

**Effectiveness of Proprioceptive Neuromuscular  
Facilitative Stretching combined with administration  
of Diclofenac compared to Proprioceptive  
Neuromuscular Facilitative Stretching and placebo  
medication for the treatment of Cervical Facet  
Syndrome.**

BY

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*Dissertation submitted to the Faculty of Health in partial  
compliance with the requirements for the Master's Degree in  
Technology: Chiropractic at Technikon Natal.*

*I, Heidi Upneck, do hereby declare that this dissertation represents  
my own work in both conception and execution.*

  
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## DEDICATION

This work is dedicated to my parents

Jackie and Ron,  
who always believed in me

## ACKNOWLEDGEMENTS

*I would like to express my sincere thanks and appreciation to the following people for their assistance in the completion of this dissertation:*

Dr. C Myburgh, my supervisor, for his patience, guidance and expertise.

Dr. D Moodley for his assistance with administering the medication.

Mr. K. Thomas for his assistance with statistical analysis

The staff at the Technikon Natal Day Clinic, Pat Linda and Mrs Ireland.

Novartis for sponsoring the medication.

Dr.A.G. Till, and the Chiropractic Department at Technikon Natal.

To all those patients who participated in the study without which the project would have been impossible.

To my family, friends and colleagues, whose support and encouragement made all the difference.

Finally, to my Lord, without whom nothing would be possible.

## ABSTRACT

The purpose of this study was to test the Effectiveness of Proprioceptive Neuromuscular Facilitative Stretching combined with administration of Diclofenac compared to Proprioceptive Neuromuscular Facilitative Stretching and placebo medication for the treatment of Cervical Facet Syndrome in a clinical experimental setting.

Neck pain is a common disorder, which can often be attributed to mechanical dysfunction of the cervical spine. The patient with facet syndrome may complain of sudden onset of unilateral neck pain, often with referred pain. Muscle spasm is usually present causing restricted movement. Pain increases with movement and is relieved by rest. The pain is aggravated by hyperextension and relieved by flexion and often follows a sclerotomal rather than a dermatomal pattern.

Forty subjects with mechanical neck pain were screened for facet syndrome and randomly divided into two groups of twenty. Each patient received Proprioceptive Neuromuscular Facilitative (PNF) stretching of the Posterior Cervical and Trapezius musculature. In conjunction with this, half the patients received Cataflam D while the other half received placebo medication. The patients were treated five times over a period of two weeks.

Both groups were evaluated in terms of subjective and objective clinical findings by making use of questionnaires (Numerical Pain Rating Scale 101, Short Form McGill Pain Questionnaire and the CMCC) and algometer and goniometer measurements respectively. The data was collected at the initial, middle and final treatments for each patient.

The data was analysed statistically for intra-group as well as inter-group comparison by making use of the Wilcoxon Signed Rank test and the Mann Whitney U- test, respectively.

It was noted in this study that a large proportion of the patients had jobs involving desk and/or computer work.

The results indicated an improvement in both groups after the two week study period. At the 95% confidence level, neither group showed any advantage over the other in terms of treatment effectiveness.

This study suggests that both treatment protocols are effective in the treatment of cervical facet syndrome. Further studies with rigorous methodologies are needed to clearly evaluate the use of stretching in the treatment of cervical facet syndrome.

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## **DEFINITION OF TERMS**

### **ALGOMETER**

A mechanical device capable of measuring the amount of pressure tolerated by a person on a painful spot (Fisher, 1986).

### **CONTRACT- RELAX-AGONIST-CONTRACT (CRAC)**

A form of PNF stretching where the muscle is placed on a stretch and the agonist contracted for eight seconds against resistance. This causes the antagonist to reflexively relax. The stretch is released and the antagonist contracts and the stretch position is increased. This process is repeated three times (Grana and Kalenak, 1991: 253).

### **CONTRAINDICATION**

Any condition, especially any condition of disease, that renders one particular line of treatment improper or undesirable (Gatterman, 1995: 407).

### **FACET SYNDROME**

Pain or dysfunction arising primarily from the zygapophyseal joints and their immediately adjacent soft tissues (Gatterman, 1995: 415)

### **GONIOMETER**

Instrument measuring angles (Gatterman, 1995: 410).

### **JOINT DYSFUNCTION**

Joint mechanics showing area disturbance of function (Gatterman, 1995: 409).

### **OBJECTIVE CLINICAL FINDINGS**

For the purpose of this study, this refers to the data obtained from algometer readings as a measure of pain threshold, and goniometer readings taken in degrees of cervical spine forward flexion and left and right lateral flexion.

### **SUBJECTIVE CLINICAL FINDINGS**

For the purpose of this study this refers to the data obtained from the Numerical Rating Scale 101, the Short-Form McGill Pain Questionnaire and the CMCC Neck Disability Index.

### **TRIGGER POINT**

A focus of hyperirritability in a tissue, that when compressed, is locally tender and, if sufficiently hypersensitive, gives rise to referred pain and tenderness, and sometimes to referred autonomic phenomena and distortion of proprioception (Travel and Simons, 1983).

## 1.0 INTRODUCTION

### 1.1 Introduction

Neck pain is a common disorder, which can often be attributed to mechanical dysfunction of the cervical spine (Gore et al., 1987). Cervical spine syndromes are probably the fourth most common cause of pain and at any specific time and as many as 12% of the adult female population and 9% of the adult male population experience pain in the neck, with or without associated arm pain (Bland, 1994: 3). In addition Bland (1994: xiii and 3) states that 35% of people can recall an episode of neck pain in the U.S.A at some stage in their lives.

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, as well as tendon and fascial shortening, which are components of cervical facet syndrome. Plaughner (1993: 88, on the other hand, 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. However, the findings of Bourdillion et al. (1992:283) conclude that local epidural injections of anti-inflammatory steroid and anesthetic drugs close to the nerve root alleviate the symptoms of many spinal joint dysfunctions thus implicating inflammation as a causative factor.

Allopathic physicians usually prescribe non-steroidal anti-inflammatory drugs (NSAID) as the first line of treatment for conditions such as mechanical neck

pain (Dabbs and Lauretti, 1995). The authors were unable to locate a randomized controlled trial examining the value of NSAIDs used specifically for neck pain.

It has been documented that NSAIDs are the most useful medication in both acute and chronic low back pain (Heldeman, 1992:543), but no indication was given for similar conditions in the neck.

A randomized clinical trial comparing Contract-Relax-Agonist-Contract (CRAC) stretching, a component of Proprioceptive Neuromuscular Facilitation (PNF) stretching, with static stretching in the treatment of active myofascial trigger points of the shoulder girdle muscles, showed significant subjective and objective improvement within both groups during the treatment program (Mac Dougal, 1999). McCarthy et al. (1997) conducted a study to determine the effects of PNF (CRAC) stretching procedures on active range of motion of the cervical spine in the transverse plane. The results showed that there was significantly increased active cervical spine range of motion (ROM) in the experimental group as compared to the control group.

Treating the cervical spine may be inadequate and must change toward more specific treatments with the ultimate goal being to restore the affected area to normal function (Fitz-Ritson, 1990).

This study endeavoured to determine the more effective treatment protocol: PNF alone or PNF combined with a NSAID. Should the combined treatment



demonstrate greater efficacy, it could be argued that chiropractors should consider incorporating the use of low schedule NSAID medication.

The information obtained and the inferences made from the outcome of this study will hopefully help identify a more effective protocol for treating Cervical Facet Syndrome.

## 1.2 Aim

The purpose of this placebo-controlled investigation was to compare the effectiveness of PNF stretching combined with administration of Diclofenac to PNF stretching and placebo medication, in terms of subjective and objective clinical findings, for the treatment of Cervical Facet Syndrome.

## 1.3 Objectives

### 1.3.1 Objective One

The first objective was to evaluate the efficacy of PNF stretching combined with administration of Diclofenac and also the effectiveness of PNF stretching and placebo medication in terms of objective clinical findings, in the treatment of Cervical Facet Syndrome.

### **1.3.2 Objective Two**

The second objective was to evaluate the efficacy of PNF stretching combined with administration of Diclofenac and also the effectiveness of PNF stretching and placebo medication in terms of subjective clinical findings, in the treatment of Cervical Facet Syndrome.

### **1.3.3 Objective Three**

The third objective was to evaluate the data from Objectives One and Two in order to determine whether one of these treatments protocols was more beneficial than treating Cervical Facet Syndrome.

## 2.0 REVIEW OF THE RELATED LITERATURE

### 2.1 INTRODUCTION

Neck pain is a common complaint in the general public according to (Cassidy, et al. 1992). This chapter gives an 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 Proprioceptive Neuromuscular Facilitative (PNF) stretching and the effects it has on the cervical spine are presented. Various aspects of Non-steroidal Anti-inflammatory Drugs (NSAID), such as their safety and uses are also discussed.

### 2.2 FACET SYNDROME SYNONYMS

Gatterman (1990:205) states that the most common injury to the neck is Joint Sprain with articular locking and accompanying muscle spasm. Other names also given to this same condition include: Cervical Zygapophyseal Pain (Dwyer et al., 1990); Cervical Joint Pain (Dwyer et al., 1990); Posterior Facet Syndrome (Kirkaldy-Willis, 1992: 122) and Facet Syndrome (Gatterman, 1990: 369). 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 INCIDENCE, PREVALENCE & GENDER DISTRIBUTION OF NECK PAIN SUFFERERS

Kelsey (1982: 146) reports that 40-50% of the general population will have neck pain with some limitation of movement at some time in their lives. Neck pain is a costly entity in terms of treatment, individual suffering and time lost from work (Jordan et al. 1998). Frymoyer (1991: 137) puts the prevalence of cervical spine disorders in the working population at 14-18% while Grieve (1988:190) showed that 5% of industrial workers were unable to work because of neck pain. Nygren et al. (1997:21) state that neck and shoulder disorders are the most common work related diagnosis in Sweden. It is clear that effective treatment protocols are needed to address this common and debilitating disorder.

The cervical spine is the most mobile area of the spine, and as a result it is prone to the greatest number of injuries. In the U.S.A., about 10,000 spinal cord injuries occur each year with approximately 80% of the victims under the ages of 40 years and with the highest proportion of these injuries between the ages of 15 and 35 years (Serena et al., 1995: 212). The authors also state that injuries to the cervical spine and possibly involving the spinal cord are potentially the most devastating and life-altering of all injuries compatible with life.

Drews (1995) compared the types of conditions seen in private chiropractic practice in South Africa to the types of conditions seen at the Technikon Natal Chiropractic Clinic. It was found that 54.4% of new patients (N=162) presenting at the teaching clinic complained of neck pain compared to 57.4% of patients treated in private practice.

Many of these patients concurrently suffered from headaches and/or arm pain. 14,8% of private practice patients and 16,7% of clinic patients had neck pain only.

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). Serena et al. (1995: 212) states that 80% of all people who suffer from spinal column injuries are male. 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).

Cassidy, Quon et al. (1992) report a paucity of clinical research into the efficacy and effects of various forms of treatment for neck pain. This study endeavours to contribute to the available information.

In a study by Jordan et al. (1997) the 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 ROM 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.

**TABLE 2.1** Incidence, Prevalence and gender distribution of Neck Pain Sufferers

AUTHOR		
Drews (1995)	54.4% of new patients presenting at Technikon Natal complained of neck pain	57.4% of patients treated in private practice complained of neck pain
Lau et al. (1996)	15% prevalence of neck pain in Hong Kong Chinese men	17% prevalence of neck pain in Hong Kong Chinese women
Cote et al. (1998)	66.7% of patients with neck pain were between the ages of 20-69. More women experience high-disability neck pain than men	
Serena et al. (1995)	80% of all people suffering from spinal cord injuries are male	
Jordan et al. (1997)	Patients with chronic neck pain found to have a greater muscular deficiency in cervical extensor muscle group. Active ROM in extension was also decreased (this was more common in females)	

Although the incidence, prevalence and the number of patients seeking help from chiropractors for their neck pain seem to vary from author to author, the number of people suffering from this condition is clearly significant. Women seem to be more affected by neck pain than men and geographical distribution has variations in numbers of sufferers.

## 2.4 FACET SYNDROME

### 2.4.1 Definition

Gatterman (1995: 11) defines facet syndrome 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. Panzer (1995: 415) broadly defined facet syndrome as

pain or dysfunction arising primarily from the zygapophyseal joints and their immediately adjacent tissues.

#### **2.4.2 Aetiology**

A wide variety of factors seem to be identified by many authors in relation to the cause of mechanical neck pain. In some cases a single cause for joint dysfunction may be identified, but more often a combination of factors seem to play a role.

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

According to Mennell (1990) there are three constant etiological factors associated with mechanical joint dysfunction:

- intrinsic trauma (i.e.: trauma pertaining exclusively to that joint)
- immobilisation, with which disuse and ageing must be considered, and
- factors residual from the healing of some more serious pathological condition.

The locking or fixation of a facet joint is often presumed to be from mechanical derangement like intra-articular jamming, shortening, adhesions and incongruency of the joint surfaces (Mootz 1995: 178-180).

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).

#### **2.4.3 Clinical Presentation Of Cervical Facet Syndrome**

Zygapophyseal joint facet syndrome is common, but because it is usually not demonstrable on radiographs it is frequently overlooked (Halderman, 1992: 208).

The patient with facet syndrome may complain of sudden onset of unilateral neck pain, often with referred pain. Muscle spasm is usually present causing restricted movement. Pain increases with movement and is relieved by rest. The pain is aggravated by hyperextension and relieved 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 zygapophyseal joints.



Bergmann et al. (1993: 63) used the following diagnostic criteria to identify joint dysfunction:

- **Pain and tenderness**

Most primary musculoskeletal disorders manifest themselves by a painful response. The patient's description of pain; its location and the intensity of tenderness are obtained from observation, percussion and palpation of osseous and soft tissue in the neck. There is a high inter- and intraexaminer reliability for osseous and paraspinal tenderness (Brantingham et al., 1995).

- **Asymmetry**

Asymmetric qualities may be noted at multiple segmental levels or at an individual level in the cervical spine. Asymmetry and misalignment of vertebral segments is identified through observation, static palpation, and static radiography.

