved in the study and the level of significance of the study, \( \alpha \). The smaller the power of a test, the larger becomes the likelihood of a Type II error (incorrectly accepting the null hypothesis).

The power of non-parametric tests is usually low, thereby indicating that results obtained from non-parametric tests are not necessarily reliable as a decision-making tool.

The power should be as close to one as possible, therefore with the probability of a Type II error being \( \beta \), the power of statistical test is \( (1-\beta) \).
4.6.1 NON-PARAMETRIC PAIRED HYPOTHESIS TESTS

Table 4.9 Statistical results of the subjective and objective data comparing consultation 1 and 6 in Group A:

GROUP A

<table>
<thead>
<tr>
<th>CONSULTATION 1</th>
<th>CONSULTATION 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>GONIOMETER</td>
<td></td>
</tr>
<tr>
<td>MEAN</td>
<td>MEAN</td>
</tr>
<tr>
<td>MEDIAN</td>
<td>MEDIAN</td>
</tr>
<tr>
<td>S.D</td>
<td>S.D</td>
</tr>
<tr>
<td>S.E</td>
<td>S.E</td>
</tr>
<tr>
<td>P-VALUE</td>
<td>P-VALUE</td>
</tr>
<tr>
<td>VERT</td>
<td>VERT</td>
</tr>
<tr>
<td>51.66</td>
<td>60.66</td>
</tr>
<tr>
<td>50</td>
<td>63</td>
</tr>
<tr>
<td>12</td>
<td>12.56</td>
</tr>
<tr>
<td>12.01</td>
<td>6.24</td>
</tr>
<tr>
<td>0.007</td>
<td>0.003</td>
</tr>
<tr>
<td>VERT</td>
<td>VERT</td>
</tr>
<tr>
<td>60.13</td>
<td>61.13</td>
</tr>
<tr>
<td>63</td>
<td>62</td>
</tr>
<tr>
<td>12.56</td>
<td>12.18</td>
</tr>
<tr>
<td>3.24</td>
<td>3.18</td>
</tr>
<tr>
<td>0.003</td>
<td>0.0014</td>
</tr>
<tr>
<td>VERT</td>
<td>VERT</td>
</tr>
<tr>
<td>63.66</td>
<td>64.13</td>
</tr>
<tr>
<td>60</td>
<td>62</td>
</tr>
<tr>
<td>9.42</td>
<td>12.18</td>
</tr>
<tr>
<td>2.45</td>
<td>3.18</td>
</tr>
<tr>
<td>0.0008</td>
<td>0.0014</td>
</tr>
<tr>
<td>VERT</td>
<td>VERT</td>
</tr>
<tr>
<td>45.06</td>
<td>40.73</td>
</tr>
<tr>
<td>41</td>
<td>39</td>
</tr>
<tr>
<td>12.54</td>
<td>12.85</td>
</tr>
<tr>
<td>3.29</td>
<td>3.32</td>
</tr>
<tr>
<td>0.045</td>
<td>0.016</td>
</tr>
<tr>
<td>VERT</td>
<td>VERT</td>
</tr>
<tr>
<td>46.16</td>
<td>44.4</td>
</tr>
<tr>
<td>45</td>
<td>40</td>
</tr>
<tr>
<td>9.33</td>
<td>10.08</td>
</tr>
<tr>
<td>2.46</td>
<td>2.60</td>
</tr>
<tr>
<td>VERT</td>
<td>VERT</td>
</tr>
<tr>
<td>2.06</td>
<td>2.64</td>
</tr>
<tr>
<td>1.9</td>
<td>2.4</td>
</tr>
<tr>
<td>0.97</td>
<td>9.21</td>
</tr>
<tr>
<td>0.25</td>
<td>2.37</td>
</tr>
<tr>
<td>0.0014</td>
<td>0.0003</td>
</tr>
<tr>
<td>VERT</td>
<td>VERT</td>
</tr>
<tr>
<td>2.9</td>
<td>2.3</td>
</tr>
<tr>
<td>2.27</td>
<td>0.58</td>
</tr>
</tbody>
</table>

When comparing the subjective and objective data between consultation 1 and 6 it can be seen that with the exception of left lateral flexion, there was a significant improvement within the experimental group for all other readings. The null hypothesis is therefore accepted for left lateral flexion and rejected for all other readings.
Table 4.10  Statistical results of the subjective and objective data comparing consultation 1 and 6 in Group B:

**GROUP B**

<table>
<thead>
<tr>
<th>GONIOMETER</th>
<th>CONSULTATION 1</th>
<th>CONSULTATION 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>MEDIAN</td>
</tr>
<tr>
<td>FLEX</td>
<td>53.33</td>
<td>52</td>
</tr>
<tr>
<td>EXT</td>
<td>64.53</td>
<td>64</td>
</tr>
<tr>
<td>L-ROT</td>
<td>60.13</td>
<td>61</td>
</tr>
<tr>
<td>R-ROT</td>
<td>64.53</td>
<td>68</td>
</tr>
<tr>
<td>L-LAT. FLEX</td>
<td>41.8</td>
<td>43</td>
</tr>
<tr>
<td>R-LAT. FLEX</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td>ALGOMETER</td>
<td>2.19</td>
<td>1.9</td>
</tr>
<tr>
<td>CMCC</td>
<td>26.46</td>
<td>22</td>
</tr>
<tr>
<td>MCGILL</td>
<td>28.38</td>
<td>25.01</td>
</tr>
<tr>
<td>NPRS 101</td>
<td>52.33</td>
<td>50</td>
</tr>
</tbody>
</table>

When comparing the results of the subjective and objective data from consultation 1 and 6 within the Group B, it can be seen that there was a significant improvement in all readings with the exception of right rotation and left lateral flexion. The null hypothesis is therefore accepted for right rotation and left lateral flexion and rejected for all other readings.
Table 4.11  Statistical results of the subjective and objective data comparing consultation 6 and the 1 month follow-up consultation in Group A:

GROUP A
CONSULTATION 6  1 MONTH FOLLOW-UP

<table>
<thead>
<tr>
<th>GONIOMETER</th>
<th>MEAN</th>
<th>MEDIAN</th>
<th>S.D</th>
<th>S.E</th>
<th>P-VALUE</th>
<th>MEAN</th>
<th>MEDIAN</th>
<th>S.D</th>
<th>S.E</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLEX</td>
<td>60.2</td>
<td>60</td>
<td>11.82</td>
<td>600</td>
<td>0.7518</td>
<td>60.66</td>
<td>61</td>
<td>92.8</td>
<td>3.14</td>
</tr>
<tr>
<td>LAT</td>
<td>63.2</td>
<td>63</td>
<td>9.52</td>
<td>6.66</td>
<td>0.2888</td>
<td>63.86</td>
<td>66</td>
<td>88.7</td>
<td>2.25</td>
</tr>
<tr>
<td>LAT ROT</td>
<td>70.86</td>
<td>75</td>
<td>7.96</td>
<td>208</td>
<td>1.0000</td>
<td>71.52</td>
<td>71</td>
<td>88.55</td>
<td>2.20</td>
</tr>
<tr>
<td>LG ROT</td>
<td>73</td>
<td>77</td>
<td>9.40</td>
<td>10.3</td>
<td>0.1138</td>
<td>78.58</td>
<td>72</td>
<td>90.69</td>
<td>2.24</td>
</tr>
<tr>
<td>REAL FLEX</td>
<td>46.13</td>
<td>43</td>
<td>9.53</td>
<td>2.46</td>
<td>0.1138</td>
<td>46.06</td>
<td>45</td>
<td>9.83</td>
<td>2.53</td>
</tr>
<tr>
<td>REAL ROT</td>
<td>44.4</td>
<td>40</td>
<td>10.08</td>
<td>2.60</td>
<td>0.5049</td>
<td>43.75</td>
<td>40</td>
<td>9.92</td>
<td>2.56</td>
</tr>
<tr>
<td>ALGOMETER</td>
<td>2.91</td>
<td>2.5</td>
<td>2.27</td>
<td>0.58</td>
<td>0.7226</td>
<td>2.76</td>
<td>2.1</td>
<td>2.00</td>
<td>0.51</td>
</tr>
<tr>
<td>CMCC</td>
<td>8.24</td>
<td>8</td>
<td>5.25</td>
<td>1.45</td>
<td>0.5790</td>
<td>10.17</td>
<td>6</td>
<td>12.41</td>
<td>3.21</td>
</tr>
<tr>
<td>MCGRILL</td>
<td>7.15</td>
<td>5.71</td>
<td>6.06</td>
<td>1.56</td>
<td>1.0000</td>
<td>7.64</td>
<td>3.21</td>
<td>7.36</td>
<td>1.93</td>
</tr>
<tr>
<td>NPRS 101</td>
<td>21.6</td>
<td>15</td>
<td>22.57</td>
<td>3.82</td>
<td>0.5791</td>
<td>18.3</td>
<td>10</td>
<td>20.63</td>
<td>5.33</td>
</tr>
</tbody>
</table>

From the above results it can be seen that there was no significant improvement between consultation 6 and the one month follow-up within group A. The null hypothesis is therefore accepted for all subjective and objective readings, indicating that the improvement was maintained.
Table 4.12  Statistical results of the subjective and objective findings comparing consultation 6 and the 1 month follow-up in Group B:

<table>
<thead>
<tr>
<th>Measure</th>
<th>Consultation 6 MEAN</th>
<th>Median</th>
<th>S.D.</th>
<th>S.E.</th>
<th>P-VALUE</th>
<th>1 Month Follow-up MEAN</th>
<th>Median</th>
<th>S.D.</th>
<th>S.E.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLEX</td>
<td>64</td>
<td>65</td>
<td>11.32</td>
<td>2.92</td>
<td>0.3864</td>
<td>60.16</td>
<td>61</td>
<td>11.68</td>
<td>2.86</td>
</tr>
<tr>
<td>EXT</td>
<td>71.73</td>
<td>71</td>
<td>13.71</td>
<td>2.63</td>
<td>0.5049</td>
<td>72.13</td>
<td>75</td>
<td>12.06</td>
<td>3.11</td>
</tr>
<tr>
<td>L ROT</td>
<td>73.26</td>
<td>72</td>
<td>9.42</td>
<td>2.43</td>
<td>0.5464</td>
<td>71.22</td>
<td>72</td>
<td>6.47</td>
<td>1.67</td>
</tr>
<tr>
<td>R ROT</td>
<td>70.93</td>
<td>71</td>
<td>7.83</td>
<td>2.02</td>
<td>1.0000</td>
<td>71.4</td>
<td>71</td>
<td>7.60</td>
<td>1.47</td>
</tr>
<tr>
<td>L-EAR FLEX</td>
<td>48</td>
<td>49</td>
<td>9.97</td>
<td>2.57</td>
<td>1.0000</td>
<td>47.87</td>
<td>50</td>
<td>0.79</td>
<td>2.63</td>
</tr>
<tr>
<td>R-EAR FLEX</td>
<td>45.4</td>
<td>47</td>
<td>11.10</td>
<td>2.85</td>
<td>0.5791</td>
<td>44.8</td>
<td>48</td>
<td>9.46</td>
<td>2.44</td>
</tr>
<tr>
<td>ALGOMETER</td>
<td>2.58</td>
<td>2.5</td>
<td>0.72</td>
<td>0.19</td>
<td>0.0233</td>
<td>2.36</td>
<td>1.9</td>
<td>0.71</td>
<td>0.18</td>
</tr>
<tr>
<td>CMCC</td>
<td>15.6</td>
<td>14</td>
<td>13.86</td>
<td>3.57</td>
<td>0.7728</td>
<td>15.34</td>
<td>16</td>
<td>14.43</td>
<td>2.95</td>
</tr>
<tr>
<td>MCGILL</td>
<td>12.08</td>
<td>13.18</td>
<td>8.79</td>
<td>2.27</td>
<td>0.7892</td>
<td>12.61</td>
<td>5.9</td>
<td>17.23</td>
<td>4.45</td>
</tr>
<tr>
<td>NPRS 101</td>
<td>26.5</td>
<td>20</td>
<td>19.86</td>
<td>3.12</td>
<td>1.0000</td>
<td>29.83</td>
<td>15</td>
<td>25.55</td>
<td>6.60</td>
</tr>
</tbody>
</table>

The above table shows that the improvement between consultation 6 and the one month follow-up with respect to the subjective and objective readings was maintained, with the exception of the algometer readings, within group B. With exception of the algometer readings, the null hypothesis is accepted for all other readings.
Table 4.13 Statistical results of the subjective and objective data comparing consultation 1 and the 1 month follow-up in Group A:

<table>
<thead>
<tr>
<th>GONIOMETER</th>
<th>MEAN</th>
<th>MEDIAN</th>
<th>S.D</th>
<th>S.E</th>
<th>P-VALUE</th>
<th>MEAN</th>
<th>MEDIAN</th>
<th>S.D</th>
<th>S.E</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLEX</td>
<td>51.66</td>
<td>50</td>
<td>12</td>
<td>1.01</td>
<td>0.0025</td>
<td>50.66</td>
<td>61</td>
<td>12.18</td>
<td>3.14</td>
</tr>
<tr>
<td>EXI</td>
<td>60.12</td>
<td>50</td>
<td>12.56</td>
<td>1.78</td>
<td>0.0161</td>
<td>58.88</td>
<td>66</td>
<td>3.73</td>
<td>2.25</td>
</tr>
<tr>
<td>P. ROT</td>
<td>63.66</td>
<td>50</td>
<td>9.42</td>
<td>2.41</td>
<td>0.0008</td>
<td>61.59</td>
<td>71</td>
<td>8.55</td>
<td>2.20</td>
</tr>
<tr>
<td>R. ROT</td>
<td>64.13</td>
<td>62</td>
<td>12.18</td>
<td>2.14</td>
<td>0.0158</td>
<td>65.37</td>
<td>72</td>
<td>9.69</td>
<td>2.34</td>
</tr>
<tr>
<td>L. LAT. FLEX</td>
<td>45.06</td>
<td>44</td>
<td>12.54</td>
<td>3.25</td>
<td>1.0000</td>
<td>46.66</td>
<td>46</td>
<td>9.83</td>
<td>2.33</td>
</tr>
<tr>
<td>R. LAT. FLEX</td>
<td>40.73</td>
<td>30</td>
<td>12.85</td>
<td>3.72</td>
<td>0.0961</td>
<td>43.83</td>
<td>40</td>
<td>9.92</td>
<td>2.56</td>
</tr>
<tr>
<td>ALGOMETER</td>
<td>2.06</td>
<td>1.9</td>
<td>0.97</td>
<td>0.25</td>
<td>0.0014</td>
<td>2.78</td>
<td>2.1</td>
<td>2.00</td>
<td>0.51</td>
</tr>
<tr>
<td>CMCC</td>
<td>26.43</td>
<td>24</td>
<td>9.21</td>
<td>2.37</td>
<td>0.0003</td>
<td>10.17</td>
<td>6</td>
<td>12.41</td>
<td>3.21</td>
</tr>
<tr>
<td>MCGILL</td>
<td>32.21</td>
<td>33.83</td>
<td>15.53</td>
<td>4.90</td>
<td>0.0019</td>
<td>35.54</td>
<td>3.21</td>
<td>2.46</td>
<td>1.93</td>
</tr>
<tr>
<td>NPRS-101</td>
<td>52.36</td>
<td>50</td>
<td>18.45</td>
<td>4.76</td>
<td>0.0003</td>
<td>18.58</td>
<td>10</td>
<td>20.67</td>
<td>5.33</td>
</tr>
</tbody>
</table>

