THE RELATIVE EFFECTIVENESS OF NON-STEROIDAL ANTI-INFLAMMATORY MEDICATION AS COMPARED TO A HOMOEOPATHIC COMPLEX IN THE TREATMENT OF CERVICAL FACET SYNDROME

BY

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I, Stuart Estridge Hepburn, do declare that this dissertation is representative of my own work.

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DEDICATION

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ABSTRACT

The literature shows neck pain, including cervical facet syndrome, to be a common problem. It also provides evidence that inflammation plays a role in cervical facet pathology. Prescription of nonsteroidal anti-inflammatory drugs (NSAIDs) is the first line treatment of allopathic physicians for neck pain. Traumeel S is a complex of homoeopathic remedies indicated in a variety of anti-inflammatory, traumatic and degenerative disorders. It has been clinically shown that Traumeel S is effective in the treatment of inflammation. There is a paucity of clinical research into the treatment of acute neck pain, including cervical facet syndrome, with anti-inflammatory agents. The aim of this study was to compare the relative effectiveness of piroxicam, an NSAID, with Traumeel S in the treatment of acute cervical facet syndrome.

The study was a double-blind, comparative, clinical trial. Fifty consecutive patients complying with all inclusion criteria were randomly assigned to either the Traumeel S group or the piroxicam group. Each patient in the NSAID group received 40 mg of piroxicam per day for the first two days and 20 mg per day for the following 5 days. The Traumeel S group received the same dosage of placebo piroxicam capsules and 3 Traumeel S tablets in crushed form, per day. Placebo Traumeel S tablets, also in crushed form, were taken 3 times a day by the NSAID group to facilitate blinding.

Patients were assessed on days 1, 3 and 7 of the trial. Subjective assessment involved two questionnaires: the CMCC Neck Disability Index, and the NRS-101

Pain Scale. Objective assessment involved goniometer and pressure algometer readings as well as motion palpation of the cervical spine.

The data obtained was statistically analysed. Mann-Whitney Unpaired Tests were used to compare the results between the two groups (α = 0.05 level of significance). Wilcoxon Signed Rank Tests were used to compare the results obtained within the groups (α = 0.05 level of significance). The power of the between-group tests were calculated to determine the likelihood of making a type II error.

Within group tests showed overall significant ($p \leq 0.025$) improvement in both groups in the NRS-101 Pain Scale scores, the CMCC Neck Disability Index ratings and motion palpation findings. In the case of the CMCC Neck Disability Index, early improvement occurred and was maintained throughout the treatment in both groups. The Traumeel S group showed a rapid significant ($p \leq 0.025$) improvement in motion palpation findings, while the piroxicam group showed a rapid significant improvement ($p \leq 0.025$) in NRS-101 pain ratings. Overall significant ($p \leq 0.025$) improvement occurred in the Traumeel S group in terms of algometer readings and in the piroxicam group in terms of goniometer readings in flexion, and left and right lateral flexion.

Between-group tests revealed neither group showing statistically significant ($p \leq 0.025$) superiority over the other, in terms of any of the variables tested.

This study shows that the use of Traumeel S is as effective as using piroxicam in the treatment of acute cervical facet syndrome. For use in the treatment of acute cervical facet syndrome it is the opinion of the researcher that Traumeel S should be chosen over piroxicam in order to eliminate the risk of side effects. If, however, the patient is in extreme pain as a result of cervical facet syndrome, the use of piroxicam should be considered due to its rapid pain reducing action.

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DEFINITION OF TERMS

ADJUSTMENT

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

FIXATION

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

SPONDYLOSIS (CERVICAL)

A general term for the degenerative changes due to osteoarthritis (*Dorland's Illustrated Medical Dictionary* , 1985).

1. INTRODUCTION

Takala et al. (1982) found a prevalence of neck pain of 16% in men and 18% in women. Cassidy, Lopes and Yong-Hing (1992) agree that neck pain is a common problem and state that most cases are attributable to mechanical dysfunction. The common misdiagnosis of neck pain without neurological signs has lead to more attention being paid to the cervical facet joints as a source of pain (Aprill and Bogduk, 1992).

Roy et al. (1988) claim the causative pathology of cervical facet syndrome to be inflammation in the synovial capsule of the facet joints and irritation of the nerve roots.

Panzer (1995: 420), following a review of studies, claims that injection of local anaesthetic or cortisone into a specific facet joint, which results in pain relief, is generally considered as confirmation of facet syndrome.

According to Dishman (1988) cervical spine injury results in the release of several chemical mediators of inflammation, the actions of which may be inhibited by steroidal and non-steroidal anti-inflammatory drugs.

According to Koes et al. (1997) NSAIDs appear to be the most commonly prescribed type of medication. The first line treatment of allopathic physicians for

neck pain is usually the prescription of nonsteriodal anti-inflammatory drugs (Dabbs and Lauretti, 1995).

Notwithstanding this, Dabbs and Lauretti (1995) were unable to locate even one randomised, controlled trial examining NSAID use specifically for neck pain. Since then an unpublished trial by Williamson A.R. (1998) on manipulation in conjunction with NSAIDs compared to manipulation in conjunction with placebo in the treatment of cervical facet syndrome has been completed. Both groups of intervention proved to be effective but neither showed a statistically significant superiority over the other. No other studies involving NSAIDs and acute neck pain were found since 1995.

A pilot clinical trial comparing acupuncture, an NSAID and spinal manipulation was conducted on chronic spinal pain syndromes. Spinal manipulation was the only group which achieved statistically significant improvement (Giles and Müller, 1999).

Despite the perceived safety of NSAIDs, they have a significant risk of severe complications. The most frequent and serious of these are gastrointestinal ulcers and haemorrhage (Dabbs and Lauretti, 1995). Edwards and Bouchier (1993: 773) suggest that 20% of all hospital admissions for bleeding ulcers in patients over 60 years of age are directly attributable to taking NSAIDs.

Traumeel S is a complex of homoeopathic remedies indicated for a variety of anti-inflammatory, traumatic and degenerative disorders (Oberbaum, 1998). Although the anti-inflammatory mechanism of action of Traumeel S has not yet been

clarified, it has been shown experimentally to reduce oedema in acute induced inflammation in rats by 15%. This effect is equal to that of 30mg/Kg dose of aspirin. Traumeel S also proved superior to controls in reducing acute inflammation (Conforti et al. 1997). Bohmer and Ambrus (1992) showed Traumeel S to be superior to placebo in the treatment of acute sprains and contusions in terms of pain reduction and increased maximal muscle force and time until resumption of training.

Traumeel S has no known toxic side effects. The ingredients of Traumeel S are diluted by several orders of magnitude below toxic levels in accordance with homoeopathic practices (Oberbaum, 1998).

The literature shows neck pain and cervical facet syndrome to be common problems. The literature also provides evidence that inflammation plays a part in cervical facet pathology. Hence it follows that the prescription of NSAIDs is a logical choice for cervical facet syndrome. Although the prescription of NSAIDs is the first line treatment of allopathic physicians for neck pain, no randomised control trial using NSAIDs for acute neck pain or acute cervical facet syndrome was found. This study should help fill that gap in our knowledge and provide information on the efficacy of Piroxicam and Traumeel S in the treatment of acute cervical facet syndrome. NSAID drugs have proven toxic effects, which can lead to severe morbidity and even mortality. On the contrary Traumeel S has no known toxic effects (Oberbaum, 1998). Traumeel S is indicated in the treatment of inflammation and has been shown to be effective in this area. No studies involving Traumeel S and neck pain could be found upon searching the literature. This study should

therefore also provide information on the efficacy of Traumeel S in the treatment of cervical facet syndrome which may then be compared to that of an NSAID. If Traumeel S proves to be equal or superior to Piroxicam in efficacy it may provide an alternative to NSAID medication for acute facet syndrome without the risk of side-effects.

2. REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

This chapter gives an overview of the available information on cervical facet syndrome and the interventions used in the treatment thereof. Evidence of the existence of inflammation in cervical facet syndrome and the efficacy of spinal manipulation is presented later for comparative purposes. Piroxicam and Traumeel S are both discussed in terms of their uses, adverse effects, pharmacological properties and safety.

2.2 INCIDENCE AND PREVALANCE

In Western countries neck complaints occur relatively frequently. An estimated 80% of Westerners will experience low back pain during their active lives. Neck pain is reported less frequently, but constitutes a major health problem as well. (Koes et al. 1992)

A study by Takala et al. (1982) on the prevalence of neck pain in a middle aged population in South Western Finland in which there was a 93,3% participation rate, revealed a prevalence rate of 16% of men and 18% of women.

A comparative study on complaints seen by six chiropractic college teaching clinics indicated that neck pain accounted for between 19 – 27% of patient problems (Nyiendo et al. 1989: 83). Drews (1995) studied epidemiological information from 162 new patients at the Technikon Natal Teaching Clinic over a three month period.

Of these new patients 16.7% presented with neck pain, 21.6% with neck pain and headache and 16.1% with neck and arm pain.