- **Range of Motion Abnormality**

Changes in active, passive and accessory joint motions due to increased, decreased or aberrant motion are noted. Bergmann et al. (1993: 63) state that it is thought that a decrease in motion is a common component of joint dysfunction. Abnormalities in motion is a common component of joint dysfunction. Abnormalities in motion in the cervical spine are identified through motion palpation and stress radiography. Gatterman (1990: 232) refers to protective muscle spasm aiding restricted vertebral motion and segment fixation detected on motion palpation.. Good to

moderate intraexaminer reliability for detecting loss of accessory motion (joint play and end feel spring) has been reported (Brantingham et al., 1995).

- **Tone, Texture and Temperature Abnormality**

Changes in the associated soft tissue including skin, fascia, muscle and ligaments are noted. They are identified through observation, palpation and possibly instrumentation.

- **Special tests**

Special procedures and techniques will aid in the final diagnosis of joint dysfunction (Walker 1986 refers to placing the cervical spine into a combination of extension, lateral flexion and rotation to compress and elicit pain at or proximal to the effected side-also referred to as Kemp's Test).

Merrill et al. (1995:163) states that with a cervical sprain there has been damage to the ligamentous and capsular structures connecting the facet joints and vertebrae. There is limitation of motion and pain in the area of injury and also pain along the muscle groups overlying the area of injury. No neurological symptoms are present.

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 joint, abnormal quality of resistance to motion and pain on palpation of segmental accessory movements (Panzer, 1995: 419, 424).

Mechanical analysis of joint function has shown that some elasticity is present in the normal ligamentous structure of each joint. This analysis, described as motion palpation, can be accomplished by springing each vertebra in each of its planes of motion or by monitoring the relative motion between bony landmarks (Fechtel, 1990: 75). Motion palpation is employed to determine the joints in dysfunction and the specific direction of motion loss (Haldeman, 1992:305).

#### **2.4.4. Anatomy**

Many important structures are crowded together in the neck (Moore, 1992: 783). The cervical spine is area in which stability has been sacrificed for mobility, making it particularly vulnerable to injury (Magee, 1992: 34)

There are seven vertebrae in the cervical spine, with the body of each vertebra supporting the weight of those above it. The facet joints play only a small role in weight bearing. The superior facets of the cervical spine face upward, backward and medially while the inferior facets face downward, forward and laterally. This plane facilitates flexion and extension (Magee 1992:34)

The cervical spine is made up of two anatomically and functionally distinct regions i.e. an upper and a lower cervical region. These two regions provide for a wide range of movement in all planes. The occipitoatlantal joints (C0-C1) and the atlanto-axial joints are atypical joints in that they have no intervertebral discs,

no zygapophyseal (facet) joints and show different movement to the rest of the cervical joints. C0-C1 allows for flexion and extension while C1-C2 accounts for 50% of total cervical rotation (Gattermann, 1990: 13, Moore, 1992: 348-350).

The lower cervical vertebra form a "3 joints complex" with the adjacent vertebra. The first joint is between the bodies of the vertebra. They are joined by a fibrocartilagenous disc. This intervertebral disc serves to unite as well as to keep the vertebra apart (Gatterman, 1990: 14). The other two joints are the posterior (zygapophyseal or facet) joints. They are true diarthrodial joints, have articular cartilage, a loose capsule lined with synovial membrane, reinforced with ligaments and related muscles (Gatterman, 1990: 14). These joint complexes or motion segments act together as a unit to produce movement. Flexion-extension, side-bending and rotation are products of this synergism or coupling (Haldeman 1992: 130).

According to White and Panjabi (1990:537), these physiological movements of the cervical spine are inherently connected and the phenomenon of joint coupling is due to the geometry of the individual vertebrae, the attachment of the ligaments and disc and the curve of the spine.

The structures in and around the vertebral joints: muscle, tendon, ligaments, periosteum, disc and facets, are extensively innervated by nerves that relay sensory information to the central nervous system (Bolton, 1997). The cervical facet 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 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) further pointing to the facet joints as a more likely source of pain than the intervertebral disc in any painful mechanical neck condition.

#### **2.4.5 Evidence Of Inflammation**

Facet joint pain is thought to be caused by inflammation of the capsule and irritation of the nerve roots (Roy *et al.*, 1988). Dorland (1994: 839) defines inflammation as 'a localised protective response elicited by injury or destruction of tissues which serves to destroy, dilute or wall off both the injurious agent and the injured tissue. It is characterised in the acute form by the classical signs of pain (dolor), heat (calor), redness (rubor), swelling (tumour) and loss function (functio laesa).

Histologically, it involves a complex series of events, including dilatation of arterioles, capillaries and venules with increased permeability and blood flow, exudation of fluids, including plasma proteins, and leukocytic migration into the inflammatory focus.

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 ranges of movement, tendon and fascial shortening. Presumably, this kind of reaction can

be inhibited by anti-inflammatory drugs (Dishman, 1988). 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 remodelling and subsequent limitation of joint movement (Lantz, 1995:166).

Bourdillion et al. (1992:283) states that inflammation is likely to be a factor in many spinal joint dysfunctions, as a result of the success of local epidural injections of anti-inflammatory steroid and anaesthetic drugs close to the nerve root.

Reid (1992: 829) states that it is the inflammatory flare-ups of facet joint pain and synovitis that produce the facet joint syndrome. He advocates the use of NSAIDs for the treatment of these flare-ups. In contrast, Bogduk (1994:433) believes that it is mechanical changes and not inflammatory changes that determine if the zygapophyseal joint becomes symptomatic or not.

In a dysfunctional joint, an inflammatory reaction around a nerve root or nerve may cause persistent pain.

The duration of symptoms in painful neck conditions are a possible indicator to the severity of inflammation present in the joint (Gifford, 1994:507). Farfan (1992:160) hypothesized 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). According to Lantz (1995:163), when there is chronic inflammation in the cervical spine the clinical picture changes. Inflammatory spillover into the surrounding tissues from the joint can result in chemical radiculitis, a feature of the neurologic component of chronic facet syndrome.

The normal resolution of inflammation is fibrosis, which progresses to the development of scar tissue with the 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 to not only eradicate all signs and symptoms of inflammation, but to also restore joint mobility by abolishing fibrotic adhesions (Schafer and Faye, 1990: 306).

## **2.5 PROPRIOCEPTIVE NEUROMUSCULAR FACILITATIVE STRETCHING**

### **2.5.1 Introduction**

PNF procedures are purported to reduce muscle spasm, increase muscle strength and flexibility, and promote functional use of muscles following natural patterned motions (Hsieh, 1994). It was developed in the early 1950's by Herman Kabat, PhD, MD, a neurophysiologist and physician. Later, it was widely disseminated to therapists by Margaret Knott, PT, and Dorothy E. Voss, PT, as a system of total body motor learning (McAtee, 1993:2). Currently, PNF

is being used by many professionals, such as occupational therapists, athletic trainers, physical educators, kinesiologists, and chiropractors, who show interest in a total approach to patient care via therapeutic exercises (Hsieh, 1994).

### **2.5.2 Definition**

PNF is defined as methods of promoting or hastening the response of the neuromuscular mechanism through stimulation of the proprioceptors (Knott, 1968).

### **2.5.3 Contraindications To PNF Stretching**

Facilitation procedures may be used to treat patients with any diagnosis or condition, although a patient's condition may rule out the use of some techniques. Basically, initiating or increasing pain should be avoided. Other contraindications are mainly common sense (Adler, 1993:3).

Chaitow (1998: 52) states that if pathology is suspected no Muscle Energy Techniques (MET), a stretching technique similar to PNF, should be used until an accurate diagnosis has been established. Pathology (osteoporosis, arthritis etc.) does not rule out the use of MET, but its presence needs to be established so that dosage of application can be modified accordingly (amount of effort used, number of repetitions etc.).



#### 2.5.4 Hypothesized Mechanism Of PNF Stretching

PNF is based on several neurophysiological mechanisms, the understanding of which provides necessary insight into the basis of PNF practices (McAtee, 1993:3). The author states that PNF is a form of stretching that uses an isometric contraction prior to the stretch to achieve greater gains than from static stretching alone. This type of stretching consists of three phases. The first is to place the muscle to be stretched in a stretch position and have it contract against resistance for 8 seconds. This phase causes fatigue to the muscle allowing it to relax and stretch. The second phase is to contract the antagonist.

This initiates a neurophysiological principle called 'reciprocal inhibition' to produce muscle stretching. The third phase is to put the muscle on a passive stretch. These procedures are repeated three times (Adler, 1993: 36, Nook, 1997).

Voss (1985) states that PNF concepts are derived from fundamentals of neurophysiology and developmental neurology:

- reciprocal innervation and inhibition: when the agonist contracts the antagonist will relax
- a-y interaction: after the muscle contracts, it will relax itself
- irradiation: when the muscles contract strongly, the nerve impulses can overflow into other adjacent or related areas

- task-specific theory: natural movements are seldom unidirectional; therefore training follows patterned motions
- motor skills are built upon sequentially learned patterns: in the developmental sequence

Prentice (1983) wrote that the effectiveness of PNF may be attributed to an alteration of the myotatic stretch reflex, which involves the muscle spindles, Golgi tendon organs and the gamma system. Guyton (1992: 408) explains the stretch reflex as occurring when sudden stretch of a muscle excites the muscle spindle, and this in turn sends strong impulses to the spinal cord, which then transmits signals through the alpha efferent nerve fibres to the extrafusal muscle fibres, causing reflex contraction of the same muscle. On the other hand, the development of excessive tension within the muscle activates the Golgi tendon organs whose sensory impulses are carried back to the spinal cord.

These impulses have an inhibitory effect on the motor impulses returning to the muscle, thus causing the muscle to relax (Prentice, 1983).

When a muscle is stretched, motorneurons supplying that muscle receive both excitatory and inhibitory impulses from the receptors. If the stretch is continued for a slightly extended period of time, the inhibitory signals from the Golgi tendon organs eventually override the excitatory impulses, therefore causing relaxation. This phenomena is known as autogenic inhibition (Prentice, 1983). A second mechanism known as reciprocal inhibition deals with the relationships of the agonist and antagonist muscles. When motorneurons of the agonist muscle receive excitatory impulses from afferent nerves, the motorneurons which supply the antagonist muscles are inhibited by the afferent impulses. Thus contraction

or stretch of the agonist muscle will elicit relaxation of the antagonist (Prentice, 1983).

Moore and Kukulka (1991) investigated the depression of Hoffmann Reflexes following voluntary contraction and found that postcontraction amplitudes were strongly depressed. These results provide support for PNF relaxation technique claims of postcontraction inhibition with the possibility that multiple neurological mechanisms may be involved.

A series of studies by various researchers using electromyography found levels of electrical activity in target muscle that indicate the absence of reciprocal or autogenic inhibition during PNF procedures (Moore and Hutton, 1987; Osternig et al. 1987, 1990).

Recent studies have shown that PNF stretching techniques actually increase electromyographic (EMG) activity, yet paradoxically result in greater gains in range than those obtained from passive stretching techniques (Wilkinson, 1992). These studies raise serious questions about the validity of Kabat's and others' hypotheses concerning mechanisms like the stretch reflex, reciprocal innervation and autogenic inhibition and their contribution to the effectiveness of PNF techniques.

The mechanism behind the effectiveness of PNF techniques remains indistinct (Magnusson, 1996), but the efficacy of PNF is evident in the following literature review.

### 2.5.5 Effects And Effectiveness of PNF Stretching

Although much is surmised about the effects of stretching exercise on spinal range of motion, little has been published, those that have using symptomatic subjects (McCarthy et al., 1997). The authors conducted a study to determine the effects of PNF (CRAC) stretching procedures on the active range of motion of the cervical spine in the transverse plane. Forty asymptomatic male volunteers were equally divided into either a stretch or control group. The stretch group performed stretching twice a day for seven days. The results showed that there was significantly increased active cervical spine range of motion in the stretch group by the seventh day of the study as compared to the control group.

A randomized clinical trial comparing Contract-Relax-Antagonist-Contract (CRAC) stretching, a component of PNF stretching in the treatment of active myofascial trigger points of the shoulder girdle and neck muscles, showed significant subjective and objective improvement within both groups during the treatment program (MacDougal, 1999: 96).

Louis and Osternig (1987) state that PNF stretching techniques are often used to induce increased joint motion and muscle relaxation. In a multiple-interrupted, time series designed case study assessing the chiropractic management of a patient who presented to a college outpatient clinic with neck stiffness, treatment consisted of two different approaches for myofascial pain syndrome, in conjunction with spinal manipulative therapy. One of the techniques used was the spray and stretch method of Travell, and the other was a combination of a

vibrating machine (G5 unit), PNF and ice. Both treatments showed improvements in ROM, but the latter treatment resulted in greater improvements as well as maintenance of improvement in ROM during follow-up (Boline et al., 1990).

Lewit and Simons (1984) conducted a study in which patients suffering from myofascial pain syndromes were treated using PNF (CRAC) stretching techniques. The patients were scored as having either immediate or lasting relief (3 months or more). The results showed that 94% experienced immediate relief, 63% experienced lasting relief and 23% experienced lasting relief of point tenderness of the sites treated.

Sady, Wortman and Blanke (1982) compared the effects of ballistic, static and PNF stretching on shoulder, trunk and hamstring flexibility. They found that only the PNF technique (CRAC) significantly increased range of motion compared to the control group. Prentice (1983) compared static stretching and PNF for increasing flexibility at the hip joint and found that, although both methods were effective, PNF was significantly better than static stretching.

## 2.6 NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

### 2.6.1 Introduction

These drugs have in various degrees analgesic, anti-inflammatory and antipyretic actions (Neal, 1992:66, Arky, 1997:833). Worldwide, NSAIDs seem to be the most commonly prescribed medications (Koes et al., 1997) and they

are usually chosen as the first line of treatment for conditions such as mechanical neck pain by allopathic physicians (Dabbs and Lauretti, 1995). The popularity of these agents is largely attributable to their success in relieving pain and maintaining functional status (Goldstein et al., 1997).

There has been substantial progress in elucidating the mechanism of action of NSAIDs, although a precise understanding of their therapeutic activities and side effects is still lacking (Goodman Gilman et al., 1990: 638). Despite their widespread use and safety, they have a significant risk of severe complications, the most frequent being gastrointestinal ulcers and haemorrhage (Dabbs and Lauretti, 1995).