According to the above table there was a significant improvement of the subjective and objective readings within group A with the exception of left and right lateral flexion. The null hypothesis is therefore accepted for left and right lateral flexion and rejected for all other readings.
Table 4.14 Statistical results of the subjective and objective data comparing consultation 1 and the 1 month follow-up in Group B:

GROUP B

<table>
<thead>
<tr>
<th>GONIOMETER</th>
<th>CONSULTATION 1</th>
<th>1 MONTH FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLEX</td>
<td>53.33</td>
<td>60.50</td>
</tr>
<tr>
<td>LAX</td>
<td>64.53</td>
<td>72.03</td>
</tr>
<tr>
<td>LROI</td>
<td>60.13</td>
<td>71.92</td>
</tr>
<tr>
<td>RROI</td>
<td>64.53</td>
<td>71.92</td>
</tr>
<tr>
<td>FLAT FLEX</td>
<td>41.8</td>
<td>47.88</td>
</tr>
<tr>
<td>FLEX FLEX</td>
<td>39</td>
<td>41.38</td>
</tr>
<tr>
<td>ALGOMETER</td>
<td>2.19</td>
<td>2.36</td>
</tr>
<tr>
<td>CMCC</td>
<td>26.46</td>
<td>29.84</td>
</tr>
<tr>
<td>MCGILL</td>
<td>28.38</td>
<td>32.61</td>
</tr>
<tr>
<td>NPRS-101</td>
<td>52.33</td>
<td>29.58</td>
</tr>
</tbody>
</table>

From the above table it can be seen that with the exception of the CMCC Neck Disability Index and algometer readings, there was a significant difference in all other readings when comparing the subjective and objective readings between consultation 1 and the one month follow-up within group B. The null hypothesis is therefore accepted for the CMCC and algometer readings and rejected for all others.
4.6.2 NON-PARAMETRIC UNPAIRED HYPOTHESIS TESTS

Table 4.15 Statistical results comparing Group A and Group B in terms of objective and subjective data from the initial consultation:

<table>
<thead>
<tr>
<th>GONIOMETER</th>
<th>CONSULTATION 1</th>
<th>CONSULTATION 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>MEDIAN</td>
</tr>
<tr>
<td>FLEX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EXT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L-ROT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R-ROT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L-LAT FLEX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R-LAT FLEX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALGOMETER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMCC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MCGILL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPRS 101</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When comparing the objective and subjective readings taken from the initial consultations for Groups A and B, it can be seen that there was no statistically significant difference between the two. The null hypothesis is therefore accepted for all readings. Therefore, they were similarly matched groups initially.
Table 4.16  Statistical results comparing Group A and Group B in terms of the objective and subjective data from the sixth consultations:

<table>
<thead>
<tr>
<th>GROUP A CONSULTATION 6</th>
<th>GROUP B CONSULTATION 6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GONIOMETER</strong></td>
<td><strong>MEAN</strong></td>
</tr>
<tr>
<td>FLEX</td>
<td>60.2</td>
</tr>
<tr>
<td>EXT</td>
<td>70.26</td>
</tr>
<tr>
<td>P-ROT</td>
<td>70.86</td>
</tr>
<tr>
<td>R-ROT</td>
<td>73</td>
</tr>
<tr>
<td>L-LAT FLEX</td>
<td>46.13</td>
</tr>
<tr>
<td>R-LAT FLEX</td>
<td>44.4</td>
</tr>
<tr>
<td>ALGOMETER</td>
<td>2.91</td>
</tr>
<tr>
<td>CMCC</td>
<td>8.24</td>
</tr>
<tr>
<td>MCGILL</td>
<td>7.15</td>
</tr>
<tr>
<td>NPRS-101</td>
<td>21.6</td>
</tr>
</tbody>
</table>

When comparing the objective and subjective readings taken from the sixth consultations for Groups A and B, it can be seen that there was no statistically significant difference between the two. The null hypothesis is therefore accepted for all readings.
Table 4.17  Statistical results comparing Group A and Group B in terms of subjective and objective data from the 1 month follow-up consultations:

<table>
<thead>
<tr>
<th></th>
<th>GROUP A</th>
<th></th>
<th>GROUP B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 MONTH FOLLOW-UP</td>
<td></td>
<td>1 MONTH FOLLOW-UP</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MEAN</td>
<td>MEDIAN</td>
<td>S.D</td>
<td>MEAN</td>
</tr>
<tr>
<td>RUTEX</td>
<td>60.66</td>
<td>60</td>
<td>12.18</td>
<td>60.86</td>
</tr>
<tr>
<td>EXP</td>
<td>67.86</td>
<td>66</td>
<td>8.74</td>
<td>67.36</td>
</tr>
<tr>
<td>L-ROT</td>
<td>71.53</td>
<td>71</td>
<td>8.55</td>
<td>71.2</td>
</tr>
<tr>
<td>R-ROT</td>
<td>71.73</td>
<td>72</td>
<td>9.09</td>
<td>71.4</td>
</tr>
<tr>
<td>L-LEAT-FLEX</td>
<td>46.06</td>
<td>45</td>
<td>9.83</td>
<td>47.21</td>
</tr>
<tr>
<td>R-LEAT-FLEX</td>
<td>43.13</td>
<td>40</td>
<td>9.92</td>
<td>43.68</td>
</tr>
<tr>
<td>AEGOMETER</td>
<td>2.78</td>
<td>2.18</td>
<td>2.00</td>
<td>2.86</td>
</tr>
<tr>
<td>CMCC</td>
<td>10.17</td>
<td>8</td>
<td>12.41</td>
<td>10.84</td>
</tr>
<tr>
<td>MCGILL</td>
<td>7.54</td>
<td>4.21</td>
<td>7.46</td>
<td>7.61</td>
</tr>
<tr>
<td>NPRS 101</td>
<td>18.3</td>
<td>10</td>
<td>20.63</td>
<td>18.33</td>
</tr>
</tbody>
</table>

When comparing the objective and subjective readings taken from the one month follow-up consultations for Groups A and B, it can be seen that there was no statistically significant difference between the two. The null hypothesis is therefore accepted for all readings.
Table 4.18  Power tests related to the Mann-Whitney Unpaired tests:

<table>
<thead>
<tr>
<th>CONTOIMETER</th>
<th>CONSULTATION 1</th>
<th>CONSULTATION 6</th>
<th>1 MONTH FOLLOW UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLEX</td>
<td>0.0624</td>
<td>0.0535</td>
<td>0.0506</td>
</tr>
<tr>
<td>EFX</td>
<td>0.1171</td>
<td>0.0915</td>
<td>0.1802</td>
</tr>
<tr>
<td>U ROTATE</td>
<td>0.1386</td>
<td>0.1053</td>
<td>0.0514</td>
</tr>
<tr>
<td>B ROTATE</td>
<td>0.0509</td>
<td>0.0986</td>
<td>0.0514</td>
</tr>
<tr>
<td>DLAT FLEX</td>
<td>0.1078</td>
<td>0.0578</td>
<td>0.0739</td>
</tr>
<tr>
<td>RLAT FLEX</td>
<td>0.0674</td>
<td>0.0568</td>
<td>0.0719</td>
</tr>
<tr>
<td>ALGOMETER</td>
<td>0.0644</td>
<td>0.0597</td>
<td>0.1097</td>
</tr>
<tr>
<td>CMC</td>
<td>0.0500</td>
<td>0.4505</td>
<td>0.2319</td>
</tr>
<tr>
<td>MCGILL</td>
<td>0.0851</td>
<td>0.3957</td>
<td>0.1643</td>
</tr>
<tr>
<td>NPRS 101</td>
<td>0.0500</td>
<td>0.6992</td>
<td>0.1747</td>
</tr>
</tbody>
</table>

The power tests for all readings indicates that there was a high possibility of a Type II error (incorrectly accepting the null hypothesis).

4.6.3 Median Value Changes

These values are taken from the summary statistics. The values shown are from the first, sixth and one month follow-up consultations for Group A and B. These values are not meant to be used to draw comparisons between the two groups, but are given to show possible affinities that have arisen.

Figures 4.3 to 4.12 reflect these values.
Figure 4.3:

Median Flexion Values

![Flexion Values Graph]

Figure 4.4:

Median Extension Values

![Extension Values Graph]
Figure 4.5:

Left Rotation Values

Figure 4.6:

Right Rotation Values
Figure 4.7:

Left Lateral Flexion Values

Figure 4.8:

Right Lateral Flexion Values
Figure 4.9:

**Median CMCC Values**

![Median CMCC Values Chart](image)

**Figure 4.10:**

**Median NPRS-101 Values**

![Median NPRS-101 Values Chart](image)
Figure 4.11:

Median McGill Values

1ST  6TH  30 Day

consultations

% pain
0  5  10  15  20  25  30  35

Manipulation and NSAIDs
Manipulation and placebo

Figure 4.12:

Median Algometer Values

1ST  6TH  30 Day

consultations

kg per square cm
0  0.5  1  1.5  2  2.5

Manipulation and NSAIDs
Manipulation and placebo
CHAPTER FIVE
5. DISCUSSION

5.1 INTRODUCTION

This chapter is concerned with the discussion of the objective and subjective data obtained from the first treatment, sixth treatment and one month follow-up consultation.

Objective data: goniometer and algometer.

Subjective data: Numerical Pain Rating Scale-101, Short Form McGill Pain Questionnaire and the CMCC Neck Disability Index.

The results are discussed in two sections:

Intra-group results: The evaluation of the data obtained from the first and sixth consultations represents the efficacy of the treatment regime. A comparison of the data obtained from the sixth to one month follow-up consultation gives an indication if the treatment efficacy was maintained. Finally, a comparison of the first and one month follow-up consultations indicates to what extent the clinical condition of the patient has returned to baseline values.

Inter-group results: The data from the first consultation from both groups is assessed to determine if there was any difference between the two groups in terms of signs and symptoms of the presenting condition. A comparison of the sixth consultations for both groups indicates which treatment regime was more effective. Finally, a comparison of the
one month follow-up consultation from both groups indicates which treatment regime maintained a more favorable response to the treatment.

5.2 INTRA-GROUP COMPARISON

5.2.3 Objective Data

5.2.3.1 Cervical Range of Motion

The range of motion data for intra-treatment comparisons can be found in tables 4.9 to 4.14 and figures 4.3 to 4.8.

Comparison of the first to sixth consultations showed that Group A demonstrated a significant improvement in flexion, extension, left and right rotation, and right lateral flexion. Left lateral flexion showed no significant improvement. In the same treatment period Group B demonstrated a significant improvement in flexion, extension, left rotation and left lateral flexion. There was no significant change in right rotation and left lateral flexion.

A comparison of the sixth and one month follow-up consultation for both groups revealed that there was no significant change in any of the respective ranges of motion, indicating the improvement was maintained.
When viewing the period between the first and one month follow up consultation for Group A, there was a significant improvement in flexion, extension and left and right rotation. Left and right lateral flexion did not show any significant change. For the same period, Group B demonstrated significant improvement in all ranges of motion.

The intra-treatment results suggest that with regard to range of motion, NSAIDs and manipulation produce better short-term results, and that manipulation alone may be of more benefit in the long term. However, this statement was not supported by the inter-group comparison, as will be discussed later on.

5.2.3.2 Algometer Readings

At the sixth consultation, both groups showed a significant change with regard to the algometer readings. There was no significant change between the sixth and one month follow-up consultations for Group A, whereas Group B showed a significant improvement.

When viewing the algometer data between the first and one month follow-up consultations, Group A demonstrated a significant change, Group B however did not. The results suggest that treatment with manipulation and NSAIDs will possibly result in the patient's pain pressure threshold being higher over a longer period than with manipulation alone. Again, this statement is not supported by inter-treatment comparison. (Tables 4.9 to 4.14 and Figure 4.12)
5.2.4 Subjective Data

5.2.4.1 The CMCC Neck Disability Index

Comparison of the first to sixth consultation shows that both groups showed significant improvement over this period. There was no significant change in disability between the sixth and one month follow-up consultation for either groups, showing that a favourable response to the treatment was maintained. When viewing the data between the first and one month follow-up consultation, Group A showed significant improvement, whereas Group B did not. This change is reflected in the median value changes. (Tables 4.9 to 4.14 and Figure 4.9)

5.2.4.2 The Short Form McGill Pain Questionnaire

Both groups showed significant improvement with regards to pain from the first to sixth consultations. There was no statistical change from the sixth to one month follow-up consultations indicating that a favourable response to the treatment was maintained by both groups. Assessment of the first to one month follow-up consultations depicts a significant decrease in pain perception in both groups. (Tables 4.9 to 4.14 and Figure 4.11)
5.2.4.3 The Numerical Pain Rating Scale-101

Comparison of the first to sixth consultations reveals a statistically significant difference in both groups, showing that both treatment protocols reduced the amount of pain experienced by the patients. Analysis of the data from the sixth to one month follow-up consultations showed that there was no significant change in pain after the last treatment. Comparison of the first to one month follow-up consultations showed that there was a significant reduction in the level of pain the patient experienced.

(Tables 4.9 to 4.14 and Figure 4.10)

5.3 INTER-GROUP COMPARISON

Inter-group comparison of the objective and subjective data suggests that patients from both treatment groups experienced relatively the same restricted range of motion (CROM), pressure pain threshold (algometer), disability (CMCC), pain intensisty (NRS-101) and sensory dimension of their pain (McGill) at the first consultation (Table 4.15 and Figures 4.3 to 4.12).
5.3.1 Objective Data

5.3.1.1 Cervical Range of Motion

Statistical analysis demonstrated that after six treatments and at the one month follow-up consultation there was no significant difference between the two groups for all ranges of motion (Table 4.16). This indicates that at a 95% confidence level the two treatment regimes are equally effective in improving range of motion in patients suffering from cervical facet syndrome. Power analysis for all three assessment periods reveals that the statistical power of the goniometer readings was poor, indicating a high probability that a Type II error was present.