An 18% incidence of neck disorders was found amongst 2500 randomly selected men and women. A slight sex difference was noted, 20% of women as opposed to 16% of men experienced neck pain (Grieve, 1988: 190). However in a group of working individuals aged 25 –29 years, an incidence of 25 –30%, of one or more attacks of neck stiffness was found. Over the age of 50 years of age the incidence increased to 50% (Bland, 1994: 6). The afore mentioned two authors report incidences higher than those of low back pain in industry. It must therefore be questioned if they were indeed referring to prevalence instead of incidence.

2.3 FACET SYNDROME

2.3.1 INTRODUCTION

Attention was first directed to facets as a source of pain by Goldthwaite in 1911, and reinforced by Putti in 1927 (Lippitt, 1984).The term "facet syndrome" was referred to for the first time on 15 June 1933 at the 84th annual session of the American Medical Association by Ralph Ghormley (Peters, 1984).

However, neck pain is a poorly understood symptom, frequently with an inaccurate diagnosis (Dwyer et al. 1990). The prevalence of facet joint pain should not be underestimated. Neck pain without neurological signs is often misdiagnosed as "cervical spondylosis" or "soft tissue injury". Soft tissue injury is often the diagnosis resulting from a history of trauma with normal radiographs. The type of soft tissue

injury is rarely specified. There is an equal prevalence of the radiographic signs of cervical spondylosis in patients with neck pain and those who are asymptomatic. The confusion has lead to more attention being paid to the cervical zygapophyseal joints as a source of pain. (Aprill and Bogduk ,1992)

2.3.2 AETIOLOGY

Some believe that facet syndrome is characterized by overriding of the facets of adjacent vertebrae with resultant narrowing of the intervertebral foramina. Others describe it as a state of tension, stretching, irritation or pressure of the joint capsule, due to postural strain or trauma, but without intervertebral foraminal narrowing. (Peters, 1984.)

There are three possible causes of facet joint pain according to Mooney and Robertson (1976) and Lippitt (1984). They are: chronic synovial and / or capsular reaction to trauma, spinal instability and degenerative conditions. In a study by Dwyer et al. (1990) normal cervical facet joints were stimulated by intracapsular injection of fluoroscopic contrast medium. These joints produced local and referred pain patterns similar to those of patients with neck pain. It can therefore be deduced that this neck pain was likely to be caused by the facet joints.

Stretched and torn ligaments can cause an abnormal range of motion in the zygapophyseal joints. In this situation, by inflammation and overstretching of the capsules, the zygapophyseal joints may be an ongoing source of pain. Reflexly this may result in muscle hypertonicity to stabilise and splint the aberrant motion. This

in turn may cause further abnormal cervical motion as well as affecting fine intersegmental movement. Hypertonicity of the intersegmental muscles which function to co-ordinate fine intersegmental movements occurs first, however, it is the spasm of the longer postural neck muscles that is normally clinically visible. The afore mentioned changes may initiate nociceptive stimuli.(Foreman and Croft, 1995: 313)

2.3.3 DIAGNOSIS

Facet Syndrome produces local and radiating pain. There are two main cervical facet syndromes, depending on the level of the involved joints. The cervical headache syndrome corresponds with involvement of C2-C3, and C3-C4 levels and consists of a hemi-occipital headache with or without supra-orbital radiation. The second syndrome, cervical dorsalgia involves the C5-C6 and C6-C7 levels. It is characterized by interscapular thoracic pain with or without brachial pain. (Roy et al. 1988)

Classical signs of Facet Syndrome are muscle spasm and palpable tenderness over the affected facet joint. (Gatterman, 1990:162). Osterbauer et al. (1992) claim the classical findings in closed neck injury to be neck pain, headaches, muscle pain and sometimes decreased range of motion. A literature review by Dishman (1988) re-affirms the existence of decreased range of motion in facet joints involved in the chiropractic subluxation complex. The only constant findings in joint dysfunction are motion restriction, asymmetry of vertebral segments and hypertonic muscles. (Bourdillon et al. 1992:39)

Bergmann et al. (1993: 63) claim there are 5 diagnostic criteria for spinal dysfunction:

1. Pain and tenderness: This is elicited by palpation of osseous and soft tissue structures.
2. Asymmetry / Alignment: This is determined by the posture and gait observations as well as palpation, for misalignment of vertebral segments
3. Range of motion abnormality: Motion palpation and stress radiographs are used to determine changes in active, passive and accessory joint motion.
4. Tissue tone, texture and temperature abnormality: These are evaluated by means of observation and palpation.
5. Special Tests: These are orthopedic tests, which may be required to obtain a final diagnosis. An example is Kemp's Test.

Roy et al. (1988) and Gatterman (1990:163) suggest that the diagnosis of Facet Syndrome should be based mainly on clinical evaluation since radiographs are most often negative.

Neurological examination usually reveals nothing abnormal. However, it has been noticed on occasion that deep tendon reflexes may be repressed, possibly due to noxious stimuli from the irritated facets which may inhibit anterior horn cells. (Peters, 1984)

2.3.4 PROGNOSIS

Gore et al. (1987) completed a study on 205 neck pain patients over 10 years in an attempt to determine which factors were important in determining a prognosis for neck pain. Patients who had been injured and initially had severe pain were the most likely to have an unsatisfactory outcome. No other clinical or radiographic features were of value in predicting the patient's outcome.

Most people suffering from mechanical neck pain recover satisfactorily, but up to one third can continue to experience moderate to severe pain 15 years after its onset. (Gore et al. 1987)

2.3.5 TREATMENT

The primary chiropractic treatment for cervical facet syndrome is vertebral manipulation. This is used to restore normal joint and muscle function (Fitz-Ritson, 1990, Reggars and Pollard, 1995). More recently nonspecific exercises and modalities have been used (Fitz-Ritson, 1990). The author did not describe the relative effectiveness of the previous two treatments. Mooney and Robertson (1976) claim that

anaesthetic injection of facet joints has been found to be therapeutic in the short term and due to the length of resultant remission of clinical symptoms (20% of the 100 patients studied had complete remission at 6 months, 32% had partial remission at 6 months).

2.4 THE CHIROPRACTIC ADJUSTMENT

2.4.1 EFFICACY OF THE CHIROPRACTIC ADJUSTMENT

Brunarski (1984) reviewed the literature to determine if there was sufficient evidence to suggest that spinal manipulative therapy may be more effective than standard medical care in the management of painful neuromuscular conditions. Fifty studies were reviewed and improvement in manipulative groups averaged above the non-manipulative groups by 20%. It must be noted that many of the studies could have had better designs. Spinal manipulative therapy has been well studied and shown to be an effective treatment for mechanical neck pain (Sloop et al. 1982; Howe et al. 1983; Terret and Vernon, 1984; Mennel, 1990; Nansel et al. 1990; Nansel et al. 1992; Yeomans, 1992; Cassidy, Quon et al. 1992, Cassidy, Lopes and Yong-Hing, 1992; Koes et al. 1992; Williamson, 1998; Giles and Müller 1999).

Johnson et al. (1989) compared the cost of care and numbers of days lost by patients receiving treatment from chiropractors, medical and osteopathic practitioners. The conditions were sprains and strains including those of the back and neck. The mean number of compensated days lost from work by those receiving care from chiropractors was at least 2.3 days less than from those who were treated by medical doctors and at least 3.8 days less than for those who were treated by osteopaths. Chiropractic care provided fewer lost workdays and smaller amounts of disability compensation payment.

2.4.2 SAFETY OF THE CHIROPRACTIC ADJUSTMENT

Dabbs and Lauretti (1995) completed a review of the medline literature from 1966 – 1994 on the risk of cervical manipulation versus NSAIDs for the treatment of neck pain. Only studies which provided a numerical estimate for the risk of adverse affects or death in each case were considered. Their findings show an agreement between studies of 1-3 incidents of stroke due to cervical manipulation per million treatments. The results from the collated data are as follows : risk of serious gastrointestinal ulcers requiring hospitalisation as a result of NSAID use 0.4%; risk of stroke from cervical manipulation 0.001%; risk of death from gastrointestinal bleeding caused by NSAID use 0.04%; risk of death from stroke caused by cervical manipulation 0.00025%. The results of this study show that the mortality rate for NSAID usage is 160 times greater than that of manipulation of the cervical spine. The opinion of Dabbs and Lauretti (1995) following this study is that "The best evidence available indicates that cervical manipulation is one of the safest forms of treatment and it should not be considered dangerous".

2.5 THE SUBLUXATION COMPLEX

The chiropractic subluxation complex has been proposed by Dishman (1985.) to consist of five parts: neuropathophysiology (i.e. Aberrant neurological activity, kinesiopathology (i.e. abnormal joint motion such as hypermobility and hypomobility), myopathology (i.e. muscle spasm), biochemical (i.e. release of inflammatory agents such as kinins, histamine, etc.) and histopathology (i.e. connective tissue changes such as scar tissue and intra-articular adhesions). With

cervical facet syndrome being one manifestation of the vertebral subluxation complex, the relevance of the above to cervical facet syndrome is noteworthy.