The NSAIDs form a chemically diverse group (Neal, 1992: 66), and include 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 a benzeneacetic acid derivative, designated chemically as 2-[(2,6-di-chlorophenyl)amino] benzeneacetic acid, monopotassium salt (Arky, 1997: 833).

### 2.6.3 Pharmacological Properties

Diclofenac possesses analgesic, antipyretic and anti-inflammatory activities; it is an inhibitor of cyclooxygenase, and its potency is substantially greater than that of indomethacin, naproxen and several other agents (Goodman Gilman et al., 1990:669). As with other NSAIDs, its mode of action is not known; its ability to inhibit prostaglandin synthesis, however, may be involved in its anti-inflammatory activity, as well as contribute to its efficacy in relieving pain related to inflammation and primary dysmenorrhea (Arky, 1997: 833).

Prostaglandins produce little pain by themselves, but potentiate the pain caused by other mediators of inflammation e.g. histamine, bradykinin. The role of prostaglandins in inflammation is to produce vasodilatation and increase vascular permeability. Inhibition of prostaglandin synthesis by NSAIDs attenuates rather than abolishes inflammation, because the drugs do not inhibit other mediators of inflammation (Neal, 1992: 67).

Cataflam Immediate-Release Tablets are formulated to release diclofenac in the stomach (Arky, 1997: 833). Diclofenac is rapidly and completely absorbed after oral administration; peak concentrations in plasma are reached within 2 to 3 hours. Administration with food slows the rate but does not alter the extent of the absorption.

There is a substantial first-pass effect, such that only about 50% of diclofenac is available systemically. The drug is extensively bound to plasma proteins (99%), and its half-life in plasma is 1 to 2 hours (Goodman Gilman et al., 1990: 669).

Only 5 % of the unchanged drug is excreted in the urine and the bile. This may vary as the free concentrations of diclofenac may be higher in patients with low serum albumin levels e.g. due to cirrhosis or rheumatoid arthritis (DiPiro, 1989: 908)

As with other NSAIDs, diclofenac diffuses into and out of the synovial fluid. Diffusion into the joint occurs when plasma levels are higher than those in the synovial fluid (Arky, 1997: 834). Diclofenac accumulates in synovial fluid after oral administration, which may explain the duration of therapeutic effect that is considerably longer than the plasma half-life (Goodman Gilman et al., 1997: 669). This makes it an excellent choice for treatment of facet syndrome.

#### **2.6.4 Therapeutic Uses**

Diclofenac is indicated for acute and chronic treatment of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis (Arky, 1997: 834).

It may also be useful for short-term treatment of acute musculoskeletal injury, painful shoulder, postoperative pain and dysmenorrhea (Goodman Gilman et al., 1990:699).

In a review of randomised clinical trials (n=26) on the efficacy of NSAIDs for low back pain, it was 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 (Koes et al., 1997). It seems reasonable to assume that patients suffering from



uncomplicated neck pain would receive similar relief from NSAIDs, but cannot be assured.

In a pharmacy-based surveillance of Cataflam in Dunedin, it was found that Cataflam was purchased predominantly for sprains, strains and muscular pain. It was reported that 71% (n=82) of purchasers indicated "complete" or "moderate" relief while 16% reported adverse drug reactions (Emmerton et al., 1995).

#### **2.6.5 Contraindications**

Cataflam D Dispersable (diclofenac sodium) is contra-indicated in the case of gastric or intestinal ulcer, where there is allergy to the active substance, in asthmatic patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or by other medicines with prostaglandin-synthetase inhibiting activity. Cataflam D should not be used in patients with porphyria, nor in pregnancy or in children under 14 years of age (Cataflam package insert).

#### **2.6.6 Side-Effects, Special Precautions And Drug Interactions**

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

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 reasons for stopping therapy (Goodman and Simon, 1994). In extreme cases, bleeding and ulceration or perforation of the intestinal wall may occur (Goodman Gilman et al., 1990: 669).

Although the incidence of adverse effects of NSAIDs is low, the extremely widespread use of these drugs and the fact that some patients may suffer major morbidity or mortality means that the possibility of side-effects must be taken seriously and watched for (Goodman and Simon, 1994).

### **Precautions**

- Cataflam Immediate-Release Tablets should not be used concomitantly with other diclofenac-containing products since they also circulate in plasma as the diclofenac anion (Arky, 1997: 834).
- As with other NSAIDs, diclofenac should be used with caution in patients with a history of cardiac decompensation, hypertension or other conditions predisposing to fluid retention (Arky, 1997: 834).
- In instances where peptic ulceration or gastro-intestinal bleeding occur in patients under treatment, the medicine should be withdrawn (Cataflam D package insert: Appendix!).
- Caution should be exercised in patients with impaired renal function, heart failure, liver dysfunction, those taking diuretics and the elderly. In these patients, administration of an NSAID results in a dose-dependent decrease in

prostaglandin synthesis and secondarily, in a reduction of renal blood flow, which may precipitate overt renal failure (Arky, 1997: 834).

- During prolonged treatment blood counts and monitoring of hepatic and renal function are indicated (Cataflam D package insert: Appendix!)
- The use of diclofenac in patients with hepatic porphyria should be avoided (Arky, 1997: 834)
- If signs or symptoms of meningitis develop in a patient on diclofenac, the possibility of its being related to diclofenac should be considered (Arky, 1997: 834).
- Diclofenac should not be administered to asthmatic patients with an aspirin sensitivity and should be used with caution in all patients with preexisting asthma (Arky, 1997: 834).
- The pharmacologic activity of diclofenac may reduce fever and inflammation, thus diminishing their utility as diagnostic signs in detecting underlying conditions (Arky, 1997: 834).
- Patients experiencing dizziness or other central nervous disturbances should refrain from driving a vehicle or operating machines (Cataflam D package insert: Appendix 1)

### **Drug Interactions**

Cataflam D should not be given in combination with the following preparations due to the various interactions that may occur: lithium, digoxin, aspirin, anticoagulants, methotrexate, cyclosporin, glucocorticoids or other NSAIDs (Cataflam D package insert: Appendix!).

### 2.6.7 Efficacy

In a review of current literature and issues on drug therapy for low back pain, it was concluded reasonable to recommend NSAIDs for patients with acute back pain, with efforts to minimise costs and complications (Deyo, 1996). 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. The evidence supporting the effectiveness of NSAIDs for neck pain is extremely limited (Dabbs and Lauretti, 1995) but it could be surmised that NSAIDs would be an effective therapy for neck pain.

Kantor (1986) states that Diclofenac has been established as a leading NSAID in worldwide studies and has been used successfully for acute as well as chronic or relapsing syndromes marked by pain and inflammation. Kantor (1986) found that when compared with placebo, diclofenac provided consistently superior relief of symptoms. Comparisons with other NSAIDs or with opioids, such as pentazocine or Spasmofen, demonstrate that symptom relief with diclofenac was either comparable to or better than that obtained with these agents.

There is evidence that diclofenac is transferred across the synovial membrane to the synovial fluid, from which it is eliminated more gradually than from plasma (Radermacher et al., 1991). It has been suggested that the clearance of diclofenac from the synovial fluid to blood occurs slowly because the drug binds with high affinity to the albumin that is sequestered in the synovial space in

arthropathy (Owen et al., 1994). Therefore, the prolonged antinociceptive effect of diclofenac may be explained by the fact that the drug is retained by the albumin-enriched synovial fluid.

In a study by Torres-Lopez et al. (1997), it was found that slow equilibrium kinetics between diclofenac concentration in blood and at its site of action, leads to a delayed onset of the antinociceptive effect as well as a longer duration of the response resulting from drug accumulation in synovial fluid. These factors make diclofenac an excellent choice for the treatment of fact syndrome.

Koes et al. (1997) performed a computer aided search to assess the efficacy of NSAIDs in the treatment of low back pain. The results of the 26 randomized trials that were analysed suggest that NSAIDs might be effective for short-term symptomatic relief in patients with uncomplicated low back pain, but are less effective or ineffective in patients with low back pain with sciatica and patients with sciatica with nerve root symptoms. No similar assessment was found for neck pain but it could be surmised that the results would be the same based on anatomical similarities.

#### **2.6.8 The Placebo Effect**

Placebo is an agent employed in medical practice with the primary aim of gratifying the patient. The agent employed is usually pharmacologically inert, at least in the dosage and form employed, and leads to certain effects on the individual. These effects are not determined by the known pharmacological properties of the substance; it is the psychological state of the individual at the

time of its administration that determines the effect produced by the placebo (Dawie 1985:18). The placebo effect is a very controversial topic, and much has been written on it in the past decade. Vernick (1995) states that many modern scientific studies have been able to verify the effectiveness of such treatments, showing that about a third of patients improve when given placebo.

Roberts et al. (1993) evaluated the hypothesis that the power of nonspecific effects may account for as much as two thirds of successful treatment outcomes when both the healer and the patient believe in the efficacy of the treatment. Five medical and surgical treatments, once considered to be efficacious by their proponents but no longer considered effective based upon later control trials, were selected according to strict inclusion criteria. For these five treatments combined, 40% excellent, 30% good, and 30% poor results were reported by proponents. It was concluded that, under conditions of heightened expectations, the power of nonspecific effects far exceeds that commonly reported in the literature.

In a randomized trial, the effectiveness of manual therapy, physiotherapy, continued treatment by the general practitioner, and placebo therapy (detuned ultrasound and detuned short-wave diathermy) were compared for patients (n= 256) with nonspecific back and neck complaints lasting for at least 6 weeks (Koes et al., 1991). The patients in the placebo group were reported to have responded remarkably well. Although the improvement of the main complaint in the physiotherapy and manual therapy group was consistently better than in the placebo group at 3 and 6 weeks, the differences were not statistically significant at the conventional 95% confidence level.

## 2.7 SUMMARY

Neck pain is a common disorder which will affect 40 – 50% of the general population at some time in their lives (Cassidy, Lopez et al. , 1992). Current treatments may be inadequate and must change toward more specific treatments with the ultimate goal being to restore the affected area to normal function (Fitz-Ritson, 1990).

Uncertainty as to the exact cause of Cervical Facet Syndrome has lead to differing approaches to treatment. Facet Syndrome is characterised by pain and tenderness, asymmetry, range of motion abnormality, tone, texture and temperature abnormality as well as positive findings of various special tests (Bergmann et al., 1993:63). Facet joint pain is thought by some to be caused by inflammation of the capsule and irritation of the nerve roots, (Roy et al., 1988) while others cite mechanical changes as the main causative factor (Bogduk, 1994:453).

PNF procedures are purported to reduce muscle spasm, increase muscle strength and flexibility and promote functional use of muscles following natural patterned motions (Hsieh, 1994). These procedures have also been proven to increase active range of motion of the cervical spine (McCarthy et al., S 1997).

Diclofenac possesses analgesic, antipyretic and anti-inflammatory activities and its potency is substantially greater than that of indomethacin, naproxin and several other NSAID's (Goodman Gilman et al., 1990:669).

This study endeavoured to address the various aspects of Cervical Facet Syndrome by combining PNF stretching with administration of Diclofenac. More specifically, it

was thought that the PNF would address the aspects of loss of range of motion, asymmetry, abnormal tone and texture as well as reducing muscle spasm, increasing muscle strength, and promoting functional use of muscles. Concurrent administration of Diclofenac was aimed at addressing pain and inflammation of the relevant areas.



### 3.0 **MATERIALS AND METHODS OF THE STUDY**

#### 3.1 **INTRODUCTION**

This chapter deals with the location and the collection of the data and the research methodology utilized. The treatment interventions and process of statistical analysis are discussed here. The study design chosen was that of a single-blind, comparative, clinical trial. This involved two groups receiving PNF stretching and each group receiving either NSAID's or placebo medication, respectively.

#### 3.2 **MEASUREMENT AND OBSERVATION**

##### 3.2.1 **Method Of Measurement**

Subjective and objective measurements were taken before the initial, middle and final consultations. The initial measurements were taken before commencement of treatment to establish a baseline from where to start. The measurements at the middle and final consultations were taken after treatment to establish the efficacy of the respective treatments.

##### **SUBJECTIVE MEASUREMENTS**

Subjective measurements were taken from questionnaires, which the patient had to complete in writing. This was done at the initial, third and final consultations.

The questionnaires used were the Numerical Pain Rating Scale 101 (Appendix N), the CMCC Neck Disability Index (Appendix L) and the Short-Form McGill Pain Questionnaire (Appendix M).

1) **Numerical Pain Rating Scale 101**

In a study by Jenson et al. (1986) where six methods of assessing pain intensity were compared, it was found that the Numerical Pain Rating Scale 101 had practical advantages over the other measures because:

- 1) It was simple and practical to administer and score.
- 2) It can be administered in either written or verbal form.
- 3) The scale does not appear to be associated with age.

It was concluded that "...the superior measure seems to be the Numerical Pain Rating Scale 101." (Jenson et al., 1986). For this reason, the NRS was chosen to measure the subjective pain intensity of the patients in this study.

The patient was required to indicate by means of a percentage, the intensity of the pain experienced prior to treatment, when (a) it was at it's worst, and (b) when it was at it's least. The average of these two figures gives an indication of the average pain intensity experienced by the patient.

## 2) **Neck Disability Index**

The neck Disability Index (NDI) is a revised form of the Oswestry Low Back Pain Index, which was developed by Fairbank et al. (1980). It consists of ten sections dealing with different aspects of the patient's lifestyle. Each section has six options with the first scoring '0' and the next five increasing progressively by a value of 1 to a maximum of '5'. All the scores were added together and were expressed as a percentage of the maximum score (50).

The NID 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). For this reason, the NDI was chosen to subjectively evaluate the level of disability experienced by the patients.

## 3) **Short- Form McGill Pain Questionnaire (SFMPQ)**

The McGill Pain Questionnaire has become one of the most widely used tests for the measurement of pain as it provides information on the sensory, affective and evaluative dimensions of pain experience (Reading, 1987: 66). In a study by Melzack (1987), short form McGill Pain Questionnaire scores obtained from patients in post-surgical and obstetrical wards and physiotherapy and dental departments, were compared to scores obtained with the standard McGill Pain Questionnaire. The correlations were consistently high and significant.