Comparison of the median value changes showed that Group B demonstrated greater movement in extension than Group A at the one month follow-up consultation (Figure 4.4). At the sixth consultation Group A demonstrated a greater increase in right rotation than Group B. Comparison of the sixth to one month follow-up consultation showed that Group B demonstrated a greater improvement in right lateral flexion. It must be noted that median value changes do not represent statistical differences between the two groups, but merely clinical trends.
5.3.1.2 Algometer

After the six treatments and at the one month follow-up consultations there were no statistical differences between the two groups with respect to pressure pain thresholds. Power analysis for all three assessment periods were weak, indicating the possibility of a Type II error. The median value changes for the groups indicate a similar response to their respective treatments (Figure 4.12).

5.3.2 Subjective Data

5.3.2.1 CMCC Neck Disability Index

As mentioned previously, baseline values for both groups were very similar (Table 4.15). At the sixth consultation and one month follow-up consultation there was no significant statistical difference between the two groups in terms of disability. Power analysis shows that highest value for the CMCC sixth consultation of 0.4505 (Table 4.18). This however still indicates the possibility of a Type II error.

Median value changes demonstrates a 66% improvement in Group A, and a 36% improvement in Group B from the first to sixth consultation. From the sixth to the one month follow-up consultation Group A continued to improve, whereas Group B gained two percentage disability points (Figure 4.9). The mean shows similiar trends.
5.3.2.2 The Short Form McGill Pain Questionnaire

Comparison after six treatments and at the one month follow-up consultation revealed that there was no statistical difference between the two groups, indicating that both treatment protocols were effective in influencing the quality of pain in cervical facet syndrome and maintaining the improvement after one month. Power analysis for all three assessment periods was low, indicating the possibility of a Type II error.

Median value changes indicate that Group A had a lesser percentage of pain perception than Group B at the sixth and one month follow-up consultations. This was despite the fact that Group A had a slightly higher percentage pain perception (+8.83%) than Group B at the first consultation.

5.3.2.3 The Numerical Pain Rating Scale-101

Statistical comparison of the first consultation revealed no statistical significant difference in the initial level of pain for both treatment groups.

Analysis of the data taken from the sixth and one month follow-up consultation showed that there was no statistically significant difference indicating that both treatment protocols were effective in influencing the severity of pain in cervical facet syndrome and maintaining the improvement after one month. Power analysis for all three assessment periods was low, indicating the likelihood of a Type II error.
Median value changes demonstrated a greater percentage improvement in Group A at the sixth and one month follow-up consultation periods.

5.4 DISCUSSION OF THE SUBJECTIVE AND OBJECTIVE DATA

5.4.1 Intra-group Hypotheses

From the statistical data it can be seen that both groups improved significantly between treatment one and six, and between treatment one and the one-month follow-up consultation. The treatment efficacy was also maintained from the last treatment to the one month follow-up consultation. The hypothesis is therefore accepted that there would be a significant difference in both treatment groups in terms of objective and subjective findings. As stated earlier, the only data that was not significantly different between the first and sixth consultation was left lateral flexion in both groups, and right rotation in Group B which was very close to the desired p value (0.026). The only data reading between the sixth and one-month follow-up that significantly regressed was the algometer readings in Group B.

With regards to the CMCC and McGill data readings between the first and one month follow-up consultation, it can be seen that baseline readings from the first consultation for both groups was relatively the same. At the one month follow-up Group A displayed a greater improvement than Group B in terms of mean, median and p-values readings.
It is perhaps presumptuous to attribute this greater decrease in overall pain and disability to the medication taken, as it is well recognised that NSAIDs only provide symptomatic short-term relief of pain (Koes et al 1997). It is also unlikely that this was the case when one considers that the patients only took the medication for five days. This notion is confirmed by the inter-group comparison in which there was no statistical difference for the CMCC and McGill readings.

It can be concluded that both treatment protocols were effective in treating cervical facet syndrome and maintaining the treatment efficacy over a one month period.

5.4.2 Inter-group Hypotheses

It was hypothesized that there would be a significant difference between the two groups in terms of objective and subjective clinical findings, demonstrating one treatment protocol to be more effective than the other.

The hypotheses for all three data collecting consultations is rejected as no one treatment protocol showed any significant statistical advantage over the other.

Power readings related to all the Mann-Whitney Unpaired tests were low. This is consistent as to what can be expected from small sample sizes. Thus, even if significant changes were present, they would not be detected due to the small sample size.

Although, in terms of pain and disability the median value changes did seem to favour NSAIDs and manipulation, this is of no statistical consequence in this study as the level of
confidence was set at 95%. P-values for all inter-group comparison of all objective and subjective data showed that no treatment protocol was more effective than the other.

To conclude, the data suggested that NSAIDs and manipulation was more effective than manipulation alone in terms of pain and disability in treating cervical facet syndrome, but this was not statistically supported.

5.5 DISCUSSION OF THE DEMOGRAPHIC DATA

The gender distribution was similar in the two groups, with a higher ratio of females (Table 4.3). From table 4.4, it can be seen that the two groups had a relatively equal distribution in the 15 to 35 year old age interval. Patient age distribution in Group B was higher in the 46 to 55 year old interval, and Group A had a higher distribution in the 36 to 45 year old interval. Even with these inequalities, the mean age for each group was the same. Mean height and weight was very similar for the groups (Table 4.6).

The occupations of the patients are shown in Table 4.5. The fact that 40% of patients occupations involved computer work, may give an insight into the types of musculoskeletal conditions that may prevail in the future, as computers become more predominant in our society.
5.6 DISCUSSION OF THE MANIPULATION AND NSAID DATA

Figure 4.1 and 4.2 demonstrate the types and number of adjustments given according to motion palpation findings. More rotatory adjustments were given in the lower cervical spine than lateral adjustments, and more lateral adjustments were given in the upper cervical spine than rotatory adjustments. The most common level at which a fixation was found was the C5/6 level. The least common level that a lateral adjustment was delivered to was the C7/T1 level. The least common level a rotatory adjustment was delivered to was the C4/5 level. No supine C1/2 adjustments were given due to preference of the researcher to the seated technique.

When looking at Table 4.8, it can be seen that the majority of the patients taking NSAIDs did not think they were in the experimental group. This indicates that this study was well blinded.

5.7 STUDY LIMITATIONS

When comparing the baseline characteristics between the patients in each group, it can be seen that although the ratio of male to females within each group was unequal, it was comparative between the two groups. Although not exact, age distribution and mean height and weight were relatively the same in each group. The base line characteristics that were different were the occupations of the patient. This may have had an impact on the
study, as some patients may have returned from the treatment to adopt a stressful position related to their occupation, possibly causing their pain and disability to return relatively quickly. Emotional stress was not taken into account when setting out the factors that made up the exclusion criteria. In terms of time and financing, it was not possible to have patients with a high homogeneity.

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

The objective measurements have the possibility of containing some error due to human reliability in taking the readings. Of particular note, the researcher felt that the algometer readings were at times suspicious due to certain cases of patients having very tender posterior cervical muscles over the involved articular pillar. Thus, it was difficult in determining if the patient was experiencing pain due to compression of the involved facet joint or from the tender overlying musculature.

Perhaps the biggest limitation of this study was the small sample size of 15 patients, which is reflected in the power readings. It was, however, not possible to have a very large sample size due to time and financial constraints.