The inflammatory and vascular components of the Vertebral Subluxation Complex are thought to include vascular congestion, ischaemia and inflammation (Bergmann, 1993:60). Spinal injuries must be accompanied by soft tissue pathology, which initiates an inflammatory process (Dishman, 1988, Bergmann, 1993: 55). The inflammation spreads to adjacent areas inducing prostaglandin hyperalgesia, which mediates pain. Secondary effects ensue, such as muscle contraction and referred pain amongst others (Dishman, 1988). The end result is a self-perpetuating cycle of pain and muscle spasm (Bergmann et al. 1993: 60). The inflammatory reaction with its accompanying muscle length decrease produces restricted range of motion and tendon and fascial shortenings (Dishman, 1988)

Trauma and immobilisation may result in fibrous adhesion formation. Adhesions due to trauma result from inflammation, subsequent repair and fibrosis or scar tissue formation. Adhesions due to immobilisation are due to a reduction in glycosamino-glycans, a decrease in water content and an increase in intermolecular cross-links in the collagen fibres. (Gatterman, 1990: 45) Studies done by Kahanovitz et al. (1984) and Rubak et al. (1982) into the effects of immobilisation of joints in animals both showed intra-articular adhesion and gross defect formation. It has been mentioned earlier that muscle splinting may occur around joints involved in the subluxation complex as well as cervical facet syndrome. This may immobilise that joint to varying degrees, as is evident in decreased ranges of motion. It is for this reason that the results of the work of

Kahanovitz et al. (1984) and Rubak et al. (1982) are of importance with reference to joints involved in the subluxation complex.

2.6 EVIDENCE OF INFLAMMATION.

The following literature provides evidence that inflammation is an aspect of cervical facet syndrome and hence why anti-inflammatory agents could be used in its treatment. *Dorland's Illustrated Medical Dictionary* (1985) 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 tissues. " Bourdillon et al. (1992: 283) state 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. They do, however, concede that if the mechanical aspect of the joint dysfunction is not altered, these injections may have very short-term benefit or none at all.

In the subluxation complex, the inflammatory response is thought to be a composite of cellular and biochemical processes. It is thought to be largely mediated by the vascular system but is initiated by local events. (Lantz, 1995: 163) Bergmann et al. (1993: 60) state inflammation is a component of the vertebral subluxation complex and that it may result from joint injury, joint immobilisation or chronic joint derangement. These inflammatory reactions act as an intrinsic source of pain. (Bergmann et al. 1993: 60; Lantz. 1995: 166)

Roy et al. (1988) evaluated the effectiveness of cervical facet joint infiltration with corticosteroids under fluoroscopic guidance. Diagnosis was made on clinical evaluation in accordance with Maigne's description of cervical facet syndrome. There were 22 intra-articular injections and 17 periarticular injections in the 21 patients taking part in the study. Thirty-three percent of patients experienced complete pain relief, ranging from 1 week to 9 months duration, and 57% experienced partial relief from 2 to14 months duration. It should be noted that no placebo infiltrations were used. Since introduction of an anti-inflammatory agent into the affected joints decreased pain in 91% of the patients it is reasonable to suspect that inflammation plays a role in cervical facet syndromes. Panzer (1995: 420) following a review of studies, claims that the injection of local anaesthetic or cortisone into a specific facet joint, which results in pain relief, is generally considered diagnostic of facet syndrome.

Due to the proximity of the posterior branches of the dorsal rami to the capsules of the facet joints, inflammation of these joints may irritate the nerve roots (sic) and cause facet joint pain (Roy et al. 1988; Bourdillon et al. 1992: 301).

Reid (1992: 829) proposes that flare-ups of synovitis and facet joint pain produce facet joint syndrome. Bourdillon et al. (1992: 301), Gifford (1994: 507) and Reid (1992: 829) advocate the use of NSAIDS to treat these inflammatory flare-ups.

Cervical spine injury is thought to result in the release of histamine, bradykinin, thromboxane, monohydroxy fatty acids, leucotrienes and prostaglandins. The

chemical reactions of these mediators of inflammation are inhibited by steroidal and non-steroidal anti-inflammatory drugs. (Dishman, 1988)

The normal resolution of inflammation is fibrosis, which leads to scar tissue formation, which in turn restricts normal joint motion and produces its biomechanical, neurological and circulatory consequences (Schafer & Faye, 1990: 306). Because of this it becomes essential to include in a patient management programme anything which will reduce the likelihood of such occurring.

2.7 MEDICATION

2.7.1 INTRODUCTION

The costs of the two medications were considered, but neither one was significantly cheaper than the other. However, when dosage was considered, piroxicam required a smaller number of doses per day (ie. Traumeel S must be taken three times daily as opposed to piroxicam, which must be taken twice a day for the first two days and only once a day thereafter). This may promote better compliance in piroxicam users.

2.7.2 NSAIDs

2.7.2.1 INTRODUCTION

Worldwide, NSAIDs appear to be the most commonly prescribed medication (Koes et al. 1997). Many people having a significant episode of musculoskeletal or mechanical neck pain will seek treatment. This results annually in millions of visits

to allopathic physicians, whose first line of treatment is usually the prescription of NSAIDS (Dabbs and Lauretti, 1995). NSAIDS are prescribed extensively for their anti-inflammatory, analgesic and antipyretic properties (Goodman and Simon, 1994).

Despite NSAID's perceived safety they have a significant risk of severe complications. The most frequent and serious of these are gastrointestinal ulcers and haemorrage. (Dabbs and Lauretti, 1995) There are many different NSAIDS from several chemical classes. The NSAIDS chosen for this study was Piroxicam 20mg, under the propriety of Adco-Piroxicam. Piroxicam was chosen for this study based on the results of Amlie et al. (1987) who found piroxicam to have rapid action in an acute spinal condition.

2.7.2.2 PIROXICAM

Piroxicam is an oxicam derivative in the class of enolic acids. (Insel,1990: 668) It is chemically designated as:

4 - Hydroxy - 2 - methyl - N - 2 - piridinyl - 2H - 1,2 - benzothiazine - 3 - carboxamide 1,1 dioxide (Arky, 1997: 833).

2.7.2.3 PHARMACOLOGICAL PROPERTIES

Piroxicam possesses anti-inflammatory, analgesic and antipyretic activity (Insel, 1990: 668; Arky, 1997: 2008). The exact mechanism of action is not yet fully established (Arky 1997: 2008). The proposed mechanism for action is the inhibition

of biosynthesis of prostaglandins (Insel, 1990: 668; Arky, 1997: 2008). This involves the inhibition of cyclo-oxygenase, the enzyme that catalyses the synthesis of cyclic endoperoxides from arachidonic acid to form prostaglandins (Goodman and Simon, 1994). Further modes of action have been proposed for piroxicam due to its inability to inhibit neutrophil activation even in the presence of cyclo-oxygenase products (Insel, 1990: 668).

Piroxicam is well absorbed following oral administration (Arky, 1997: 2008, Adco-Piroxicam package insert (Appendix B)). Peak plasma concentrations occur 2 - 4 hours after consumption (Insel, 1990: 668; Adco-Piroxicam Package Insert (Appendix B)). According to Arky (1997: 2008) piroxicam has a mean plasma half-life of 50 hours. Goodman and Simon (1994) state a mean plasma half-life of 57 hours. This long plasma half-life allows for the use of single daily doses. After 7 to 10 days a steady state is attained at which plasma concentration equals that of synovial fluid (Arky, 1997: 2008; Insel, 1990: 668; Adco-Piroxicam package insert (Appendix B)). Following absorption, piroxicam becomes 99% protein bound (Insel 1990: 668, Goodman and Simon, 1994). Piroxicam is metabolised in the liver by hydroxylation of the piridyl ring of the piroxicam side chain followed by conjugation with glucoronic acid (Adco-Piroxicam Package Insert (Appendix B); Arky, 1997: 2008).

The metabolised products are excreted in the urine and faeces. Twice as much is excreted in the urine (Arky, 1997: 2008). Less than 5% of the unchanged drug is excreted in the urine (Insel, 1990: 668).

2.7.2.4 INDICATIONS

Piroxicam is indicated in many conditions requiring anti-inflammatory and analgesic activity. This includes rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout and acute musculo-skeletal disorders (Adco-Piroxicam Package Insert (Appendix B)). Aoki et al. (1983) found piroxicam to be effective in the treatment of painful lumbar disorders and noted that their findings were consistent with the literature of previous trials on rheumatoid arthritis, osteoarthritis and ankylosing spondylitis.

2.7.2.5 TOXIC EFFECTS

Insel (1990:668) reports an incidence of peptic ulceration at 1% as a result of piroxicam usage as well as gastro-intestinal bleeding, oedema, raised blood urea nitrogen levels, decreased platelet aggregation and prolonged bleeding time, skin rash, Stevenson-Johnson syndrome, decreased haemoglobin and hematocrit, thombocytopenia and non-thrombocytopenic purpura, aplastic anaemia, leucopenia, eosinophilia, dizziness, headache, somnolence, vertigo and bronchoconstriction in aspirin-sensitive individuals. Adco-Piroxicam raises plasma lithium levels and should not be taken with coumarin-type anticoagulents (Adco-Piroxicam Package Insert (Appendix B)). Aoki et al. (1983) reported patients developing abdominal pain, anorexia, diarrhoea, oedema, dry mouth and rash following a piroxicam trial.