The SFM PQ was also shown to be sufficiently sensitive to demonstrate differences due to treatment at statistical levels comparable to those obtained with the standard form (Melzack, 1987).

The SFMPQ consists of fifteen adjectives which the patient grades, according to their pain, into none, mild, moderate or severe each having a score of 0, 1, 2, or 3 respectively. The scores are added and expressed out of a total of 45.

### **OBJECTIVE MEASUREMENTS**

The objective data was obtained by means of an algometer and a goniometer. Both types of readings were taken on the initial, third and final consultation and recorded on the relevant form (Appendix K)

#### **1) Cervical Range of Motion Goniometer**

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

This instrument was chosen in this study 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.

Steps of CROM reading:

- The patient was seated in a chair.
- The plastic frame was placed on the nose-bridge and ears and was secured by velcro.
- The 2 orthogonally arranged dials were checked to ensure that they were set to zero.
- Both flexion and left and right lateral flexion were assessed by gravity-dependant goniometers.
- Flexion was measured by asking the patient to place their chin on their chest.
- Lateral flexion was measured by asking the patient to put their ear to their shoulder.

2) **Algometer**

The algometer used in this clinical trial was the Algometer Commander, a product of JTech Medical Industries.

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

- Kemp's test
- Motion and static palpation for fixations and subluxations
- Tenderness

Force readings were measured in Newtons.

In a study done by Antonaci et al. (1998), pain perception thresholds were assessed with a mechanical pressure algometer (n=21).

Inter-examiner reliability was good (0,75) and intra-examiner reliability was excellent (0,84).

Steps of algometer reading:

- Minimum pressure threshold set at 1,3N
- Test time set at 5s (seconds)
- Metal disc was place over the involved facet
- The patient was told to express the point at which pain was perceived.
- Pressure was applied and then increased gradually.
- Pressure was released once the patient expressed the point at which pain was perceived.
- repeated x 2

Average of 3 pressure readings as given by the digital algometer was recorded.

### 3.3 **STUDY PROTOCOL AND DESIGN**

#### 3.3.1 **Sampling Procedure**

Non-probability random sampling techniques from population with neck pain were used to acquire the sample. Public interest in the research was generated via advertising in local newspapers and posters, which were placed on notice boards in public places e.g. local shopping centres, health shops and around Technikon Natal.

Patients who presented with neck pain were considered for the study. Each patient was required to complete a questionnaire (Appendix B) and undergo a case history, a physical examination and a cervical spine regional examination. Diagnosis of cervical facet syndrome was made according to the following criteria (Bergmann et al., 1993: 63 and Schafer and Faye, 1990: 98-110):

- 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 included Kemp's and facet joint challenge, done at the level of dysfunction.

### **3.3.2 Allocation Of The Subjects**

The patients were divided into Groups 1 and 2 by random allocation as described by Scott Dawkins (1995:48). Forty slips of paper (20 of each of the two treatment protocols) were put into a hat and randomly drawn to plan the sequence of treatments in the study.

Group 1 was treated using PNF stretching of the posterior cervical and trapezius musculature and NSAID's.

Group 2 was treated using PNF stretching of the above-mentioned muscles and placebo medication.

### **3.3.3 Ethics**

Each patient had to complete and sign an informed consent form (Appendix A) prior to the treatment commencing. Each patient was told the precise nature of the study, including the possible side-effects of the NSAID used (Appendices G and E). 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 any time and for whatever reason they so wished (Appendix G). All patient information was treated as confidential. Each patient underwent substantial screening before being allowed to participate in the study (Appendices B, H and



l). In addition, a medical practitioner advised the researcher on whether it was safe for patients to take Diclofenac. This was done to ensure no more than minimal risk to the patients as the procedure was designed to exclude patients who might have developed adverse reactions to the Diclofenac

Furthermore, this study complied with the ethics standards are set by the institution ethics review committee.

#### **3.3.4 Inclusion And Exclusion Criteria For Acceptance Of Subjects**

- Patient's between 18-65 years were accepted.
- An informed consent form was required to be completed before commencement of the treatment (Appendix A).
- Patients had to fill in and sign a screening questionnaire (Appendix B) declaration (Appendix B) and indemnity (Appendix D). Each patient received a copy of the Cataflam D package insert (Appendix E).
- If any conditions which contraindicate NSAID administration were present, such patients were rejected from the study i.e. Diclofenac in all formulations is contraindicated in patients with known hypersensitivity to diclofenac and diclofenac-containing products. Diclofenac should not be given to patients who have experienced asthma, urticaria or other allergic reactions after taking aspirin or other NSAIDs (Arky, 1997:834).

- Women who were pregnant or breast-feeding were excluded from the study (Appendix B).
- Patients taking aspirin, anticoagulants, digoxin, methotrexate, cyclosporin, lithium, diuretics, phenobarbital or any other NSAID (including diclofenac) were not included in the study due to the varied interactions these drugs have with the medication used (Appendix E).
- If any patient developed side effects that may have been related to the medication given, such a patient was excluded from the study under the guidance of the involved medical practitioner. In a study of treatment periods, 718 patients were treated for 2 weeks or less with Cataflam Immediate-Release Tablets. Adverse reactions were reported one-half to one-tenth as frequently as by patients treated for longer periods. By far the most common adverse effects were gastrointestinal symptoms, most of them minor. Gastrointestinal symptoms were followed in frequency by central nervous system side effects such as headache (7%) and dizziness (3%). Other side effects to be aware of include: abdominal pain, fluid retention, abdominal distention, diarrhea, indigestion, nausea, constipation, flatulence, liver test abnormalities, peptic ulcer, with or without bleeding and/or perforation, or bleeding without ulcer, rash, pruritus and tinnitus (Arky 1997:836)
- Any other treatment received during the duration of the study for the diagnosed condition resulted in exclusion of the subject.

- Patients were excluded from the study if active myofascial trigger points were the primary source of pain.
- All patients were required to follow the researcher's instructions during the course of the study. This was ensured by careful questioning of the patient at each consultation and each patient was required to fill in a medication diary to improve patient compliance (Appendix F).

### **3.3.5 Interventions**

At the initial consultation, the patient was required to complete and sign a screening questionnaire, declaration, indemnity form and informed consent form.

Also required was completion of the Numerical Pain Rating Scale 101, CMCC and Short form McGill Pain Questionnaire. Active ranges of motion in flexion and lateral flexion as well as algometer readings were measured.

Each patient was treated five times over a period of two weeks. The treatment of both groups 1 & 2 consisted of PNF stretching of the Posterior Cervical and Trapezius musculature.

In addition, group 1 received Cataflam D and Group 2 received placebo medication.

### 3.3.5.1 Proprioceptive Neuromuscular Facilitative Stretching

The CRAC technique of PNF stretching of posterior cervical and trapezius muscles was performed as follows (Adler, 1993: 36, Nook, 1995)

#### 1) Stretch Position

*Posterior Cervicals* - Patient seated in a chair, forward flexes neck as far as comfortable. Researcher's hands cupping back of head with elbows in front of patient's shoulders.

*Trapezius* - Patient laterally flexes head as far as comfortable, Researcher crosses arms and places one hand on shoulder and other over the ear on the same side as that being stretched.

#### 2) Contract Phase

The patient then pushed against the researcher's cupped hands in the case of the Posterior Cervicals (i.e. as if patient was trying to extend neck) OR

Patient pushed against the hand cupping the ear (i.e. as if patient was trying to return head to a neutral position) in the case of the trapezius. This was held for a count of eight seconds.

3) **Relaxation Phase**

The patient then relaxes the muscle briefly.

4) **Antagonist Contraction Phase**

The patient then returned head and neck to the stretch position: forward flexion in the case of Posterior Cervicals and lateral flexion in the case of Trapezius.

5) **Stretch Phase**

The researcher then held the head as in step one, where the stretch was felt by the patient in the relevant muscle.

The patient then pushed their head against the researcher's hand/s and thus began the next set of PNF stretches. This was repeated a total of three times each in forward flexion (Posterior Cervicals), right lateral flexion (left trapezius) and left lateral flexion (right trapezius).

### 3.3.5.2 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 D, which was used for the following reasons (Arky 1997:833) :

- Masurable 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 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 available over the counter, although it is a schedule three drug.

The NSAID tablets were individually crushed using a pestle and mortar, such that they had the same consistency as the placebo medication. The placebo medication consisted of lactose powder. The placebo medication and the powdered NSAID were then placed in the same type of sachets .

The dosages for patients in the experimental group was one sachet three times per day 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). All the data from the questionnaires was then converted to percentages and enlisted together with the goniometer (in degrees) and algometer (in Newtons) measurements onto a spreadsheet. This was then entered into the statisticians computer for the statistical analysis.

## DIAGRAM INDICATING THE RESEARCH METHODOLOGY

### **SAMPLING PROCEDURE**

Non-probability convenience sampling techniques  
along with questionnaires were used



### **INCLUSION AND EXCLUSION OF PATIENTS**

Patients were included or excluded according to the  
Inclusion and exclusion criteria



### **ALLOCATION OF THE SUBJECTS**

Patients were allocated into either Group 1 or 2 by  
random allocation



### **TREATMENT PROTOCOL**

Each patient received 5 treatments  
over a period of 2 weeks



#### **GROUP 1**

Treated using PNF  
stretching & NSAIDs

#### **GROUP 2**

Treated using PNF  
stretching & placebo  
medication



### **MEASUREMENTS**

These were taken at the initial, middle and final  
consultations and included subjective and objective measurements



### **STATISTICAL ANALYSIS**

Statistical analysis was done via non-parametric methods  
Intra-group analysis was done using Wilcoxon's Signed Rank Test  
Inter-group analysis was done using Mann Whitney-U Test



### 3.4 THE LOCATION OF THE DATA

The primary data was obtained from the Numerical Pain Rating Scale 101, the McGill Short form Pain Questionnaire, the CMCC Neck Disability Index, algometer and goniometer readings. These were obtained at the first, third and final consultations. In a study by Amlie et al. (1987) a NSAID was shown to be superior to placebo by day 3, but no significant difference was noted at day 7. All treatments and consultations took place at the Technikon Natal Chiropractic Day Clinic.

The secondary data was collected from current journals, text books, CD-Rom and the internet. This data was obtained through the Technikon Natal library.

### 3.5 STATISTICAL ANALYSIS

#### 3.5.1 Treatment Of The Data

Statistical analysis was done via non-parametric methods. Intra-group analysis was done using the Wilcoxon's Signed rank test and inter-group analysis was done using the Mann-Whitney-U test.

All tests were done at the 5% level of significance.

### 3.5.2 Wilcoxon's Signed Rank Test

The Wilcoxon Signed Rank Test shows any improvements within group 1 and group 2 between treatments 1 and 3, 3 and 5 and 1 and 5.

Hypothesis Test and the Decision Rule

H<sub>0</sub> : There was no improvement between the treatments.

H<sub>1</sub> : There was an improvement between the treatments

H<sub>0</sub> (null hypothesis) stated that that there was no improvement between treatments 1 and 3, 3 and 5 and 1 and 5.

H<sub>1</sub> stated that there was an improvement between treatments 1 and 3, 3 and 5 and 1 and 5.

P-value for a one-tailed test:

a)  $P = \text{reported p-value} \text{ if}$

$$2$$

1) H<sub>1</sub> is of form  $>$  and Z is positive

2) H<sub>1</sub> is of form  $<$  and Z is negative

b)  $P = 1 - (\text{reported p-value}) \text{ if}$

$$2$$

- 1)  $H_1$  is of form  $>$  and  $Z$  is negative
- 2)  $H_1$  is of form  $<$  and  $Z$  is positive

$P$  was the observed significance level.

### 3.5.3 Mann-Whitney U Test

This test was used to make comparisons between the 2 experimental groups, which were treated as being independent of one another at treatments 1, 3 & 5.

Hypothesis test and Decision Rule:

$H_0$  : There was no difference between the two groups.

$H_1$  : There was a difference between the two groups.

$H_0$  stated that there was no difference between the 2 groups at treatments 1, 3 and 5.

$H_1$  stated that there was a difference between the two groups at treatments 1, 3 and 5.

$\alpha = 0,05$  = level of significance

For a two-tailed test:

Reject:  $P \leq \alpha$

Reject:  $P > \alpha$

Note  $P$  is the observed significance level.

### 3.6 SUMMARY STATISTICS

The summary statistics include the mean, standard deviation and standard error to support the results from the Wilcoxon Signed Rank Test and Mann-Whitney U Tests.

If the two statistical tests calculated a significant difference between the two groups, the mean was used to identify the superior group. The reliability of the mean was then measured using the standard deviation, which measures the spread of data around the mean. The larger the value the larger the spread of values and hence the less reliable the data. The standard error was used to measure the reliability of the mean used in statistical tests.

### 3.7 VISUAL REPRESENTATION OF THE DATA

Bar charts and tables will be constructed to represent the major findings of the study, giving summary to results obtained from the Wilcoxon Signed Rank test and Mann-Whitney U tests. Bar charts will be made using the Microsoft Excel 97SR-1 software package and the tables will be constructed using Microsoft Word 97 SR-1 software package. The demographic data used from the patients files will be displayed using pie charts and tables produced in Microsoft Excel. The statistical package SPSS will be used for data entry and analysis.

## 4.0 THE RESULTS

### 4.1 INTRODUCTION

This chapter covers the results obtained from the statistical analysis of the data collected from the following measurement criteria:

Objective Measurements:

- Algometer readings
- Goniometer readings

Subjective measurements:

- Numerical Pain Rating Scale- 101
- CMCC Neck Disability Index
- Short form McGill Pain Questionnaire

### **KEY FOR ABBREVIATIONS**

S.D: Standard Deviation

s : Significant

ns : Non-Significant

The treatment of both groups 1 & 2 consisted of PNF stretching of the Posterior Cervical and Trapezius musculature. In addition, Group 1 received Cataflam D and Group 2 received Placebo medication.

## 4.2 NON – PARAMETRIC WILCOXON SIGNED RANK TEST

### 4.2.1 Subjective Data

**TABLE 4.1** Statistical results of the subjective findings comparing the interval between consultation 1 and 3 in Group 1

	CONSULTATION 1		CONSULTATION 3		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	50.80	17.18	28.75	17.41	0.000	s
CMCC	29.33	16.69	17.17	14.73	0.001	s
McGILL	12.90	5.43	5.15	5.03	0.000	s

The results indicate that at the 5% level of significance there was an improvement between consultation 1 and 3 in Group 1.