Although every effort was made to ensure all the patients took their medication as prescribed, this may not have been the case. Patient medication diaries were screened at
the first three consultations, but there is the possibility that this still did not ensure that complete compliance existed. Patients may have falsely filled in medication times so as not to disappoint the researcher.

One aspect of this research that may well be criticised is that the manipulative procedures were performed by a student, and not by a therapist who had many years of experience.

5.8 COMPARISON OF THE RESULTS

To date there is no study involving NSAID use in the treatment of neck pain, thus it is difficult to make exact comparisons to other research topics.

Group B’s results can be compared to those of Parkin-Smith and Penter (1998) who compared two manipulative approaches in the treatment of mechanical neck pain, by adjusting only the cervical spine in one group and both the cervical and thoracic spines in the other. The sample size, and outcome measures were identical to this research study. The number of treatments was also the same but the treatment spanned three weeks in their studies as opposed to two in this one. Age distribution for both groups was very similar to this study, but gender distribution favoured a higher ratio of males. One major difference in Parkin-Smith’s and Penter’s (1998) research is that goniometric readings were performed before and after each data collecting consultation.
It can be seen from the figure below that a comparison of the first to sixth consultation of the NPRS 101 mean readings from the cervical manipulation group to Group B's mean readings show similar trends.

The above comparison with Parkin-Smith's and Penter's (1998) study shows that manipulation alone is effective in reducing overall neck pain. Both groups demonstrated roughly a 50% reduction in pain, showing that in separate studies, manipulation is effective. Although this is significant it is not confirmed with a control group (purely placebo).

In another study by Hopkins (1997) of similar design, with the same outcome measures as this study, it also showed similar trends. The only difference in study design was that patients were treated ten times over five weeks in Hopkin's (1997) study. Her study
involved treating cervical mechanical dysfunction (spondylosis) with manipulation in the one group of patients and manipulation and an anthroposophical remedy (Disci comp.cum Stanno) in the other.

The comparison is shown in the figure below.

Although not glaringly obvious, the above figure does show that the experimental group from both respective studies tended to have marginally less pain and disability when looking at the average values for the CMCC and NPRS 101. This can be interpreted that both NSAIDs and Disci, when combined with manipulation are effective for the treatment of neck pain.

Cassidy et al (1992) conducted a study in which patients with unilateral neck pain were given a single rotational manipulation on the side of the pain. NRS-101 and goniometric
readings were taken before and after the treatment. The pre-treatment and post-treatment means for the NRS-101 in Cassidy et al (1992) study are compared to the same readings for the first and sixth consultations in the figure below.

It must be noted from the above figure that the pre- and post-treatment mean readings for this study refer to the first and sixth treatments respectively. It is suggested from the above figure that six treatments as opposed to one may be more beneficial in relieving neck pain. The trend once again is that manipulation is an effective treatment for neck pain.

The findings of this research study support those of Howe et al (1983), Koes et al (1992) and Cilliers and Penter (1998) in concluding that cervical manipulation is an effective method for treating neck pain.
CHAPTER SIX
6.0 RECOMMENDATIONS AND CONCLUSION

6.1 RECOMMENDATIONS

A larger sample size is recommended that would allow for the use of both paired and unpaired t-tests so that subtle changes in the objective and subjective data could be made apparent. A larger sample size would also minimise the chances of incorrectly accepting the null hypothesis (Type II error).

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

It is recommended that patients be matched between groups in terms of age, sex, duration of complaint, extent of pain and disability and occupation, to ensure stratification.

What would also increase the validity of this study is if the objective reading taking was blinded, with someone else other than the researcher taking the readings. As the goniometer increment is $2^\circ$, a more accurate and sensitive instrument would be able to detect more subtle changes in range of motion readings, especially if the sample size was greater.
In future studies of this type, a data collecting consultation should be included after the sixth day, as this is when the experimental group would have completed the course of NSAIDs. Thus, pain may be at its lowest at this point in the research.

It is also recommended that a third group consisting of sham manipulation with placebo medication treatment be included, so as to be able to compare the other two treatment protocols, and have an indication of the natural progression of cervical facet syndrome.

6.2 CONCLUSION

The results of this study indicate both treatment protocols were effective in treating cervical facet syndrome. At a 95% confidence level neither group showed any advantage over the other in treatment efficacy. The median and mean data taken from the subjective data did however favour cervical manipulation and NSAIDs as a treatment protocol that is more effective in relieving pain and disability. This is not conclusive as it does not fit into the statistical confidence parameter this trial employed, and will only be clarified by future research trials of this nature.

One possible reason that Group A did not demonstrate any significant statistical advantage over Group B is that the same NSAID was given to all the patients. It is well recognised that patient response to a particular NSAID is individualistic and that one NSAID that is effective for one person may not be effective for another (Edwards and Bouchier 1991: 774).
The use of NSAIDs combined with manipulation for the treatment of cervical facet syndrome may present the consulting doctor with moral and clinical dilemmas. The use of NSAIDs in chiropractic may lead to a higher cost of health care, unless it can be shown to shorten the treatment period. The health risk to the patient is also increased by combining therapies that both carry their respective complication risks. Finally, the inclusion of an allopathic approach into a chiropractic one, may lead to the jeopardy of a distinction the chiropractic profession as held from other health professions, which has perhaps ensured the survival of chiropractic over the last 103 years. We already know that the use of manipulation alone is effective in treating neck pain, so it would be the clinical judgement of the consulting doctor as to whether the use of NSAIDs at this stage would be beneficial. Although this study has highlighted the risks of NSAID use, it must be remembered that cervical manipulation does pose its dangers, which are perhaps proportional to the clinical and manipulative skills the manipulative therapist possesses.

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


*Spine.* 23 (15) : 1689-1698.


*Spine.* 21 (24) : 2840-2849.


Appendix A

Cataflam* D Dispersible Tablets

Compositions
One CATAPARL D Tablet contains 300 mg of diclofenac free base, which is equivalent to 50 mg of diclofenac sodium.

Pharmacological classification
A 3.1 Antirheumatics (anti-inflammatory agents)

Pharmacological action
CATAPARL D is a non-steroidal compound with antirheumatic, antipyretic and antinflammatory properties. In vivo, its active substance strongly inhibits prostaglandin-synthesis and also has a inhibitory effect on platelet aggregation. Inhibition of prostaglandin biosynthesis, which has been documented experimentally, is regarded as having an important bearing on its mechanism of action. Prostaglandins play a major role in the causation of inflammation, pain and fever.

Absorption
Absorption of diclofenac from CATAPARL D sites in rapidly after administration. The plasma concentrations show a linear relationship to the size of dose. Peak levels are at 2 hours after ingestion of an empty stomach. The active compound is subject to first-pass metabolism. Protein binding: 97.6 %.

The main terminal elimination half-life of the unchange drug is 1 to 2 hours.

Occurrence
Approximately 60 % of the dose administered is excreted via the kidneys in the form of metabolites and less than 1 % in the unchanged form. About 36 % of the dose is excreted in metabolised form in the faeces.

Indications
As short-term treatment in the following acute conditions:
- Pain of osteoarthritis
- Painful musculoskeletal conditions.
- Non-specific rheumatic pain.
- Acute attacks of gout.
- Painful post-operative and traumatised inflammation and swelling, pain following surgery, wound healing activity.

Symptomatic treatment for primary dysmenorrhoea.

Gastro-intestinal ulceration. Allergy to the active substance.