2.7.2.6 SAFETY

Case control studies have suggested that 20% of all hospital admissions with bleeding gastric and duodenal ulcers in patients over 60 years of age are directly attributable to taking NSAIDS. Endoscopic evidence of ulcers is found in 20% of NSAID users, even in the absence of symptoms. (Edwards and Bouchier, 1993: 773) Dabbs and Lauretti (1995) note that the chance of a patient on NSAID therapy having a gastric ulcer is 5 to 10 times greater than in non-users. Wilcox et al. 1994, in a study of 461 patients with upper gastrointestinal bleeding found a prevalence of 56% of NSAID use during the week before admission.

In the light of the above it is interesting that Goodman and Simon (1994) say that the incidence of adverse effects of NSAIDS is low. However, because they have extremely widespread usage, some patients may suffer major morbidity and mortality. (Goodman and Simon, 1994) The above evidence supports this and thus the possibility of side effects must be taken seriously. Patients in this trial have undergone intensive screening (see Chapter 3) to rule out patients at risk.

2.7.2.7 EFFICACY

There is a lack of literature on the topic of NSAID use for neck pain. There is, however, a relatively large amount of literature on NSAID use in low back pain. Due to the likely similarities in pathophysiology of low back pain and neck pain, it would seem reasonable to extrapolate knowledge gained from studies on low back pain to the subject of neck pain.

In a review on the current literature on drug therapy for low back pain, NSAIDs, including piroxicam, were superior to placebo. There was also strong evidence for the efficacy of NSAIDs in treating uncomplicated acute back pain and moderate evidence for treating chronic back pain. (Deyo, 1996.)

A meta-analysis of randomised clinical trials by Koes et al. (1997) demonstrated the superiority of NSAIDs over placebo. Each trial was given a methodology quality score. The highest scoring trial showed Ibuprofen to be statistically inferior to placebo. The second highest scoring trial by Amlie et al. (1987) compared piroxicam to placebo in the treatment of acute low back pain. The piroxicam posology used was identical to that used in this study. Pain was measured with a visual analogue scale after 3 and 7 days. This was the highest scoring trial to measure the effects so soon after beginning treatment. Piroxicam was superior to placebo after 3 days but there were no significant differences after 7 days. Piroxicam has thus been shown to be a fast-acting and effective treatment for low back pain. It stands to reason that it was a good choice of NSAID for this study.

Moran (1990) compared Diclofenac sodium, Piroxicam and placebo in the treatment of acute ankle sprains (N=108). The findings were that both were significantly superior to placebo with respect to improvement of pain on walking and overall reduction of pain and inflammation. However, diclophenac sodium was significantly better than Piroxicam. This study suggests perhaps that Diclophenac sodium would be a better choice, however, in the light of the results of the study done by Amlie et al. (1987), and the fact that Moran's study involved the ankle joint

and not the spine, it was deemed that piroxicam was the better option. Englert et al. (1996) in an uncontrolled study of 151 patients, found Piroxicam fast-dissolving dosage form to be effective and well- tolerated in the treatment of acute low back pain. Aoki et al. (1983) showed Piroxicam to be effective and superior to indomethacin in the treatment of painful lumbar disorders. Opiates, NSAIDs and acetaminophen remain the drugs of choice in treatment of lumbar and cervical spine syndromes. Newer NSAIDs have shown some advantages over the aforementioned drugs. (DiPalma and DiGregario, 1994.)

In an unpublished study by Williamson (1998) comparing manipulation in conjunction with NSAIDs to manipulation in conjunction with placebo, both treatment protocols proved to be effective in the treatment of cervical facet syndrome. Although neither group showed a statistically significant advantage over the other in treatment effect, the data seemed to indicate a trend towards more effective pain relief and disability in favour of the NSAIDs.

Giles and Müller (1999) conducted a pilot clinical trial comparing acupuncture, an NSAID and spinal manipulation in chronic spinal pain syndromes. In 32 patients the pain syndrome involved the neck. Overall only the manipulation group achieved statistically significant improvement. It must however be noted that the results for the cervical patients alone were not detailed.

Bosch et al. (1997) conducted a controlled randomised multicentre study on the efficacy and tolerability of Meloxicam as compared to Piroxicam in 169 patients with acute lower back pain. Medication was given orally for 7 days and intramuscularly

on the first day. In the Piroxicam group, greater than 80% of investigators and patients' ratings on overall efficacy were "very good" and "good". Ratings were done on a 4-point verbal rating scale. It was not stated how the investigators assessed this. The median time of onset of pain reduction following intramuscular injection of Piroxicam was 40 minutes. There was a reduction from greater than 80% of patients suffering "severe" to "very severe pain" on movement, to 10% 90 minutes after the injection of piroxicam (Bosch et al. 1997)

2.7.3 TRAUMEEL S

2.7.3.1 INTRODUCTION

Traumeel S is a complex of homoeopathic remedies. Each tablet contains: Arnica D2, Calendula D2, Hammamelis D2, Millefolium D3 ana 15 mg; Belladonna D4 75 mg; Aconitum D3, Mercurius solubilis Hahnemanni D8, Hepar sulfuris D8 ana 30 mg; Chamomilla D3, Symphytum D8 ana 24 mg; Bellis Perennis D2, Echinacea angustrifolia D2, Echinacea purpurea D2 ana 6mg; Hypericum D2 3mg (Heel, 1989: 89). By way of explanation "D" means that the substance has been diluted in a water and alcohol solution in a ratio of 1:10 and then succussed. Therefore D2 for example, indicates that the process has been carried out twice and that the original substance has been diluted to one part in a hundred.

2.7.3.2 PHARMACOLOGICAL PROPERTIES

The anti-inflammatory mechanism of action of Traumeel S has not been clarified (Conforti et al. 1997). The effect of Traumeel S was tested in vitro, on platelet

adhesion and granulocyte superoxide production. Conventional anti-inflammatory compounds are known to inhibit one or both of these inflammatory cellular functions. The normal defensive and homeostatic functions of these cells were maintained in the Traumeel S tests. This may be of significance for use in immunocompromised patients or those with inflammation of endogenous origin e.g. auto-immunity. Traumeel S does not appear to exert its effects through interaction with specific cell types or through biochemical mechanisms studied thus far. It appears to inhibit the acute inflammatory process through fine control at the local level where it is known that neuropeptides released by sensitive nerve endings play an important role. An hypothesis for further investigation is that Traumeel S effects neurogenic mechanisms of inflammation. (Conforti et al. 1997)

2.7.3.3 INDICATIONS

Traumeel S is indicated in a variety of inflammatory, traumatic and degenerative disorders (Oberbaum 1998). Included in these are post-operative and post-traumatic oedema and swelling of soft tissues and inflammatory processes, and degenerative processes associated with inflammation, in particular involving the support and mobility apparatus (tendovaginitis, styloiditis, epicondylitis, bursitis, scapulohumeral periarthritis and arthrosis of the hip, knee and small joints) (Heel, 1989:90).

2.7.3.4 TOXIC EFFECTS

Traumeel S has no known toxic side-effects, its ingredients being diluted by several orders of magnitude below toxic levels. (Oberbaum, 1998)

2.7.3.5 EFFICACY

Böhmer and Ambrus (1992) conducted a double-blind, placebo-controlled trial (N=102) in the treatment of sports injuries, which included acute sprains and contusions, using Traumeel S and Traumeel Sine ointments. By the fifteenth day after beginning the medication both Traumeel S and Traumeel Sine proved superior to placebo (base ointment with no active ingredients) in terms of abatement of swelling ($p < 0,01$), pain reduction ($p < 0,01$), increase in maximum muscle force ($p < 0,01$) and time until resumption of training ($p < 0,01$). The mean number of days until the athletes resumed training was 12.1 days in the Traumeel S group, 12.2 days in the Traumeel sine group and 13.5 days in the placebo group. Only skin temperature revealed no significant difference. Although improvements occurred in all variables by the fifth day none of these were statistically significant.

A placebo-controlled, randomised, double-blind study on the efficacy of Traumeel ointment in the treatment of acute ankle sprains in 73 patients was conducted by Zell et al. (1989). All patients received interferential current therapy on days 1,3,5,8,10,12 and 15, after the injury. The test group (N=33) received Traumeel ointment while the placebo group received the ointment base only. Whether the

ointment was placebo or Traumeel was undetectable to either patient or practitioner. Treatments were administered and patients assessed on the aforementioned days. The Traumeel group when compared to placebo showed a more rapid increase in range of motion ($p < 0.01$) and was superior in reducing pain on movement ($p < 0.001$). In a very similar study on acute ankle sprain by Stock (1988) similar results were found.