**TABLE 4.2** Statistical results of the subjective findings comparing the interval between consultation 1 and 3 in Group 2

	CONSULTATION 1		CONSULTATION 3		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	48.98	19.73	37.88	26.97	0.029	s
CMCC	30.36	10.71	21.60	16.80	0.003	s
McGILL	15.95	8.95	11.45	10.50	0.022	s

The results indicate that at the 5% level of significance there was an improvement between consultation 1 and 3 in Group 2

**TABLE 4.3** Statistical results of the subjective findings comparing the interval between consultation 3 and 5 in Group 1

	CONSULTATION 3		CONSULTATION 5		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	28.75	17.41	29.25	24.59	0.796	ns
CMCC	17.17	14.73	13.48	13.32	0.043	s
McGILL	5.15	5.03	5.00	5.09	0.000	s

Both the CMCC and McGILL results indicate that at the 5% level of significance there was an improvement between consultations 3 and 5 in Group 1. The NRS results indicate that at the 5% level of significance there was no improvement between consultation 3 and 5 in Group 1.

**TABLE 4.4** Statistical result of the subjective findings comparing the interval between consultation 3 and 5 in Group 2

	CONSULTATION 3		CONSULTATION 5		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	37.88	26.97	35.43	25.17	0.297	ns
CMCC	21.60	16.80	19.18	14.87	0.092	ns
McGILL	11.45	10.50	9.05	10.20	0.114	ns

The results indicate that at the 5% level of significance there was no improvement between consultation 3 and 5 in Group 2.

**TABLE 4.5** Statistical results of the subjective findings comparing the interval between consultation 1 and 5 in Group 1

	CONSULTATION 1		CONSULTATION 5		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	50.80	17.18	29.25	24.59	0.001	s
CMCC	29.33	16.69	13.48	13.32	0.000	s
McGILL	12.90	5.43	5.00	5.09	0.000	s

The results indicate that at the 5% level of significance there was an improvement between consultation 1 and 5 in Group 1

**TABLE 4.6** Statistical results of the subjective findings comparing the interval between consultation 1 and 5 in Group 2

	CONSULTATION 1		CONSULTATION 5		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	48.98	19.73	35.43	25.17	0.016	s
CMCC	30.36	10.71	19.18	14.87	0.003	s
McGILL	15.95	8.95	9.05	10.20	0.009	s

The results indicate that at the 5% level of significance there was an improvement between consultation 1 and 5 in Group 2



#### 4.2.2 Objective Data

**TABLE 4.7** Statistical results of the objective findings comparing the interval between consultation 1 and 3 in Group 1

	CONSULTATION 1		CONSULTATION 3		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	47.10	12.72	53.25	10.49	0.022	s
RLF	31.05	10.92	34.10	9.31	0.015	s
LLF	35.65	9.61	41.05	8.56	0.010	s
ALGOM	14.31	6.21	15.77	6.54	0.177	ns

The CROM results (forward flexion, right lateral flexion and left lateral flexion) indicate that at the 5% level of significance there was an improvement between consultation 1 and 3 in Group 1.

The Algometer results indicate that at the 5% level of significance there was no improvement between consultation 1 and 3 in Group 1.

**TABLE 4.8** Statistical results of the objective findings comparing the interval between consultation 1 and 3 in Group 2

	CONSULTATION 1		CONSULTATION 3		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	46.10	14.04	51.05	14.83	0.033	s
RLF	32.30	10.16	36.15	10.84	0.020	s
LLF	38.40	10.90	40.95	7.64	0.198	ns
ALGOM	16.12	7.44	16.94	7.46	0.478	ns

The CROM results in terms of forward flexion and right lateral flexion indicate that at the 5% level of significance there was an improvement between consultation 1 and 3 in Group 1.

The CROM results in terms of left lateral flexion and the Algometer results indicate that at the 5% level of significance there was no improvement between treatments 1 and 3 in Group 2.

**TABLE 4.9** Statistical results of the objective findings comparing the interval between consultation 3 and 5 in Group 1

	CONSULTATION 3		CONSULTATION 5		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	53.25	10.49	57.90	12.96	0.005	s
RLF	34.10	9.31	36.60	10.83	0.235	ns
LLF	41.05	8.56	42.05	11.30	0.556	ns
ALGOM	15.77	6.54	17.16	8.00	0.263	ns

The CROM results in terms of forward flexion and right lateral flexion indicates that at the 5% level of significance there was an improvement between consultation 3 and 5 in Group 1.

The CROM results in terms of left lateral flexion and the Algometer results indicates that at the 5% level of significance there was no improvement between treatments 3 and 5 in Group 1

**TABLE 4.10** Statistical results of the objective findings comparing the interval between consultation 3 and 5 in Group 2

	CONSULTATION 3		CONSULTATION 5		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	51.05	14.83	50.30	13.93	0.530	ns
RLF	36.15	10.84	35.90	9.68	0.896	ns
LLF	40.95	7.64	42.20	8.61	0.225	ns
ALGOM	16.94	7.46	18.18	9.55	0.401	ns

The results indicate that at the 5% level of significance there was no improvement between consultation 3 and 5 in Group 2

**TABLE 4.11** Statistical results of the objective findings comparing the interval between consultation 1 and 5 in Group 1

	CONSULTATION 1		CONSULTATION 5		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	47.10	12.72	57.90	12.96	0.000	s
RLF	31.05	10.92	36.60	10.83	0.031	ns
LLF	35.65	9.61	42.05	11.30	0.015	s
ALGOM	14.31	6.21	17.16	8.00	0.108	ns

The CROM results in terms of forward flexion and right lateral flexion indicate that at the 5% level of significance there was an improvement between consultation 1 and 5 in Group 1.

The CROM results in terms of left lateral flexion and the Algometer results indicate that at the 5% level of significance there was no improvement between treatments 1 and 5 in Group 1

**TABLE 4.12** Statistical results of the objective findings comparing the interval between consultation 1 and 5 in Group 2

	CONSULTATION 1		CONSULTATION 5		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	46.10	14.04	50.35	13.93	0.157	ns
RLF	32.30	10.16	35.90	9.68	0.082	ns
LLF	38.40	10.90	42.20	8.61	0.144	ns
ALGOM	16.12	7.44	18.18	9.55	0.065	ns

#### 4.3 NON – PARAMETRIC MANN-WHITNEY U-TEST

##### 4.3.1 Subjective Data

**TABLE 4.13** Statistical Results comparing Group 1 and 2 in terms of the subjective measurements from the first consultation

	GROUP 1		GROUP 2		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	50.80	17.18	48.98	19.73	0.786	ns
CMCC	29.33	16.69	30.36	10.71	0.448	ns
McGILL	12.90	5.43	15.95	8.95	0.393	ns

The results indicate that at the 5% level of significance there is no difference between the two groups at the first consultation.

**TABLE 4.14** Statistical Results comparing Group 1 and 2 in terms of the subjective measurements from the third consultation

	GROUP 1		GROUP 2		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	28.75	17.41	37.88	26.97	0.255	ns
CMCC	17.17	14.73	21.60	16.80	0.303	ns
McGILL	5.15	5.03	11.45	10.50	0.043	s

The NRS & CMCC results indicate that at the 5% level of significance there is no difference between the two groups at the third consultation. The McGill results indicate that at the 5% level of significance there is a difference between the two groups at the third consultation.

**TABLE 4.15** Statistical Results comparing Group 1 and 2 in terms of the subjective measurements from the fifth consultation.

	GROUP 1		GROUP 2		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
NRS	29.25	24.59	35.43	25.17	0.524	ns
CMCC	13.48	13.32	19.18	14.87	0.158	ns
McGILL	5.00	5.09	9.05	10.20	0.360	ns

The results indicate that at the 5% level of significance there is no difference between the two groups at the fifth consultation.

#### 4.3.2 Objective Data

**TABLE 4.16** Statistical Results comparing Group 1 and 2 in terms of the objective measurements from the first consultation

	GROUP 1		GROUP 2		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	47.10	12.72	46.10	14.04	0.957	ns
RLF	31.05	10.92	32.30	10.16	0.655	ns
LLF	35.65	9.61	38.40	10.90	0.385	ns
ALGOM	14.31	6.21	16.12	7.44	0.561	ns

The results indicate that at the 5% level of significance there is no difference between the two groups at the first consultation.

**TABLE 4.17** Statistical Results comparing Group 1 and 2 in terms of the objective measurements from the third consultation

	GROUP 1		GROUP 2		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	53.25	10.49	51.05	14.83	0.807	ns
RLF	34.10	9.31	36.15	10.84	0.644	ns
LLF	41.05	8.56	40.95	7.64	0.870	ns
ALGOM	15.77	16.94	16.94	7.46	0.882	ns

The results indicate that at the 5% level of significance there is no difference between the two groups at the third consultation.

**TABLE 4.18** Statistical Results comparing Group 1 and 2 in terms of the objective measurements from the fifth consultation

	GROUP 1		GROUP 2		P-VALUE	
	MEAN	S.D.	MEAN	S.D.		
FLEXION	57.90	12.96	50.35	13.93	0.069	ns
RLF	36.60	10.83	35.90	9.68	0.755	ns
LLF	42.05	11.30	42.20	8.61	0.914	ns
ALGOM	17.16	8.00	18.18	9.55	0.914	ns

The results indicate that at the 5% level of significance there is no difference between the two groups at the fifth consultation.

#### 4.4 DEMOGRAPHIC DATA

**TABLE 4.19** Prevalence of Age

AGE INTERVAL	GROUP 1		GROUP 2	
	No.	%	No.	%
18-25	6	15%	1	2.5%
26-35	1	2.5%	4	10%
36-45	3	7.5%	5	12.5%
46-55	9	22.5%	8	20%
56-65	1	2.5%	2	5%

The average age (mean) for group 1 was 39.

The average age (mean) for group 2 was 43.

**TABLE 4.20 Gender Distribution**

GENDER	GROUP 1	GROUP 2
	No.	No.
MALE	7	7
FEMALE	13	13

The overall male : female Ratio was 1 : 1.85

**TABLE 4.21 Race Distribution**

RACE	GROUP 1		GROUP 2	
	No.	%	No.	%
AFRICAN	1	2.5%	1	2.5%
INDIAN	4	2.5%	4	2.5%
COLOURED	2	5%	1	2.5%
WHITE	13	32.5%	14	35%