CATAPARL D is also contra-indicated in asthmatic patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicyclic acid and/or after medicines with prostaglandin-synthesis inhibiting activity.

CATAPARL D should not be used in patients with porphyria.

Pregnancy
CATAPARL D is not suitable for use in children under 14 years of age.

Warnings
It should be noted that any short-term treatment is recommended with CATAPARL D.

Strict accuracy of doses and close medical supervision are imperative in patients with symptoms indicative of gastro-intestinal ulcer disease, a history suggestive of gastritis-jejunae ulcerative colitis, Crohn's disease, in patients suffering from impaired hepatic function or symptoms suggestive of the presence of blood coagulation.

In the event of administration to patients with renal or renal failure, the dosage and treatment should be discontinued after the contraindicated use of Mesalazine and diclofenac.

Dosage and directions for use

- Oral:
For the relief of acute pain, the tablets preferably should be taken on an empty stomach. The patients are dropped into a glass of water and the liquid stirred to aid dispersion before swallowing. Since a concentration of the active substance may remain in the glass after swallowing, it is advisable to rinse the glass with a small amount of water and to swallow again.
- Adult: 1 to 3 CATAPARL D tablets daily. In most cases, 1 CATAPARL D tablet daily is usually sufficient.
- Maximum daily dose is 3 CATAPARL D tablets.

The daily dosage should generally be prescribed at two to three fractional doses.

In primary dysmenorrhoea the daily dosage, which should be individually adapted to the symptoms, should be increased in accordance with the appearance of the first symptoms and, depending on their intensity, continued for several days or weeks.

Side-effects and special precautions
Gastro-intestinal ulceration
- More frequently: Gastric pain, nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, reduction in appetite, local ulcers, local oedema.
- Less frequently: Gastro-intestinal bleeding may occur, haemorrhages, meconium, bloody diarrhoea, gastric or intestinal ulcer with or without bleeding or perforation.

Lower gut disorders such as specific non-haemorrhagic colitis and ulceration of ulcerative colitis or Crohn's disease, stomatitis, glossitis, glossitis-like ulcerative lesions, pseudomembranous enteritis, colitis and pseudomembranous enteritis, colitis and pseudomembranous enteritis, colitis and pseudomembranous enteritis, colitis and pseudomembranous enteritis, colitis and pseudomembranous enteritis, colitis and pseudomembranous enteritis.

Central nervous system
- More frequently: Headache, nervousness, vertigo, numbness.

Less frequently: Tiredness, disturbances of sensation (including paraesthesia), ataxia, confusion, memory, and memory, myelitis, irritability, convulsions, depression, anxiety, nightmares, tremor, psychopathic reactions, epileptic meningitis, special senses

Less frequently: Disturbances of vision (blurred vision, diplopia), impaired hearing, tinnitus, ear, allergy, disorders.

Skin
- More frequently: Rash and skin reactions, itching, urticaria, eczema, enzema, multimulti-systems: Stevens-Johnson syndrome, Lyell's syndrome (acute toxic epidermal necrolysis, erythroderma (erythematous rash), loss of hair, photosensitivity reaction, purpura including allergic purpura.

Kidney
- Less frequently: Oedema, acute renal failure, urinary abnormalities such as haematuria, proteinuria, interstitial nephritis, nephrotic syndrome, subdiaphragmatic.

Liver
- More frequently: Elevated transaminase levels (SGOT, SGPT).
- Less frequently: Hepatitis with or without jaundice. Pulmonary haemorrhage.

Blood
- Less frequently: Osteonecrosis (tenderness, thrombocytopenia, aplastic anaemia, haemolytic anaemia and splenomegaly).

Hypersensitivity
- Less frequently: Allergic reactions (e.g. bronchoconstriction, anaphylactoid reactions including hypotension), Vasculitis, purpura, anaphylaxis.

Central nervous system

Precautions
Gastro-intestinal bleeding or ulceration/ perforations can occur at any time during treatment, with or without warnings symptoms of a previous history. The elderly must receive close monitoring. Usage may have to be reduced in the elderly, in particular it is recommended that the lowest effective dosage be used in frail, elderly patients or those with a low body mass.

In the instance where gastric ulceration or gastro-intestinal bleeding occur in patients under treatment, CATAPARL D or the medicine should be withdrawn.

In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients. Owing to the importance of prostaglandins for maintaining renal blood flow, patients suffering from impairment of hepatic, cardiac or renal function are indicated.

In abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease onset, or of other manifestations occur (e.g. constipation, rash etc.), CATAPARL D should be discontinued. Nephritis may occur without prerenal symptoms, caution is called for when using CATAPARL D in patients with hepatic porphyria, since CATAPARL D may trigger an attack. Allergic reactions, including anaphylactic/ anaphylactoid reactions, can also occur without earlier reports to the medicine.

CATAPARL D may mask the signs and symptoms of infection due to its pharmacodynamic properties. Patients experiencing hypopyrexia or other central nervous disturbances should refrain from driving or operating machines or instruments.

When given together with preparations containing lithium or digoxin, CATAPARL D may raise their plasma concentrations.

Concomitant administration of glucocorticoids or other non-steroidal anti-inflammatory agents, may aggravate gastro-intestinal side-effects. Concomitant treatment with two or more non-steroidal anti-inflammatory agents may promote the occurrence of side-effects. The bioavailability of CATAPARL D is reduced by acetaminophen and that of acetylsalicyclic acid by CATAPARL D, where the two agents are administered together.

There are reports of an increased risk of haemorrhage with the combined use of diclofenac and an anticoagulant therapy. Because close monitoring of such patients is recommended.

In the event of CATAPARL D therapy, the plasma concentrations of heparin and its metabolites should be analysed at frequent irregular intervals.

In the event of CATAPARL D therapy, there are reports of a raised risk of haemorrhage with the combined use of diclofenac and an anticoagulant therapy. Because close monitoring of such patients is recommended.

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# TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

## CASE HISTORY

<table>
<thead>
<tr>
<th>Patient:</th>
<th>Date:</th>
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<tbody>
<tr>
<td>file #:</td>
<td>X-Ray#:</td>
</tr>
<tr>
<td>Age:</td>
<td>Sex:</td>
</tr>
<tr>
<td>Intern:</td>
<td>Occupation:</td>
</tr>
<tr>
<td></td>
<td>Signature:</td>
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</tbody>
</table>

### FOR CLINICIAN'S USE ONLY

Initial visit clinician: Signature:

### Case History:

#### Examination:
- Previous: Current:

#### X-Ray Studies:
- Previous: Current:

#### Clinical Path. lab:
- Previous: Current:

### Case Status:
- PTT: Conditional: Signed Off: Final Sign out:

### Recommendations:

### Intern's Case History

1. Source of History:
2. Chief Complaint: (patient's own words)
3. Present Illness:
   - Location
   - Onset
   - Duration
   - Frequency
   - Pain (Character)
   - Progression
   - Aggravating Factors
   - Relieving Factors
   - Associated S & S
   - Previous Occurrences
   - Past Treatment and Outcome

4. Other Complaints:

5. Past Medical History:
   - General Health Status
   - Childhood Illnesses
   - Adult Illnesses
   - Psychiatric Illnesses
   - Accidents/Injuries
   - Surgery
   - Hospitalizations
6. Current health status and life-style:
   - Allergies
   - Immunizations
   - Screening Tests
   - Environmental Hazards (Home, School, Work)
   - Safety Measures (seat belts, condoms)
   - Exercise and Leisure
   - Sleep Patterns
   - Diet
   - Current Medication
   - Tobacco
   - Alcohol
   - Social Drugs