Thiel and Borho (1994) conducted a randomised, placebo-controlled, double-blind trial on intra-articular Traumeel N infiltration on 73 patients with recent traumatic knee joint haemarthrosis. Traumeel N was shown to be superior to placebo (infiltration of the equivalent volume of physiological saline solution) in, the total number of days required until the punctate (sic) was no longer bloody, increase in knee range of motion, joint circumference reduction and total pain score. Statistical significance of this data was not reported.

In an in vivo experiment on rats, Traumeel S injection ($n = 24$) into the hindpaw showed a reduction of 15% ($p < 0.05$) in chemically induced oedema. This is equivalent to the effect of a 30mg/kg dose of aspirin. In tests on induced adjuvant arthritis in rats, intramuscular Traumeel injection led to significant reduction in acute local inflammation in comparison to the controls (i.m. 0.9% NaCl). The sample size was not stated for this experiment and measurement was also in terms of swelling of the hindpaw. (Conforti et al. 1997)

In summary, Traumeel has been seen to be effective in a variety of its indications. It is now relevant to conpare its relative effectiveness to allopathic medications.

2.8 CONCLUSION

Diagnosis and treatment of acute facet syndrome is an integral part of chiropractic training. The study by Drews (1995) provides evidence that South African chiropractors also frequently treat neck pain patients. Chiropractors, as primary health care practitioners play a role in providing patients with health care advice. Both Adco piroxicam and Traumeel S may well be recommended to patients for neck pain. Conclusive information regarding the relative effectiveness of these two medications will provide better health care advice for the chiropractic profession to provide to its patients. Furthermore, a possible change in the legislature regarding the prescription of anti-inflammatory drugs by chiropractors is apparently pending. This study will add to the base of knowledge on the specific use of NSAIDs and Traumeel S for chiropractic conditions.

3. MATERIALS AND METHODS

3.1 INTRODUCTION

This chapter describes the experimental method. The type of data required is detailed. A description of each questionnaire, each objective measure, along with an assessment of the validity and reliability of each parameter is given. Inclusion and exclusion criteria for acceptance into the study are described. Details of the medication itself, its posology, and form with respect to both groups is provided. A discussion on the statistical analysis follows.

3.2 THE DATA

3.2.1 THE PRIMARY DATA

This consists of subjective and objective data.

The subjective data included the following:

- CMCC Neck Disability Index (Appendix H) which assesses the patients' perception of their disability resulting from neck pain, in terms of normal daily functional activity.
- Numerical Pain Rating Scale -101 (Appendix I) which gauges patients perception of pain intensity at its worst and at its least.

The objective data included the following:

- C.R.O.M. (Appendix J) used to measure cervical range of motion.
- Algometer (Appendix J) used to measure pressure – pain threshold.

- Motion Palpation (Appendix J) used to detect the presence or absence of spinal fixations and their spinal level, side and direction of motion restriction.

Patients completed the subjective data questionnaires at the first consultation and again on days 3 and 7. The algometer and C.R.O.M. measurements were performed by the researcher on patients on days 1, 3, and 7. The permitted deviation from this examination schedule was 1 day only. All consultations were conducted at the Technikon Natal Chiropractic Clinic.

3.2.2 THE SECONDARY DATA

This consisted of a review of the literature relating to cervical facet syndrome , Traumeel S and NSAIDs, specifically Piroxicam. This revealed information and lack thereof on the afore mentioned areas and hence supported this study. Documentation evaluating the reliability and validity of the objective and subjective measurement methods were reviewed.

3.3 METHODS OF MEASUREMENT

3.3.1 SUBJECTIVE MEASUREMENTS

3.3.1.1 CMCC NECK DISABILITY INDEX. (Appendix H)

This questionnaire was designed to assess disability in activities of daily living as a result of neck pain (Vernon and Mior, 1991). This is a useful source of information in assessing the consequences of the progression or regression of neck pain. The questionnaire proved to have a high degree of test – retest reliability, internal

consistency and an acceptable level of validity. It is also applicable to a wide range of subjects and is not affected by gender (Vernon and Mior, 1991). The questionnaire consists of 10 questions. Each question having a maximum score of 5 points and a minimum of 0. The total out of 50 is represented as a percentage disability.

3.3.1.2 NUMERICAL PAIN RATING SCALE 101 (NRS-101 Appendix I)

The NRS-101 measures pain intensity. It consists of 2 lines on which the patient is asked to rate their pain as a number between 0 (being no pain) and 100 (being the worst pain imaginable). The first rating is for the pain when it is at its worst and the second is for the pain when it is at its least. The average between these two figures is used as an indication of the average pain intensity experienced by the patient.

Jensen et al. (1986) conducted a study on 6 pain intensity scales. Each scale was assessed in terms of 5 criteria:

1. Ease of administration of scoring
2. Relative rates of incorrect responding
3. Sensitivity as defined by the number of available response categories
4. Sensitivity as defined by statistical power
5. Magnitude of the relationship between each side and linear combination of pain intensity indices. (Jensen et al. 1986)

The findings of Jensen et al. (1986) showed all the pain intensity measures to meet these criteria at some level. The NRS-101 had practical advantages over the other scales because:

- It is more simple and practical to administer and score
- It can be administered in written or verbal form
- It does not appear to be associated with age

Bolton and Wilkinson (1998) found that NRS-101 to be the most responsive of three pain intensity scales. The NRS-101 also showed good concurrent validity with a rho spearman correlation coefficient of 0,40 ($p<0,001$).

3.3.2 OBJECTIVE MEASUREMENTS

3.3.2.1 CERVICAL RANGE OF MOTION (C.R.O.M.) (Appendix J)

This instrument measures cervical range of motion in degrees in right and left rotation, right and left lateral flexion and extension and flexion. The apparatus is produced by Performance Attainment Associates (3600 Lahore Rd., Suite 6, St. Paul, MN U.S.A. 55110 – 4144).

Youdas et al. (1991) conducted a study on 3 methods of measuring active cervical spine range of motion. All 3 methods showed high inter-examiner reliability. C.R.O.M. was demonstrated to have the highest reliability when inter-examiner reliability was assessed. Use of C.R.O.M. was additionally noted for not aggravating the patient's neck condition. (Youdas et al. 1991)

3.3.2.2 ALGOMETER

Pressure threshold is the minimum pressure that induces pain or discomfort. The algometer or pressure threshold meter may be used for quantification of tender spots. (Fischer, 1987) The greater the force applied through the algometer to the tender spot, the less is the tenderness felt by the patient and the higher the pain tolerance. In this study the algometer was applied over the articular pillar at the level of the facet joint having been diagnosed as fixated. The measurements were taken on day 1 prior to beginning medication, and again on days 3 and 7 over the same facet joint regardless of subsequent motion palpation findings. Nussbaum and Downes (1998) in a study on clinical pressure pain algometric reliability found intra-class correlation coefficients significant at $p< 0,001$ to be 0,74 – 0,89.

3.3.2.3 MOTION PALPATION

Each patient's cervical spine was motion palpated in the technique described by Faye and Wiles (1992: 314 – 318). The level (C0 – C7), the side (right or left) and the direction of motion restriction (flexion, extension, right or left rotation or right or left lateral flexion) of the fixated joint was determined and recorded.

In a recent unpublished study by Lakhani (1999) on motion palpation efficacy in the cervical spine, statistically significant correlation ($Z > 1,96$) between two examiners was found with respect to the level and side of fixation. No statistically significant correlation ($Z < 1,96$) was found with regard to direction of motion of fixation. It

should be noted that one of the examiners was experienced while the other was relatively inexperienced.

3.4 STUDY DESIGN AND PROTOCOL

3.4.1 ALLOCATION OF SUBJECTS

The study was limited to 50 patients. Participants were randomly divided into 2 groups of 25 each, by drawing a "1" or a "2" out of a hat. Patients drawing a "1" were assigned to Group 1 and those drawing a "2" were assigned to Group 2.

Group 1 received the Traumeel S sachets and the NSAID placebo capsules, whilst Group 2 received the Traumeel S placebo sachets and the Adco-Piroxicam capsules.

3.4.2 INCLUSION AND EXCLUSION CRITERIA.

- Only patients between the ages of 18 – 65 years of age were accepted.
- Only cases of acute or sub-acute cervical facet syndrome as defined as having an onset of no more than 14 days prior to beginning the study were accepted. Acute exacerbations of chronic facet syndrome were also accepted.
- Patients were required to complete and sign a screening questionnaire (Appendix C) devised by D. Moodley, a medical practitioner, to identify those at risk of developing side effects from the NSAIDs. Patients at risk were excluded. Patients under the age of 21 years required the signature of a parent or legal guardian. Patients were

also required to sign an Indemnity (Appendix D), Declaration (Appendix E) and an Informed Consent form (Appendix F).

- Patients underwent a case history, physical examination and cervical regional assessment. Following this a diagnosis of cervical facet syndrome was made according to the criteria described by Schafer and Faye (1990 : 98 – 110) and Bergmann et al. (1993 : 41 – 42)
  - Pain or tenderness over the involved osseous and soft tissue area
  - Asymmetry / misalignment qualities identified through observation and static palpation
  - Abnormal range of motion detected actively and through motion palpation
  - Tissue tone difference over the area of dysfunction detected through palpation
  - Special tests i.e. Kemp's Test

- Patients were not allowed to have any other form of treatment for their neck pain for the duration of the trial period. It was also explained to them that they should do nothing differently in their daily living during the trial period.