Figure 4.1 Graphical comparison of NRS mean scores for Groups 1 & 2

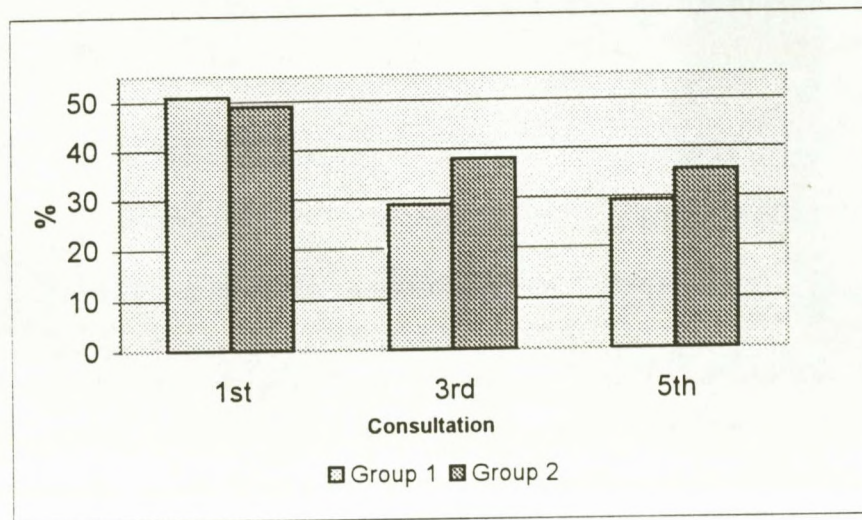


Figure 4.2 Graphical comparison of CMCC mean scores for Groups 1 & 2

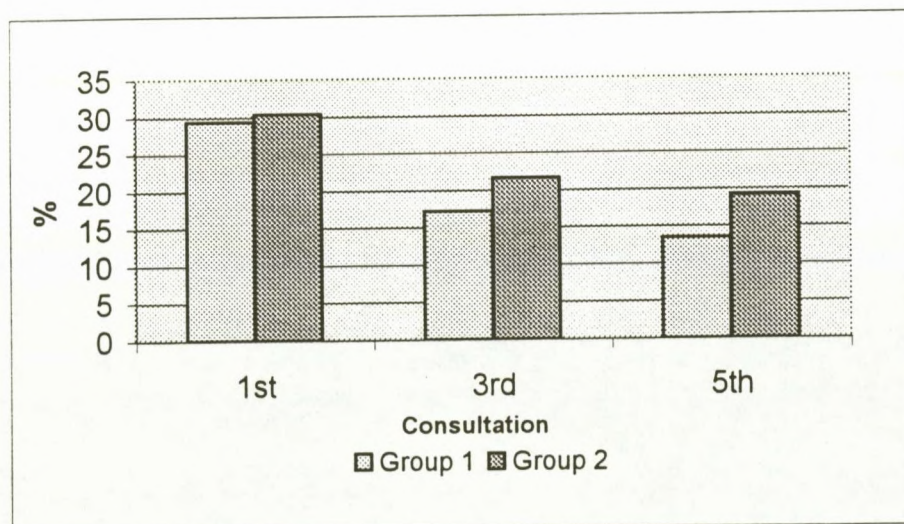




Figure 4.3 Graphical comparison of McGill mean scores for Groups 1 & 2

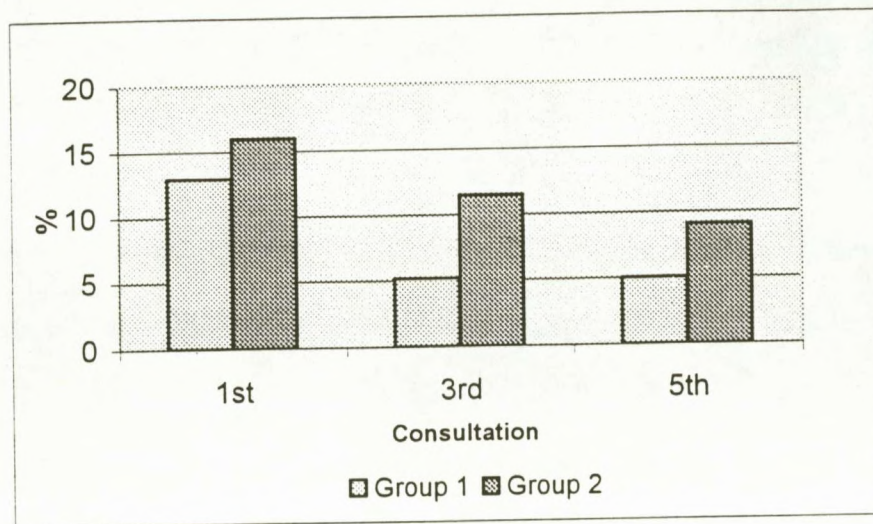


Figure 4.4 Graphical comparison of forward flexion mean scores for Groups 1 & 2

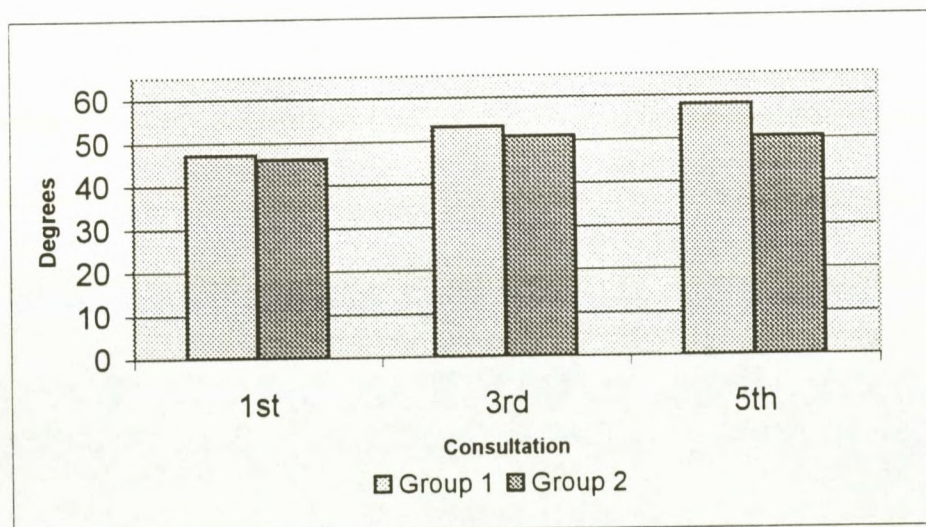




Figure 4.5 Graphical comparison of right lateral flexion mean scores for Groups 1 & 2

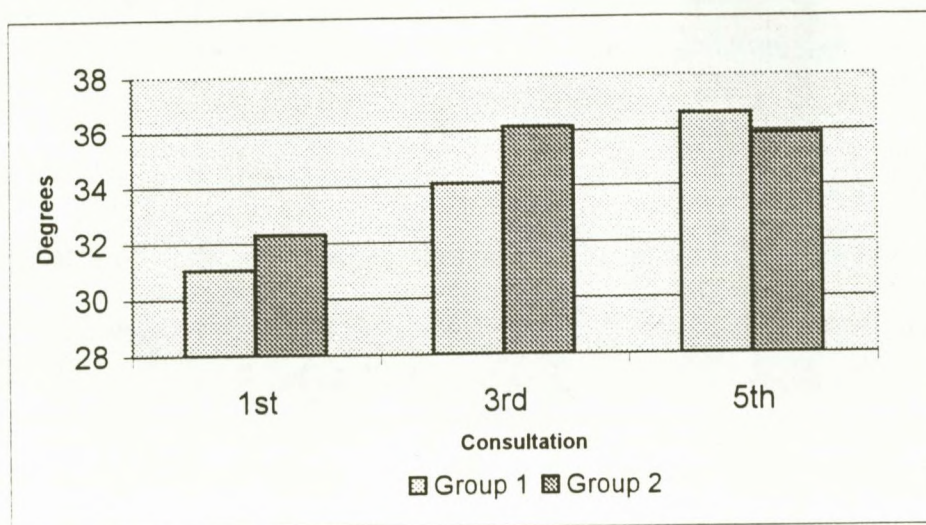


Figure 4.6 Graphical comparison of left lateral flexion mean scores for Groups 1 & 2

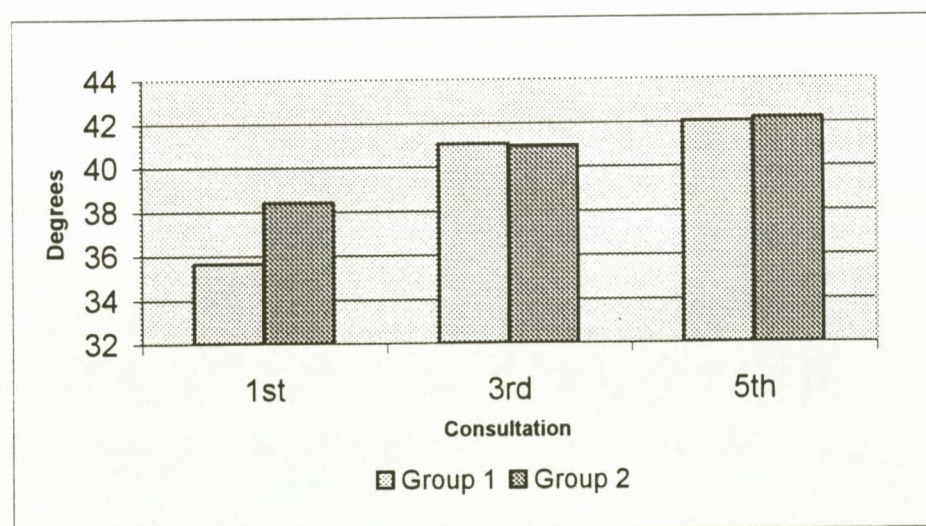
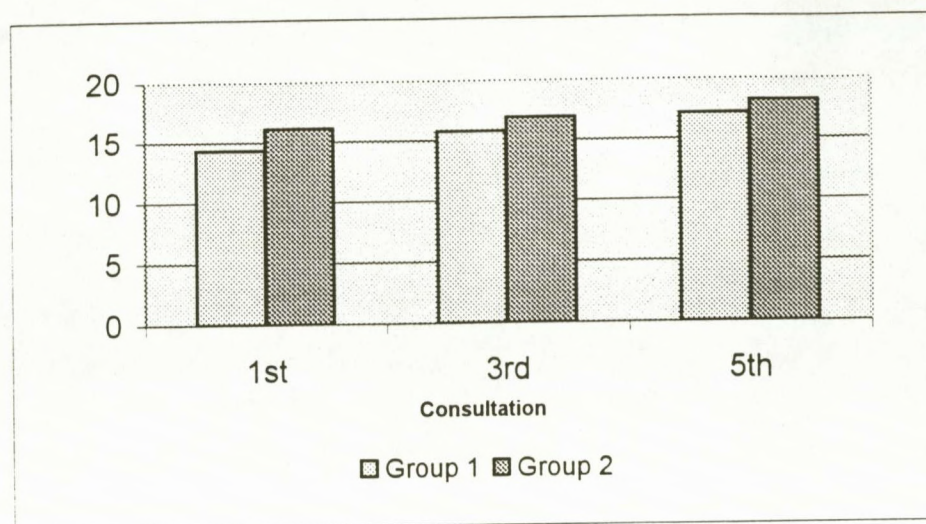




Figure 4.7 Graphical comparison of pain threshold measurements (Algometer)



## 5.0 DISCUSSION OF RESULTS

### 5.1 INTRODUCTION

This chapter involves the discussion of the results obtained from the subjective and objective data.

Intra-treatment comparison: The assessment of the subjective and objective data within groups 1 and 2 of the first to the fifth consultations represents the relative effectiveness of the respective treatment protocol.

Inter-treatment comparison: The comparison of the subjective and objective data of both groups from the first consultation exhibits any differences between the two groups in terms of their original signs and symptoms. The comparison of the results of the third consultation gives an indication of which treatment protocol has been more relatively effective initially. The comparison of the results of the fifth consultation gives an indication of which treatment protocol has been more relatively effective of the end of the study.

## 5.2 INTRAGROUP COMPARISON

### 5.2.1 Subjective Data

#### 5.2.1.1 The Numerical Pain Rating Scale- 101

Statistical analysis of the results of the Numerical Pain Rating Scale 101 for the first to the third consultation period, depicted an improvement in both Groups 1 and 2 (Tables 4.1 and 4.2)

In the comparison of the third to the fifth consultation, no improvement was revealed in both Groups 1 and 2 (Tables 4.3 and 4.4)

Analysis of the first to the fifth consultations showed an improvement in both Groups (Tables 4.5 and 4.6), indicating that both groups improved over the course of the study in terms of pain intensity measurement.

### Summary

The NRS 101 questionnaire gives an indication of pain perception experienced by patient the results. Both groups showed an improvement in the first to the fifth consultation period, as well as in the first to the third consultation period. Each treatment protocol, therefore, was effective in reducing pain levels.

#### **5.2.1.2 The CMCC Neck Disability Index**

Statistical analysis of the results of the CMCC Neck Disability Index for the first to the third consultation period depicted an improvement in both Group 1 and 2 (Table 4.1 and 4.2).

In the comparison of the third to the fifth consultation, an improvement was seen in Group 1 (Table 4.3) but not in Group 2 (Table 4.4)

Analysis of the first to the fifth consultation showed an improvement in both groups (Tables 4.5 and 4.6) indicating that a reduction of patient disability.

#### **Summary**

The CMCC Neck Disability Index is used to show the extent to which the patient's lifestyle is affected by the pain experienced. It is evident from the above results that the pain experienced and its effect on the patient's daily activities was reduced in both groups between consultation 1 and 3 and 1 and 5. In addition, there was an improvement in group 1 between consultation 3 and 5. This implies that both treatments were effective in reducing disability in daily life

#### **5.2.1.3 The Short-Form McGill Pain Questionnaire**

Statistical analysis of the results of the Short-Form McGill Pain Questionnaire for the first to the third consultation period, depicted an improvement in both Groups 1 and 2 (Table 4.1 and 4.2).

In the comparison of the third to the fifth consultation, no improvement was revealed in both Groups 1 and 2 (Tables 4.3 and 4.4).

Analysis of the first to the fifth consultation showed an improvement in both groups (Tables 4.5 and 4.6), indicating that both groups improved over the course of the study.

### **Summary**

The Short-Form McGill Pain Questionnaire provides information regarding the sensory, affective and evaluative dimensions of pain experienced. In both groups there was an improvement from the first to the third as well as the first to the fifth consultation period indicating an overall reduction in pain perceived.

### **5.2.2 Objective Data**

#### **5.2.2.1 Cervical Range of Motion**

Comparison of the first to the third consultation (Table 4.7) revealed an improvement in Group 1 in terms of all ranges of motion measured (forward flexion  $p=0.022$ , right lateral flexion,  $p=0.015$  and left lateral flexion  $p=0.01$ ).

In Group 2, an improvement was revealed in terms of forward flexion ( $p=0.033$ ) and right lateral flexion ( $p=0.02$ ) (Table 4.8), while no improvement occurred in terms of left lateral flexion ( $p=0.198$ ) (Table 4.8).



Comparison of the third to the fifth consultation (Table 4.9) revealed an improvement in Group 1 in forward flexion ( $p= 0.005$ ) but no improvement occurred in right lateral flexion ( $p= 0.235$ ) or left lateral flexion ( $p= 0.556$ ).

Comparison of the third to the fifth consultation (Table 4.10) revealed no improvement in Group 2 in terms of forward flexion ( $p= 0.535$ ), right lateral flexion ( $p= 0.896$ ) or left lateral flexion ( $p=0.225$ ).

Analysis of the data from the first to the fifth consultation (Table 4.11) revealed an improvement in Group 1 in all measured ranges of motion (forward flexion  $p= 0.000$ , right lateral flexion  $p= 0.031$  and left lateral flexion  $p= 0.015$ ).

No improvement was noted in Group 2 from the first to the fifth consultation (Table 4.12) in all measured ranges of motion (forward flexion  $p=0.157$ , right lateral flexion  $p= 0.082$  and left lateral flexion  $p=0.144$ ).

### **Summary**

It appears that certain ranges of motion improved at various consultations. An overall improvement in Group 1 from the first to the fifth consultation was noted, with no improvement noted in Group 2 during the same period.

#### **5.2.2.2 Algometer Readings**

Analysis of the Algometer readings for Groups 1 and 2 at first, third and fifth consultations revealed that subjectively there was no improvement in either group (Tables 4.7, 4.7, 4.9, 4.10, 4.11 and 4.12).

## **Summary**

Results from the other subjective findings revealed an improvement at some stages of the study so it is therefore felt that the Algometer readings may be inaccurate to some degree.

### **5.3 INTER-GROUP COMPARISON**

#### **5.3.1 Subjective Data**

##### **5.3.1.1 The Numerical Pain Rating Scale**

Statistical comparison of the first consultation of the two groups revealed no difference ( $p = 0.786$ ) in the degree of pain intensity, denoting a similarity in nature in terms of pain intensity (Table 4.13).

Analysis of the Numerical Pain Rating Scale 101 of the third consultation revealed no difference ( $p = 0.255$ ) between the two groups, indicating that both treatment protocols were equally effective (Table 4.14)

Results of data analysis of the fifth consultation indicated similar results to those of the third with no difference ( $P = 0.524$ ) being noted (Table 4.15).

## **Summary**

It is evident that both treatment protocols were equally effective in reducing the levels of pain experienced at the various treatment periods.

#### **5.3.1.2 The CMCC Neck Disability Index**

The results of the measurements of the CMCC Neck Disability Index for the first consultation for both Groups 1 and 2 disclosed no difference ( $p= 0.448$ ) in the degree of disability suffered by the patients (Table 4.13). This implies that both Groups 1 and 2 were similar in character in terms of disability.