7. Immediate Family Medical History:
   - Age
   - Health
   - Cause of Death
   - DM
   - Heart Disease
   - TB
   - Stroke
   - Kidney Disease
   - CA
   - Arthritis
   - Anaemia
   - Headaches
   - Thyroid Disease
   - Epilepsy
   - Mental Illness
   - Alcoholism
   - Drug Addiction
   - Other
8. Psychosocial history:
   - Home Situation and daily life
   - Important experiences
   - Religious Beliefs

9. Review of Systems:
   - General
   - Skin
   - Head
   - Eyes
   - Ears
   - Nose/Sinuses
   - Mouth/Throat
   - Neck
   - Breasts
   - Respiratory
   - Cardiac
   - Gastro-intestinal
   - Urinary
   - Genital
   - Vascular
   - Musculoskeletal
   - Neurologic
   - Haematologic
   - Endocrine
   - Psychiatric
TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient: ___________________________ File#: ___________________________ Date: __________
Clinician: _________________________ Signature: _________________________
Intern: ___________________________ Signature: _________________________

1. VITALS

Pulse rate: ________________________
Respiratory rate: __________________
Blood pressure: ______ R ______ L
Temperature: ______________________
Height: __________________________
Weight: __________________________

2. GENERAL EXAMINATION

General Impression: __________________________
Skin: ____________________________________
Jaundice: _________________________________
Pallor: ____________________________________
Clubbing: _________________________________
Cyanosis (Central/Peripheral): ______________
Oedema: _________________________________
Lymph nodes - Head and neck: ______________
- Axillary: _______________________________
- Epitrochlear: ___________________________
- Inguinal: ______________________________
Urinalysis: ______________________________

3. CARDIOVASCULAR EXAMINATION

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

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

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

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/cavatum: - Left precordial bulge: - Symmetry of movement: - Scars:

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

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

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

5. **ABDOMINAL EXAMINATION**

1) Is this patient in Liver Failure?

Inspection - Shape: - Scars: - Hernias:

Palpation - Superficial: - Deep = Organomegally:
- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

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

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

6. **G.U.T EXAMINATION**

External genitalia:
- Hernias:
- Masses:
- Discharges:

7. **NEUROLOGICAL EXAMINATION**

Gait and Posture - Abnormalities in gait:
- Walking on heels (L4-L5):
- Walking on toes (S1-S2):
- Romberg's 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:
- Kernig's 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:

Otoscpe examination:

IX & Gag reflex:

X 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:
CEVRICAL 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:**

<table>
<thead>
<tr>
<th>Dermatomes</th>
<th>Left</th>
<th>Right</th>
<th>Myotomes</th>
<th>Left</th>
<th>Right</th>
<th>Reflexes</th>
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**VASCULAR:**

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<tr>
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<td>Subclavian arts.</td>
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<td>Wallenberg's test</td>
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**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:  

Basic Exam: Thoracic Spine:  
Case History:  

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

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject*) *Delete whichever is not applicable.

TITLE OF RESEARCH PROJECT

________________________________________________________

________________________________________________________

NAME OF SUPERVISOR

________________________________________________________

NAME OF RESEARCH STUDENT

________________________________________________________

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO

2. Have you had an opportunity to ask questions regarding this study? YES/NO

3. Have you received satisfactory answers to your questions? YES/NO

4. Have you had an opportunity to discuss this study? YES/NO

5. Have you received enough information about this study? YES/NO

6. Who have you spoken to? _______________________________________

7. Do you understand the implications of your involvement in this study? YES/NO

8. Do you understand that you are free to withdraw from this study? YES/NO
   a) at any time
   b) without having to give a reason for withdrawing, and
   c) without affecting your future health care.

9. Do you agree to voluntarily participate in this study? YES/NO

PATIENT/SUBJECT* Name_________________________ Signature______________________
   (in block letters)

PARENT/GUARDIAN* Name_________________________ Signature______________________
   (in block letters)

WITNESS Name_________________________ Signature______________________
   (in block letters)

RESEARCH STUDENT Name_________________________ Signature______________________
   (in block letters)
CMCC NECK DISABILITY INDEX

PATIENT NAME: .................................................... FILE #: __________ DATE: __________

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

### Section 1 - Pain Intensity

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

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

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

### Section 3 - Lifting

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

### Section 4 - Reading

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

### Section 5 - Headaches

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

### Section 6 - Concentration

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

### Section 7 - Work

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

### Section 8 - Driving

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

### Section 9 - Sleeping

- I have no trouble sleeping.
- My sleep is slightly disturbed (less than 1 hr. sleepless).
- My sleep is moderately disturbed (2-3 hrs. sleepless).
- My sleep is very disturbed (4-5 hrs. sleepless).
- My sleep is completely disturbed (6-7 hrs. sleepless).

### Section 10 - Recreation

- I am able to engage in all my usual recreation activities with no neck pain at all.
- I am able to engage in all my usual recreation activities, with some pain in my neck.
- I am able to engage in most, but not all of my usual recreation activities because of pain in my neck.
- I am able to engage in a few of my usual recreation activities because of pain in my neck.
- I cannot do any recreation activities because of pain in my neck.
- I cannot do any recreation activities at all.
NUMERICAL PAIN RATING SCALE- 101 QUESTIONNAIRE

Patient Name: _______________ File no: _____ Date:_____

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

___________________________________________________________________________

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 would mean "pain as bad as it could be". Please write only one number.

___________________________________________________________________________
## Appendix H

### MEASUREMENT OF PAIN

**SHORT-FORM McGill Pain Questionnaire**

Ronald Melzack

<table>
<thead>
<tr>
<th>Pain Quality</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<td>0)___</td>
<td>1)___</td>
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<td>Shooting</td>
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<td>Stabbing</td>
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<td>1)___</td>
<td>2)____</td>
<td>3)____</td>
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<tr>
<td>Sharp</td>
<td>0)___</td>
<td>1)___</td>
<td>2)____</td>
<td>3)____</td>
</tr>
<tr>
<td>Cramping</td>
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<td>1)___</td>
<td>2)____</td>
<td>3)____</td>
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<tr>
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<td>1)___</td>
<td>2)____</td>
<td>3)____</td>
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<tr>
<td>Hot-burning</td>
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<td>2)____</td>
<td>3)____</td>
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<td>2)____</td>
<td>3)____</td>
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<td>2)____</td>
<td>3)____</td>
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<td>1)___</td>
<td>2)____</td>
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<tr>
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<td>2)____</td>
<td>3)____</td>
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<tr>
<td>Punishing-cruel</td>
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Appendix I

**Patient name:** 

<table>
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<th>Treatment no.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>1 month follow-up</th>
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<tbody>
<tr>
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<td>Adj. Techn.</td>
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**CROM DATA**

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<tr>
<td>R Rotation</td>
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<tr>
<td>R Lat. Flex</td>
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**WAGNER DATA**

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Appendix J

PATIENT MEDICATION DIARY

Patient Name: .........................  File No.: ...........  No.: ...

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<tr>
<th></th>
<th>DAY 1</th>
<th>DAY 2</th>
<th>DAY 3</th>
<th>DAY 4</th>
<th>DAY 5</th>
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<td>1ST DOSE</td>
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<td>2ND DOSE</td>
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<tr>
<td>3RD DOSE</td>
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</table>

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