- Patients could enter the study provided that the medication that they were taking was not one of the following: aspirin, lithium, methotrexate, heparin or coumarin-type anticoagulants and was agreed to by D. Moodley. This was explained beforehand.

- Patients having or developing contra-indications to Adco-Piroxicam in accordance with the Adco-Piroxicam package insert (Appendix B) and Snyman (2000 : 67) were excluded. Such contra-indications are:
  - Previous hypersensitivity to Piroxicam

- Hepatic dysfunction
- Pregnancy
- History of gastrointestinal haemorrage, ulcers or aspirin sensitivity

- Patients were excluded if they did not come in for assessment within the permitted examination schedule.

The case history, physical examination, cervical regional examination and screening questionnaire results of each patient were discussed telephonically by the researcher with D. Moodley following the initial consultation. The medical practitioner's opinion on whether it was safe or not for the patient to take part in the study was the final determinant in initial inclusion or exclusion.

3.4.3 INTERVENTION

Each patient received a Patient Information letter (Appendix A) which describes in layman's language the nature, purpose and risks of the trial and a copy of the Adco-Piroxicam package insert (Appendix B). Upon completion of the initial consultation, provided that the inclusion criteria had been met, the patient was provided with the medication by the researcher. For a description of the blinding procedure used please refer to 3.4.5 Double Blinding. The manner in which the medication was to be taken was explained and a Patient Medication Diary (Appendix G) was given to the patient. The patients were instructed to record the times each dose of medication was taken in the table provided on the Patient

Medication Diary. Printed on the Patient Medication Diary were a further set of instructions on how to take the medication.

The following interventions occurred at the consultations on all three days. (i.e. days 1, 3 and 7):

- Completion by patients of NRS-101 and CMCC Neck Disability Index.
- Active cervical range of motion measured in degrees in left and right lateral flexion, left and right rotation and extension and forward flexion by C.R.O.M.
- Assessment of point tenderness over the involved facet in the form of pressure-pain threshold by a pressure algometer
- Motion palpation of the cervical spine in the technique described by Faye and Wiles (1992: 314 – 318). The level C0-C7, the side (right and left) and the direction of motion restriction (flexion, extension, right or left rotation or right or left lateral flexion) of the fixated joint was determined and recorded.

3.4.4 THE MEDICATION

The nature of the two medications is such that each had to be taken in a specific way i.e. the Traumeel S must be dissolved under the tongue and the Adco Piroxicam must be swallowed. Neither medication can be taken in the manner of the other, hence to make it undetectable as to which treatment the patient was getting, each patient received both the NSAID capsules and the homoeopathic powders. Only one of these contained its respective active ingredient, the other being a placebo.

The posology of Adco Piroxicam followed the regimen suggested on the package insert under acute musculoskeletal disorders i.e. 40 mg (2x20 mg capsules) orally for the first two days, followed by 20 mg (1x20 mg capsule) daily orally for the following 5 days. The placebo Adco Piroxicam treatment involved the identical afore mentioned regimen, with the identical Adco Piroxicam capsules containing base substance (cornstarch) only.

The Traumeel S was taken in accordance with the dosage described by Heel (1989:90), i.e. one tablet to be sucked 3 times a day. This continued for 7 days to equal that of the Piroxicam treatment. In order to create an apparently identical placebo remedy for the Traumeel S, the Traumeel S tablets were crushed to a powder and dispensed in sachets. The placebo will be an identical sachet containing an equal volume of lactose powder. The powders were dissolved in the mouth, as the tablet would have been. One sachet was taken 3 times a day for 7 days. Group 1 received the Traumeel S sachets and the NSAID placebo. Group 2 received the Traumeel S placebo sachets and the Adco Piroxicam capsules.

3.4.5 DOUBLE BLINDING

The medication packs for each patient were divided into their respective groups (i.e. Group 1and Group 2) by the researcher. These were then passed on to an independent observer, who, out of sight of the researcher altered the labels of the groups of medication and made a note of which new label corresponded with which old label for reference upon completion of the trial. The researcher, upon providing each patient with their medication pack, recorded from which group of medication it

had come. Upon completion of the trial the contents of each group was revealed to the researcher.

3.5 STATISTICAL ANALYSIS

3.5.1 TREATMENT OF THE DATA

3.5.1.1 SUBJECTIVE DATA

The questionnaires that the patients completed were checked to ensure that they had been filled in correctly. The raw data from the 2 questionnaires were converted to percentages and recorded. Statistical analysis of the data, at a 95% confidence level was performed.

3.5.1.2 OBJECTIVE DATA

The cervical ranges of motion (measured in degrees) were recorded separately for the 2 groups. The algometer readings (in Kg/cm^2) were recorded separately for the 2 groups.The motion palpation data for the 2 groups was recorded as, the presence or absence of a fixation, with reference to the level and side of the fixation palpated on the first visit. Statistical analysis of the data, at a 95% confidence level was performed.

3.5.2 STATISTICAL ANALYSIS OF THE DATA

Advice on how to statistically analyse the data obtained in this study was obtained from the Technikon Natal Statistician. The sample size for each group was 25, thus non-parametric tests were used to analyse the data. All data was transferred to a spreadsheet and statistical analysis was conducted.

3.5.2.1 NON-PARAMETRIC PAIRED HYPOTHESIS TESTS.

3.5.2.1.1 THE SUBJECTIVE DATA

The data from the questionnaires of consultations on days 1, 3 & 7 were compared separately within the 2 groups and statistically analysed, using the Wilcoxon's Signed Rank Test.

3.5.2.1.2 THE OBJECTIVE DATA

Each direction of range of motion, algometer readings and motion palpation findings for consultations on days 1, 3 & 7 were compared separately within the 2 groups and statistically analysed, using the Wilcoxon's Signed Rank Test.

3.5.2.2 NON-PARAMETRIC UNPAIRED HYPOTHESIS TESTS.

3.5.2.2.1 THE SUBJECTIVE DATA

The data from the questionnaires of consultations on days 1, 3 & 7 were compared between the 2 groups and statistically analysed using the Mann-Whitney's U -Test.

3.5.2.2.2 THE OBJECTIVE DATA

Each direction of range of motion, algometer readings and motion palpation findings for consultations on days 1, 3 & 7 were compared between the 2 groups and statistically analysed, using the Mann-Whitney U -Test.

3.5.2.3 SUMMARY STATISTICS

Means, medians, standard errors and standard deviations were calculated and bar charts were created to look for possible trends and significant differences in the data.

3.5.2.4 POWER ANALYSIS

Power analysis was used in assessing the sensitivity of the non-parametric tests and the likelihood of a type II error occurring (incorrectly accepting a null hypothesis).

4. RESULTS

4.1 INTRODUCTION

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

Group 1- Traumeel S and placebo Piroxicam.

Group 2- Piroxicam and placebo Traumeel S.

4.2 RECRUITMENT AND EXCLUSIONS

Sixty people were accepted into the study. Ten people dropped out or were excluded from the study. Many patients who were screened were not accepted into the study due to contra-indications to NSAIDs, a record was not kept of these patients.

Table 4.1 **Reasons for patient dropout / exclusion.**

TOOK MEDICATION DURING THE TRIAL WHICH WOULD AFFECT RESULTS	3
MISSED THEIR APPOINTMENT ON DAY 3	1
MISSED THEIR APPOINTMENT ON DAY 7	6
TOTAL	10

4.3 DEMOGRAPHIC DATA

Table 4.2 **Gender distribution**

GENDER	GROUP 1	GROUP 2
MALES	8 (32%)	7 (28%)
FEMALES	17 (68%)	18 (72%)

The overall male: female ratio was 3: 7. The two groups were similar with respect to gender distribution.

Table 4.3 **Age prevalence.**

AGE INTERVALS	GROUP 1	GROUP 2
15-25	7(28%)	8(32%)
26-35	5(20%)	8(32%)
36-45	8(32%)	3(12%)
46-55	4(16%)	5(20%)
56-65	1(4%)	1(4%)
MEAN AGE	36.5 yrs.	35.68 yrs.

The mean age for the entire sample was 36.1 years.

Table 4.4 **Occupations requiring computer work.**

	GROUP 1	GROUP 2
COMPUTER RELATED OCCUPATIONS	10(40%)	9(36%)
NON-COMPUTER RELATED OCCUPATIONS	9(36%)	11(44%)
STUDENTS	6(24%)	5(20%)

Table 4.5 **History of trauma affecting the cervical spine.**

	GROUP 1	GROUP 2
MOTOR VEHICLE ACCIDENT	11(44%)	8(32%)
HORSE RIDING ACCIDENT	2(8%)	1(4%)
FALL	0(0%)	1(4%)
RAN INTO TREE	1(4%)	0(0%)

Table 4.6 **Onset of neck pain.**

	GROUP 1	GROUP 2
RAPID ONSET*	12(48%)	13(52%)
GRADUAL ONSET*	13(52%)	12(48%)

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

Table 4.7 **Duration of neck pain prior to entering the trial.**

PATIENTS PRESENTING...	GROUP 1	GROUP 2
DURING THE 1ST WEEK AFTER ONSET	13(52%)	17(68%)
DURING THE 2ND WEEK AFTER ONSET	12(48%)	8(32%)

Table 4.8 **Chronicity of neck pain.**

	GROUP 1	GROUP 2
ACUTE *	17(68%)	13(52%)
ACUTE ON CHRONIC **	8(32%)	12(48%)

* Patients who were experiencing no neck pain prior to the onset of the present bout.