Analysis of the data from the third consultation of both groups revealed no difference ( $p= 0.303$ ), indicating that both groups responded equally well to their respective treatment protocols (Table 4.14)

Similarly, analysis of the fifth consultation for both groups revealed no difference ( $p= 0.158$ ) between the treatment protocols (Table 4.15)

#### **Summary**

It is evident that neither treatment protocol reduced pain and disability more than the other as there was no difference between the groups at the three treatment periods.

#### **5.3.1.3 The Short-Form McGill Pain Questionnaire**

Comparison of the first consultation of both groups showed a difference ( $p= 0.393$ ), indicating that both groups were relatively similar with respect to pain perception (Table 4.13).

Data analysis of the third consultation measurements revealed no difference ( $p=0.043$ ) between the two groups (Table 4.14). This indicating that Group 1 received a more effective treatment protocol.

The fifth consultation measurements showed on difference ( $p=0.360$ ), indicating that the relative effectiveness of the treatments were similar in both groups (Table 14.15).

### **Summary**

As no difference was evident between the two groups at the first and fifth consultations, it is evident that both treatment protocols were equally effective in reducing pain in respect to it's sensory, affective and evaluative dimensions.

#### **5.3.2 Objective Data**

##### **5.3.2.1 Cervical Range of Motion**

Comparison of the initial cervical range of motion measurements showed no difference between the two groups, indicating that range of motion was similar at the beginning of the trial (Table 4.16).

Comparison of data from the third consultation revealed that there was no difference between the two groups (Table 4.17). Thus it can be said that neither treatment protocol was more effective then the other in terms of range of motion.

Data analysis of the final consultation revealed no difference between the two groups, indicating that the treatment's relative effectiveness was equal in both groups (Table 4.18).

### **Summary**

As no difference was noted at any of the treatment periods, it can be said that both groups responded equally in terms of cervical range of motion

#### **5.3.2.2 Algometer Readings**

No difference was noted ( $p = 0.561$ ) between the two groups with respect to data from the first consultation, indicating that the groups were similar in terms of initial pain threshold levels at the beginning of the study (Table 4.16).

Comparison of algometer readings for the third consultation revealed no difference ( $p = 0.882$ ) between the two groups, indicating that both groups responded equally to their treatment protocol (Table 4.17).

Final consultation measurements again indicated no difference ( $p = 0.914$ ) and thus it can be concluded that the treatment's relative effectiveness was equal in both groups (Table 4.18).

### **Summary**

As no difference was noted between the two groups at all three of the treatment periods, it can be said that both groups responded equally to their treatments in terms of algometer readings.

## 5.4 DISCUSSION

### 5.4.1 Intra- group Hypotheses

It was hypothesised that there would be an improvement between consultation 1 and 3, between consultation 3 and 5 and finally between consultation 1 and 5 in terms of subjective and objective clinical findings.

The two hypotheses pertaining to improvement between consultation 1 and 3 and 1 and 5 are accepted as there was improvement in terms of subjective and objective clinical findings. The hypothesis pertaining to the improvement between consultation 3 and 5 is rejected as there was no improvement in terms of subjective and objective clinical findings.

It can be concluded that both treatment protocols were initially effective but they did not maintain the same rate of improvement during the study.

### 5.4.2 Inter- group Hypotheses

It was hypothesised that there would be a difference between the two groups with respect to the subjective and objective clinical findings, showing that one treatment protocol was more effective than the other.

On comparison of Group 1 and Group 2 in terms of subjective and objective data, it is evident that no differences occurred at the initial, or final consultations.

At the third consultation a difference did occur in terms of subjective data but no differences occurred in terms of objective data.

## **CONCLUSIONS**

Both groups showed improvement as a result of their respective treatments. Statistically, there was a difference between the two groups at the third consultation in terms of the Short-form McGill Pain Questionnaire. There were no other differences between the two groups indicating that both forms of treatment were predominantly equally effective.

Based on these results there seems to be a possibility that inflammation may not play as important a role in the facet syndrome as traditionally postulated due to the fact that the group receiving Diclofenac showed no greater improvement than the other group.

### **5.5 LIMITATIONS OF THE STUDY**

There are various reasons as to why the subjective and objective measurements may have had their limitations in terms of the condition being treated and the treatment protocol being administered.

It is possible that the questionnaires used were not fully understood by the patients who may have affected their response, and therefore outcome of the results. Patients may have also recorded improvements that were beyond those actually felt in order to please the researcher.

Objective measurements may be incorrect due to human error when recording measurements and the possibility of incorrect user methods. The accuracy of the researcher when re-finding the cervical facet on subsequent visits may also need to be considered.

The small sample size of this study is also a weakness and should be considered in future studies of this sort.

Another point to be considered is the demographics of the study. The age distribution was relatively acceptable when comparing the two groups and was good within each group, with a large percentage of the patients being between the ages of 46-55 (Table 4.19).

The race distribution of the study was poor as 67.5% of the patients were white, which is a poor representation of the general population (Table 4.21). This is a point to consider when looking at the limitations of the study.

## 5.6 **COMPARISON OF THE RESULTS WITH OTHER STUDIES**

In a search of the current literature no studies could be found combining both PNF stretching and NSAID's for the treatment of neck pain. The following studies show some similarities to this study:

Comparison to a study done by McCarthy et al. (1997)



In a study to determine if a short regime of stretching exercises could affect the cervical range of motion, it was found that contract-relax stretching procedures were effective in increasing active cervical range of motion in the short term (McCarthy et al. 1997)

It was concluded that performing stretching exercises increases active cervical range of motion in the short term but the effects wear off rapidly if the stretching regime is discontinued.

The results of this study are in keeping with those of McCarthy et al. as it was also found that the patients responded well initially, but the improvement did not continue over an extended time period.

Comparison to a study done by Mac Dougal (1999)

In a study to determine the relative effectiveness of Contract-Relax-Agonist-Contract (CRAC) stretching, a component of PNF stretching, as opposed to static stretching in the treatment of active myofascial trigger points of the shoulder and neck muscles some similarities in the results of this study exist.

Statistical analysis revealed that within both groups there was significant subjective and objective improvement during the treatment program. This improvement was, however, not maintained after the one-month follow up period. There was no clinical statistical difference between the two treatments indicating that both static and CRAC (PNF) stretching were equally effective protocols.

Comparison to a study done by Koes et al. (1991)

In a randomised trial, the effectiveness of manual therapy, physiotherapy, continued treatment by the general practitioner, and placebo therapy (detuned ultrasound and detuned short-wave diathermy) were compared for patients (n= 256) with nonspecific back and neck complaints lasting for at least 6 weeks. Physiotherapy consisted of exercises, massage and physical therapy modalities. Manual therapy consisted of manipulative techniques and continued treatment by the GP consisted of prescription of medication (eg. Analgesics and NSAIDs).

Both physiotherapy and manual therapy decreased the severity of complaints more and had a higher global perceived effect compared to continued treatment by the general practitioner.

This study is comparable to that of Koes et al. in that it combined treatments (i.e. stretching and NSAIDs) which were previously used separately (as in the study by Koes et al.)

## 6.0 RECOMMENDATIONS AND CONCLUSIONS

### 6.1 RECOMMENDATIONS

The author of this dissertation suggests the following changes to the treatment protocol for anyone wanting to repeat this study:

A larger sample size is recommended in order to obtain a better representative of the general population.

Of concern, when involving medication in a research trial, is patient compliance. Future trials should endeavour to provide a more controlled environment in which the medication is taken to ensure that both the experimental and placebo medications are taken timeously and correctly.

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 homogeneity.

The validity of this study could be increased by having someone else, as well as the researcher, taking the objective readings to test inter examiner reliability.

Double blinding the study i.e. researcher as well as patient being unaware of who is receiving experimental medication would add further weight to the findings as compared to single blind where only the patient is unaware of this.

This would entail screening of all patients, NSAID and placebo and would considerably increase the overall cost of the study.

It is recommended that a future study be done with the use of a muscle relaxant instead of an NSAID (in this case Diclofenac) as the results indicate that the NSAID was of little benefit. The rationale for the use of an NSAID was based on the traditional view that inflammation plays an important role in the aetiology of Cervical Facet Syndrome. Future studies should be done to investigate the validity of this.

## 6.2 CONCLUSIONS

The results of this study indicate that both treatment protocols were effective in treating cervical facet syndrome.

In general, no significant difference in efficacy could be demonstrated between the two treatment approaches at the 95% confidence level, with the exception of the Short-Form McGill Pain Questionnaire findings. These showed the combination of PNF and NSAID administration to be the more effective treatment protocol at the third consultation.

The median and mean data taken from the subjective questionnaires and objective measurements also indicated that neither group showed any advantage over the other in terms of treatment effectiveness. These results are comparable to those of Mac Dougal (1999).

It was found that patients initially responded well to the PNF stretching which is in keeping with the results of McCarthy et al. (1997) as mentioned previously.

Combining the use of NSAIDs with chiropractic care may present one with moral and clinical dilemmas. The use of NSAIDs in chiropractic could be said by some, to go against the very essence of the profession, not to mention the possible increase in treatment cost (unless the use of NSAIDs can be shown to shorten the treatment time). Ultimately, of primary concern, is the welfare of the patient with the best possible treatment being the one of first choice.

"The key to treating any condition is proper evaluation of the problem and then becoming problem orientated, adapting the methods to the problem rather than the problem to the methods. " DonTigney (1979).

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**INFORMED CONSENT FORM**  
( To be completed in duplicate by patient /subject )

Appendix A

Date : \_\_\_\_\_

Title of research project : \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Name of supervisor : \_\_\_\_\_

Name of research student : \_\_\_\_\_  
\_\_\_\_\_

Please circle the appropriate answer

YES NO

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

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

Please Print in block letters:

Patient /Subject Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Parent /Guardian Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Witness Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Research Student Name: \_\_\_\_\_ Signature: \_\_\_\_\_

**DR D.R. MOODLEY**

( B. Med.Sc. Hons ; MBCHB ) PRACTICE NO : 1565192  
GENERAL MEDICAL PRACTITIONER & CLINICAL ANATOMIST

23 KLAARWATER RD  
SHALLCROSS  
4093  
TEL : 491471  
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16 AUTUMN GROVE  
MALVERN  
4093  
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CELL : 0824659742

VAT NO : 4560179642

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

**QUESTIONNAIRE :**

1. Have you had any reaction, allergic or otherwise to any inflammatory drug, or drug used in the management of pain or musculo-skeletal disorders (e.g. Aspirin, Disprin, Voltaren, Feldene) ?  
  
YES    \_\_\_\_  
NO     \_\_\_\_
2. Have you ever had any disorder of the liver, biliary tract or pancreas ?  
  
YES    \_\_\_\_  
NO     \_\_\_\_
3. Have you ever suffered with recurrent heartburn, peptic ulcers, bleeding disorders, including the vomiting of blood or passage of blood rectally or otherwise ?  
  
YES    \_\_\_\_  
NO     \_\_\_\_
4. Are you currently taking Warfarin, Aspirin, other anticoagulants or anti-inflammatory agents or any other drug at all, whether allopathic, herbal or otherwise, including steroid based agents ?  
  
YES    \_\_\_\_  
NO     \_\_\_\_
5. Have you ever suffered any dysfunction of the kidneys, bladder or urinary system ?  
  
YES    \_\_\_\_  
NO     \_\_\_\_
6. Have you ever suffered from any medical condition not disclosed above  
  
YES    \_\_\_\_  
NO     \_\_\_\_

DETAILS \_\_\_\_\_

7. Have you had any surgery previously ?

YES \_\_\_\_\_  
NO \_\_\_\_\_

DETAILS \_\_\_\_\_  
\_\_\_\_\_

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

YES \_\_\_\_\_  
NO \_\_\_\_\_

REASON \_\_\_\_\_  
\_\_\_\_\_

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

YES \_\_\_\_\_  
NO \_\_\_\_\_

DETAILS \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

YES \_\_\_\_\_  
NO \_\_\_\_\_

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

YES \_\_\_\_\_  
NO \_\_\_\_\_

**FEMALE PATIENTS:**

1. Are you pregnant now ?

YES \_\_\_\_\_  
NO \_\_\_\_\_

2. State the onset date of your last period \_\_\_\_\_

3. Are your periods regular ? \_\_\_\_\_

**THE ABOVE DETAILS ARE TRUE TO THE BEST OF MY ABILITY.**

Patient \_\_\_\_\_

I.D. \_\_\_\_\_

Parent if under 21 \_\_\_\_\_

I.D. \_\_\_\_\_

DECLARATION :

Appendix C

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

\_\_\_\_\_

AND MAY USE THE FOLLOWING DRUG

\_\_\_\_\_

DOSAGE

\_\_\_\_\_

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

PARENT : \_\_\_\_\_

RESEARCH STUDENT : \_\_\_\_\_

CLINICAL SUPERVISOR : \_\_\_\_\_

MEDICAL DOCTOR : \_\_\_\_\_

DATE : \_\_\_\_\_

## INDEMNITY

Appendix D

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

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

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

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

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

---

**SIDE EFFECTS OF ANTI- INFLAMMATORY DRUGS :**

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

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

---

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

**PATIENT:** \_\_\_\_\_

**PARENT :** \_\_\_\_\_

**DATE :** \_\_\_\_\_



Scheduling Status (S3)

Proprietary name (and dosage form)

# Cataflam® D Dispersible Tablets

## Appendix E

### Composition

One CATAFLAM D Tablet contains 46.5 mg of diclofenac free acid, which is equivalent to 50 mg diclofenac sodium.

### Pharmacological classification

A 3.1 Antirheumatics (anti-inflammatory agents)

### Pharmacological action

CATAFLAM D is a non-steroidal compound with antirheumatic, anti-inflammatory, analgesic and antipyretic properties. *In vitro*, its active substance strongly inhibits prostaglandin-synthetase and also has an inhibitory effect on platelet aggregation. Inhibition of prostaglandin biosynthesis, which has been demonstrated experimentally, is regarded as having an important bearing on its mechanism of action. Prostaglandins play a major role in the causation of inflammation, pain and fever.

### Pharmacokinetics

#### Absorption:

Absorption of diclofenac from CATAFLAM D sets in rapidly after administration. The plasma concentrations show a linear relationship to the size of the dose. Peak levels are attained in 20 to 60 minutes after ingestion on an empty stomach.

The active substance is subject to first-pass metabolism.

#### Protein binding: 99.7 %

The mean terminal elimination half-life of the unchanged drug is 1 to 2 hours.