** Patients experiencing an acute aggravation of an existing chronic neck pain.

Table 4.9 **Complications / side effects experienced by patients during the trial.**

COMPLICATIONS /SIDE EFFECTS	GROUP 1	GROUP 2
HEADACHE	4(16%)	2(8%)
AGGREVATION OF NECK PAIN	2(8%)	1(4%)
LETHARGY	2(8%)	0(0%)

4.4 THE ANALYSED DATA.

P-Value : P was the observed level of significance. $\alpha = 0.05$ is the set level of significance at which the Ho is rejected if p is less than or equal to $\alpha / 2 = 0.025$. If p

is greater than α / 2 the Ho is accepted at the same level of significance. It should be noted that, a lack of statistically significant improvement does not necessarily imply no improvement at all. The nearer to 0.025 the p-value is, the greater the improvement, until it is below or equal to 0.025 when it is considered statistically significant.

Two-tailed tests were used in order to determine if groups were equal or if there were significant differences between them. When a significant difference was found the median values (mean values were used in the case of motion palpation as will be explained shortly), were consulted to determine if it indicated an improvement or regression of the variable in question.

Null hypothesis (Ho) : assumes that there is no significant difference between the two groups being compared.

Alternative hypothesis (H1) : assumes that there is a significant difference between the groups being compared.

Non-parametric tests : were used to analyse this data due to the size of each group being below the standard value of 30. (n = 25)

Median values have been used for comparison because they are more accurate when dealing with small sample sizes than means. The reason for this is that in a small sample outlying values may skew the means. In the case of motion palpation

use of the medians would be inappropriate as the results could only be a 1 or a 0, hence the means have been used.

Power test : The power of a statistical test is a measure of its sensitivity. This is dependant on the level of significance, the accuracy of the measurements used in the study and the sample size. As the power of a test decreases the likelihood of making a Type II error (incorrectly accepting a Ho) increases. The power should be as close to 1 as possible. β is the probability of a Type II error. The power of a statistical test is therefore $(1-\beta)$.

4.4.1 NON-PARAMETRIC INTRA-GROUP TESTS (WILCOXON SIGNED RANKS TEST) FOR GROUP 1

Table 4.10 **Comparison of subjective and objective data from days 1 and 3 in Group 1.**

	Median (Day 1)	Median (Day 3)	P-value
Flexion	60.0	68.0	0.038
Extension	50.0	50.0	0.964
L. Rotation	62.0	68.0	0.061
R. Rotation	62.0	64.0	0.044
L. Lat. Flexion	32.0	38.0	0.142
R. Lat. Flexion	34.0	36.0	0.152
Algometer	1.8	2.1	0.095
M. Palp. (μ)	1.0	0.8	**0.025**
CMCC	24.0	16.0	**0.003**
NRS-101	38.0	30.0	0.184

The comparison of subjective and objective data from day 1 and day 3 show that a significant improvement occurred only in terms of motion palpation and the CMCC Neck Disability Index.

Table 4.11 Comparison of subjective and objective data from days 3 and 7 in Group 1.

	Median (Day 3)	Median (Day 7)	P-value
Flexion	68.0	70.0	0.055
Extension	50.0	52.0	0.714
L. Rotation	68.0	68.0	0.585
R. Rotation	64.0	60.0	0.891
L. Lat. Flexion	38.0	38.0	0.285
R. Lat. Flexion	36.0	38.0	0.120
Algometer	2.1	2.1	0.387
M. Palp. (μ)	0.8	0.64	0.102
CMCC	16.0	12.0	**0.001**
NRS-101	30.0	18.0	0.031

On comparing the subjective and objective data from day 3 and day 7 it can be seen that only the CMCC Neck Disability Index scores improved significantly.

Table 4.12 Comparison of subjective and objective data from days 1 and 7 in Group 1.

	Median (Day 1)	Median (Day 7)	P-value
Flexion	60.0	70.0	**0.002**
Extension	50.0	52.0	0.957
L. Rotation	62.0	68.0	0.153
R. Rotation	62.0	60.0	0.046
L. Lat. Flexion	32.0	38.0	**0.022**
R. Lat. Flexion	34.0	38.0	**0.019**
Algometer	1.8	2.1	0.034
M. Palp. (μ)	1.0	0.64	**0.003**
CMCC	24.0	12.0	**0.000**
NRS-101	38.0	18.0	**0.014**

The comparison of subjective and objective data from day 1 and day 7 shows significant improvement in range of motion in flexion, left and right lateral flexion, motion palpation and CMCC Neck Disability Index.

4.4.2 NON-PARAMETRIC INTRA-GROUP TESTS (WILCOXON SIGNED RANKS TEST) FOR GROUP 2

Table 4.13 **Comparison of subjective and objective data from days 1 and 3 in Group 2.**

	Median (Day 1)	Median (Day 3)	P-value
Flexion	68.0	70.0	0.027
Extension	58.0	59.0	0.576
L. Rotation	62.0	60.0	0.583
R. Rotation	64.0	64.0	0.780
L. Lat. Flexion	36.0	40.0	0.084
R. Lat. Flexion	36.0	38.0	0.168
Algometer	1.5	2.0	0.060
M. Palp. (μ)	1.0	0.84	0.046
CMCC	18.0	12.0	**0.001**
NRS-101	40.0	33.0	**0.001**

When comparing subjective and objective data from day 1and day 3 it can be seen that significant improvement occurred in CMCC Neck Disability Index and NRS-101 scores.

Table 4.14 **Comparison of subjective and objective data from days 3 and 7 in Group 2.**

	Median (Day 3)	Median (Day 7)	P-value
Flexion	70.0	70.0	0.183
Extension	59.0	60.0	0.392
L. Rotation	60.0	64.0	0.040
R. Rotation	64.0	68.0	0.204
L. Lat. Flexion	40.0	40.0	0.190
R. Lat. Flexion	38.0	42.0	0.257
Algometer	2.0	2.2	0.462
M. Palp. (μ)	0.84	0.4	**0.001**
CMCC	12.0	8.0	**0.001**
NRS-101	33.0	20.0	**0.003**

The comparison of subjective and objective data from day 3 and day 7 shows a significant improvement in motion palpation, CMCC Neck Disability Index and NRS-101 scores.

Table 4.15 **Comparison of subjective and objective data from days 1 and 7 in Group 2.**

	Median (Day 1)	Median (Day 7)	P-value
Flexion	68.0	70.0	0.269
Extension	58.0	60.0	0.132
L. Rotation	62.0	64.0	0.084
R. Rotation	64.0	68.0	0.235
L. Lat. Flexion	36.0	40.0	0.030
R. Lat. Flexion	36.0	42.0	0.033
Algometer	1.5	2.2	**0.023**
M. Palp. (μ)	1.0	0.4	**0.000**
CMCC	18.0	8.0	**0.000**
NRS-101	40.0	20.0	**0.000**

On comparing subjective and objective data from day 1 and day 7 a significant improvement could be seen in algometer readings, motion palpation, CMCC Neck Disability Index and NRS-101 scores.

4.4.3 NON-PARAMETRIC INTER-GROUP TESTS (MANN-WHITNEY U TEST) GROUP 1 AND 2.

Table 4.16 **Comparison of objective data from days 1, 3 and 7, between Groups 1 and 2.**

	Median Gp1	Median Gp2	p-value
Flexion 1	60.0	68.0	0.148
Flexion 3	68.0	70.0	0.196
Flexion 7	70.0	70.0	0.712
Extension 1	50.0	58.0	0.366
Extension3	50.0	59.0	0.217
Extension7	52.0	60.0	0.206
R. Rotation 1	62.0	64.0	0.167
R. Rotation 3	64.0	64.0	0.586
R. Rotation 7	60.0	68.0	0.170
L. Rotation 1	62.0	62.0	0.876
L. Rotation 3	68.0	60.0	0.341
L. Rotation 7	68.0	64.0	0.930
R. Flexion 1	34.0	36.0	0.284
R. Flexion 3	36.0	38.0	0.161
R. Flexion 7	38.0	42.0	0.134
L. Flexion 1	32.0	36.0	0.592
L. Flexion 3	38.0	40.0	0.675
L. Flexion 7	38.0	40.0	0.490
Algometer 1	1.8	1.5	0.478
Algometer 3	2.1	2.0	0.669
Algometer 7	2.1	2.2	0.861
M. Palpation 1 (μ)	1.0	1.0	1.000
M. Palpation 3 (μ)	0.8	0.84	0.716
M. Palpation 7 (μ)	0.64	0.4	0.093

The comparison of objective data from both groups shows no significant difference between the groups.