#### Excretion:

Approximately 60 % of the dose administered is excreted via the kidneys in the form of metabolites and less than 1 % in the unchanged form. About 30 % of the dose is excreted in metabolised form in the faeces.

### Indications

As short-term treatment in the following acute conditions:

Flare-up of osteoarthritis.

Painful musculoskeletal conditions.

Non-articular rheumatism.

Acute attacks of gout.

Painful post-operative and post-traumatic inflammation and swelling, pain following dental surgery.

Symptomatic treatment for primary dysmenorrhoea.

### Contra-indications

Gastric or intestinal ulcer. Allergy to the active substance. CATAFLAM D is also contra-indicated in asthmatic patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or by other medicines with prostaglandin-synthetase inhibiting activity.

CATAFLAM D should not be used in patients with porphyria.

### Pregnancy.

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

### Warnings

It should be noted that only short-term treatment is recommended with CATAFLAM D.

Strict accuracy of diagnosis and close medical surveillance are imperative in patients with symptoms indicative of gastro-intestinal disease, a case history suggestive of gastro-intestinal ulceration, ulcerative colitis, Crohn's disease, in patients suffering from impaired hepatic function and pre-existing dyshaemopoiesis or disorders of blood coagulation.

CATAFLAM D should be administered with caution in patients with hepatic or renal failure.

Serious interactions have been reported after the concomitant use of methotrexate and diclofenac.

### Dosage and directions for use

#### Adults

For the relief of acute pain, the tablets should preferably be taken on an empty stomach. The tablets are dropped into a glass of water and the liquid stirred to aid dispersion before swallowing. Since a proportion of the active substance may remain in the glass after swallowing, it is advisable to rinse the glass with a small amount of water and to swallow again.

As a rule, the initial daily dosage is 2 to 3 CATAFLAM D tablets. In milder cases, 2 CATAFLAM D tablets daily are usually sufficient. The maximum daily dose is 3 CATAFLAM D tablets.

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

In primary dysmenorrhoea the daily dosage, which should be individually adapted, is 1 to 3 CATAFLAM D tablets. Treatment should be started upon appearance of the first symptoms and, depending on their intensity, continued for a few days.

### Side-effects and special precautions

#### Gastro-intestinal tract

More frequently: Epigastric pain, nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, eructation, anorexia, local irritation.

Less frequently: Gastro-intestinal bleeding may occur, haematemesis, melaena, bloody diarrhoea, gastric or intestinal ulcer with or without bleeding or perforation.

Lower gut disorders such as non-specific haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's proctocolitis, aphthous stomatitis, glossitis, oesophageal lesions, diaphragm-like intestinal strictures, constipation and pancreatitis.

#### Central Nervous System

More frequently: Headache, dizziness, vertigo and nervousness. Less frequently: Tiredness. Disturbances of sensation (including paraesthesia) and memory, disorientation, insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reactions, aseptic meningitis.

#### Special senses

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

#### Skin

More frequently: Rash and skin reactions.

Less frequently: Urticaria. Bullous eruptions, eczema, erythema

multiforme, Stevens-Johnson syndrome, Lyell's syndrome (acute toxic epidermolysis), erythroderma (exfoliative dermatitis), loss of hair, photosensitivity reaction, purpura including allergic purpura.

#### Kidney

Less frequently: Oedema, acute renal failure, urinary abnormalities such as haematuria, proteinuria, interstitial nephritis, nephrotic syndrome, papillary necrosis.

#### Liver

More frequently: Elevated transaminase levels (SGOT, SGPT). Less frequently: Hepatitis with or without jaundice. Fulminant hepatitis.

#### Blood

Less frequently: Dyshaemopoiesis (leucopenia, thrombocytopenia, aplastic anaemia, haematolytic anaemia and agranulocytosis).

#### Hypersensitivity

Less frequently: Allergic reactions (eg bronchospasm, anaphylactic / anaphylactoid systemic reactions including hypotension).

Vasculitis, pneumonitis.

#### Cardiovascular system

Less frequently: Palpitation, chest pain, hypertension, congestive heart failure.

#### Precautions

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

In the instances where peptic ulceration or gastro-intestinal bleeding occur in patients under treatment with CATAFLAM D, the medicine should be withdrawn.

In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Owing to the importance of prostaglandins for maintaining renal blood flow, patients suffering from impairment of hepatic, cardiac or renal function, as well as the elderly, patients being treated with diuretics and those with extracellular volume depletion from any cause, eg the peri- or post-operative phase of major surgical operations, should be carefully monitored.

Elevation of one or more liver enzymes may occur with CATAFLAM D. During prolonged treatment with CATAFLAM D, blood counts and monitoring of hepatic and renal function are indicated.

If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (eg eosinophilia, rash, etc), CATAFLAM D should be discontinued. Hepatitis may occur without prodromal symptoms. Caution is called for when using CATAFLAM D in patients with hepatic porphyria, since CATAFLAM D may trigger an attack.

Allergic reactions, including anaphylactic / anaphylactoid reactions, can also occur without earlier exposure to the medicine.

CATAFLAM D may mask the signs and symptoms of infection due to its pharmacodynamic properties.

Patients experiencing dizziness or other central nervous disturbances should refrain from driving a vehicle or operating machines.

#### Interactions

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

Concomitant administration of glucocorticoids or other non-steroidal anti-inflammatory agents, may aggravate gastro-intestinal side-effects.

Concurrent treatment with two or more non-steroidal anti-inflammatory agents may promote the occurrence of side-effects.

The bioavailability of CATAFLAM D is reduced by acetylsalicylic acid, and that of acetylsalicylic acid by CATAFLAM D, when the two agents are administered together.

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

Both hypoglycaemic and hyperglycaemic effects in the presence of CATAFLAM D which necessitated changes in the dosage of hypoglycaemic agents have been reported.

Increased nephrotoxicity of cyclosporin may occur through effects of CATAFLAM D on renal prostaglandins.

There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.

#### Lactation

Following oral doses of 100 mg daily, no active substance could be found in the breast milk (limit of detection: 10 ng/ml).

### Known symptoms of overdose and particulars of its treatment

See side-effects and special precautions.

#### Treatment

There is no specific antidote. Symptomatic and general supportive measures.

Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation and respiratory depression.

Specific therapies such as forced diuresis, dialysis, or haemoperfusion are probably of no help in eliminating CATAFLAM D because of its high protein-binding rate and extensive metabolism.

Absorption from tablets should be prevented as soon as possible after the overdose by means of gastric lavage and treatment with activated charcoal.

### Identification

White, flat, triangular tablets with bevelled edges. One side bears the imprint CG, the other side a raised V. Width, measured from flattened vertex: approximately 9 mm. Thickness: approximately 3.9 mm.

### Presentation

CATAFLAM D is supplied in packs of 15 tablets.

### Storage instructions

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

### Registration number

28/3.1/0306

### Name and business address of the applicant

NOVARTIS SOUTH AFRICA (Pty) Ltd

72 Steel Road

Spartan

Kempton Park, 1619

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

\*Registered Trade Mark

55760

**PATIENT TREATMENT DIARY****Appendix F**

Patient Name: \_\_\_\_\_ File No.: \_\_\_\_\_ Group: \_\_\_\_\_

Treatment No. 1	
Treatment No. 2	
Treatment No. 3	
Treatment No. 4	
Treatment No. 5	

**PATIENT MEDICATION DIARY**

	1 <sup>st</sup> Dose	2 <sup>nd</sup> Dose	3 <sup>rd</sup> Dose
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			

The dosage is three sachets spread at equal time intervals during the day. Medication is to be dissolved in half a glass of water. Please indicate in each block the time at which you took the medication.

## PATIENT INFORMATION LETTER

Appendix G

Dear Patient,

Welcome to this research study. You have been selected to participate in a clinical trial comparing two treatment protocols for your neck pain. You have a common condition seen by chiropractors, which is known as Cervical Facet Syndrome. The aim of this study is to determine if PNF stretching in conjunction with anti-inflammatory medication is more effective than PNF stretching alone.

There will be 2 groups containing 30 patients each. One group will be treated with PNF stretching and Cataflam, a non-steroidal anti-inflammatory drug and the other with PNF stretching alone. You will be randomly assigned to a group but will not know which treatment protocol you are receiving.

The medication must be taken three times daily for five days as will be explained to you. You will be required to fill in a medication diary while taking the medication. You will also be required to come in and be treated five times over two weeks.

During the study you will not be able to receive any other form of treatment for your condition and you are further asked to refrain from any new or unaccustomed activities. Please report to me immediately any change in your health which begin during the study. These may be side-effects of the medication. There is a small risk of developing side-effects to Cataflam which are listed in the attached copy of the Cataflam package insert. For your protection you will undergo a screening procedure in the form of a questionnaire which has been designed to detect if you are at risk of developing side-effects.

Your full co-operation in this study will assist the chiropractic profession in increasing its knowledge on, and improving its treatment of Cervical Facet Syndrome.

Treatment is free of charge and will be under the supervision of a qualified chiropractor. A medical doctor has been advised about the trial and may be called upon if the need arises. You are free to withdraw from the study at any time and if you have any questions please do not hesitate to ask me.

Thanking you in advance for your time.

Yours sincerely

Heidi Upneck.

(6th year chiropractic resident)

**TECHNIKON NATAL CHIROPRACTIC DAY CLINIC**  
**CASE HISTORY**

Appendix H

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

**FOR CLINICIAN'S USE ONLY**

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

**Case History:**

**Examination:**

Previous:

Current:

**X-Ray Studies:**

Previous:

Current:

**Clinical Path. lab:**

Previous:

Current:

**Case Status:**

PTT:            Conditional:            Signed Off:            Final Sign out:

**Recommendations:**

**Intern's Case History**

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

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

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC Appendix I

**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:

- Masses (intra- or extramural)
- Aorta:

**Percussion** - Rebound tenderness:

- Ascites:
- Masses:

**Auscultation** - Bowel sounds:

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

**Rectal Examination**

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

## 6. G.U.T EXAMINATION

**External genitalia:**

**Hernias:**

**Masses:**

**Discharges:**

## 7. NEUROLOGICAL EXAMINATION

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

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

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

**Evidence of head trauma:**

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

**Cranial Nerves:**

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

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



- 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:

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

Patient: \_\_\_\_\_ File: \_\_\_\_\_

Date: \_\_\_\_\_ Intern/Resident: \_\_\_\_\_

Clinician: \_\_\_\_\_ Sign: \_\_\_\_\_

**OBSERVATION:**

Posture  
Swellings  
Scars  
Discolouration  
Hair Line  
Bony & Soft Tissue Contours

Shoulder position:

Left:

Right:

Muscle spasm

Facial expression

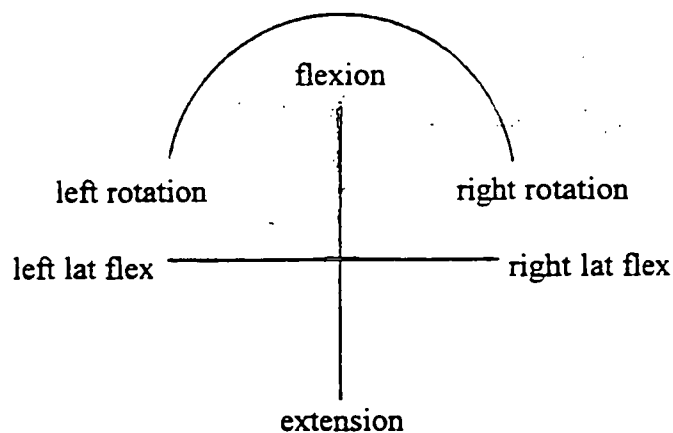
**RANGE OF MOTION:**

Flexion (45'):

L/R Rotation (70'):

Extension (70'):

L/R Lat Flex (45'):



**PALPATION:**

Lymph Nodes  
Thyroid Gland

Trachea

**ORTHOPAEDIC EXAMINATION:**

Tenderness

Trigger Points:

SCM

Scalenii

Post Cervicals

Trapezius

Lev Scap

Doorbell sign

Kemp's test

Cervical distraction

Halstead's test

Hyperabduction test

Shoulder abduction test

Cervical compression

Lateral compression

Adson's test

Costoclavicular test

Eden's test

Shoulder depression test

Patient Name: \_\_\_\_\_ File No.: \_\_\_\_\_

Date: \_\_\_\_\_

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

**CROM DATA**

Treatment no.	1	3	5
Fwd flexion			
Right lat flexion			
Left lat flexion			

**ALGOMETER DATA**

Treatment no.	1	3	5
Reading			

CMCC NECK DISABILITY INDEX

Patient Name: \_\_\_\_\_ File no.: \_\_\_\_\_ Date: \_\_\_\_\_

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

Section 1 - Pain Intensity

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

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

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

Section 7 - Work

- ☐ I can do as much work as I want to .  
☐ I can do only 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 3 - Lifting

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

Section 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 like with moderate pain in my neck.  
☐ I cannot 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 at all.

Section 4 - Reading

- ☐ I can read as much as I want to without pain in my neck.  
☐ I can read as much as I want to with slight pain in my neck.  
☐ I can read as much as I want with moderate pain in my neck.  
☐ I cannot 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 9 - Sleeping

- ☐ I have no trouble sleeping.  
☐ My sleep is slightly disturbed (<1 hour sleep loss).  
☐ My sleep is mildly disturbed (1-2 hours sleep loss).  
☐ My sleep is moderately disturbed (2-3 hours sleep loss).  
☐ My sleep is greatly disturbed (3-5 hours sleep loss).  
☐ My sleep is completely disturbed (5-7 hours sleep loss).

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 moderate headaches which come frequently.  
☐ I have severe headaches which come frequently.  
☐ I have headaches almost all the time.

Section 10 - Recreation

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

# Short-form McGill Pain Questionnaire (SF-MPQ) Ronald Melzack (1984)

Date: \_\_\_\_\_ File no.: \_\_\_\_\_ Visit no: \_\_\_\_\_

Patient name: \_\_\_\_\_

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

Numerical Rating Scale - 101 Questionnaire

Date: \_\_\_\_\_ File no: \_\_\_\_\_ Visit no: \_\_\_\_\_

Patient name: \_\_\_\_\_

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

Please write only one number.

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

Please write only one number.

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