Table 4.17 **Comparison of subjective data from days 1, 3 and 7, between Groups 1 and 2.**

	Median Gp1	Median Gp2	P-value
CMCC 1	24.0	18.0	0.173
CMCC 3	16.0	12.0	0.173
CMCC 7	12.0	8.0	0.195
NRS-101 1	38.0	40.0	0.272
NRS-101 3	30.0	33.0	0.690
NRS-101 7	18.0	20.0	0.719

The comparison of subjective data from both groups shows no significant difference between the groups.

Table 4.18 **Power Analysis of the Mann-Whitney tests.**

	DAY 1	DAY 3	DAY 7
FLEXION	0.2479	0.1963	0.0559
EXTENSION	0.0545	0.1134	0.1375
L ROTATION	0.0578	0.0955	0.0623
R ROTATION	0.3611	0.1674	0.2386
L LAT. FLEX	0.0904	0.0635	0.1066
R LAT. FLEXION	0.2462	0.1701	0.3483
ALGOMETER	0.0529	0.0566	0.737
M. PALPATION		0.0548	0.0559
CMCC	0.0611	0.01039	0.168
NRS-101	0.1632	0.0763	0.053

Power analysis for all tests indicates that there was a high possibility of making a Type II error (incorrectly accepting a thenull hypothesis). This however is of little importance as no significant differences between the groups were found in the between-group tests.

FIG. 4.1 ALGOMETER

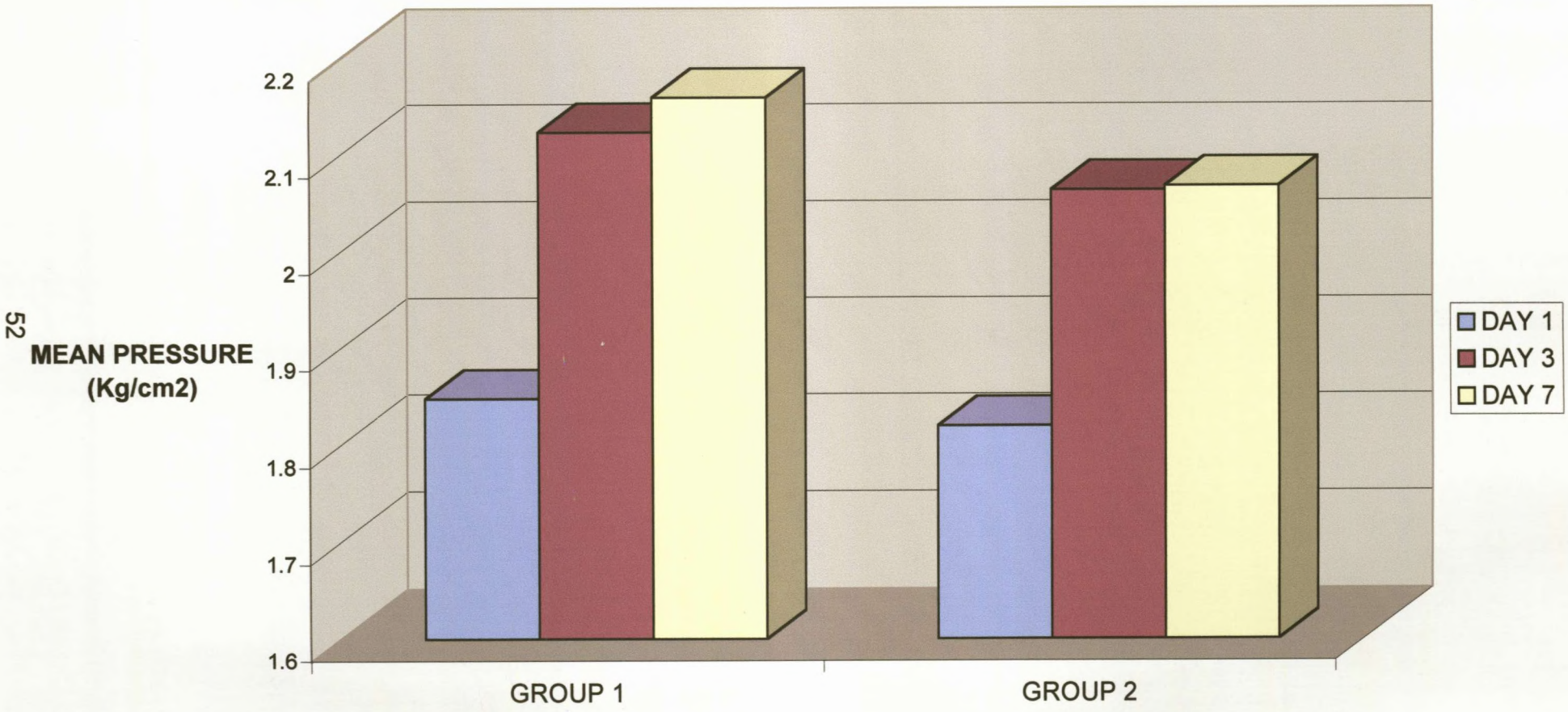


FIG. 4.2 MOTION PALPATION

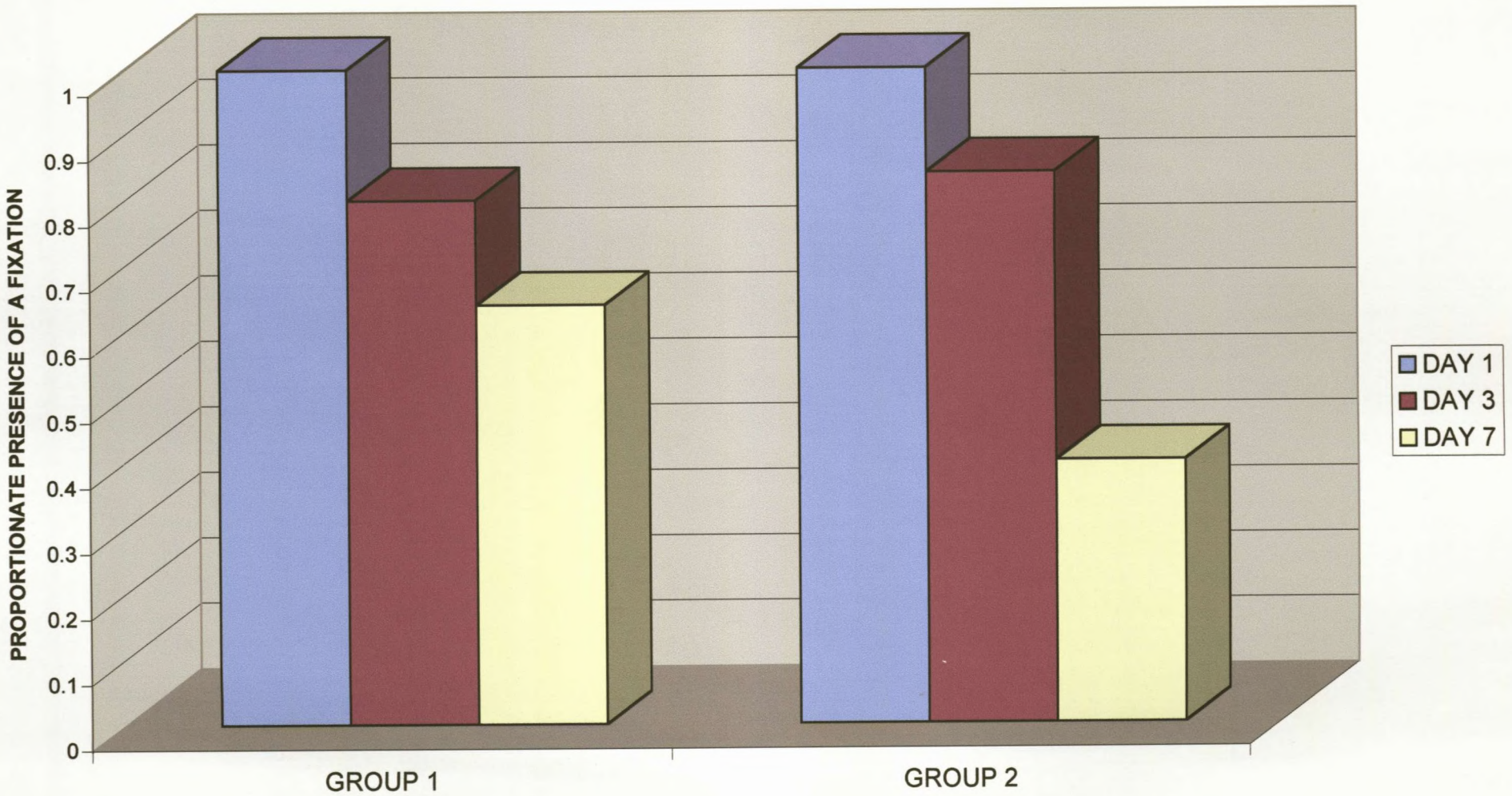


FIG. 4.3 CMCC NECK DISABILITY INDEX

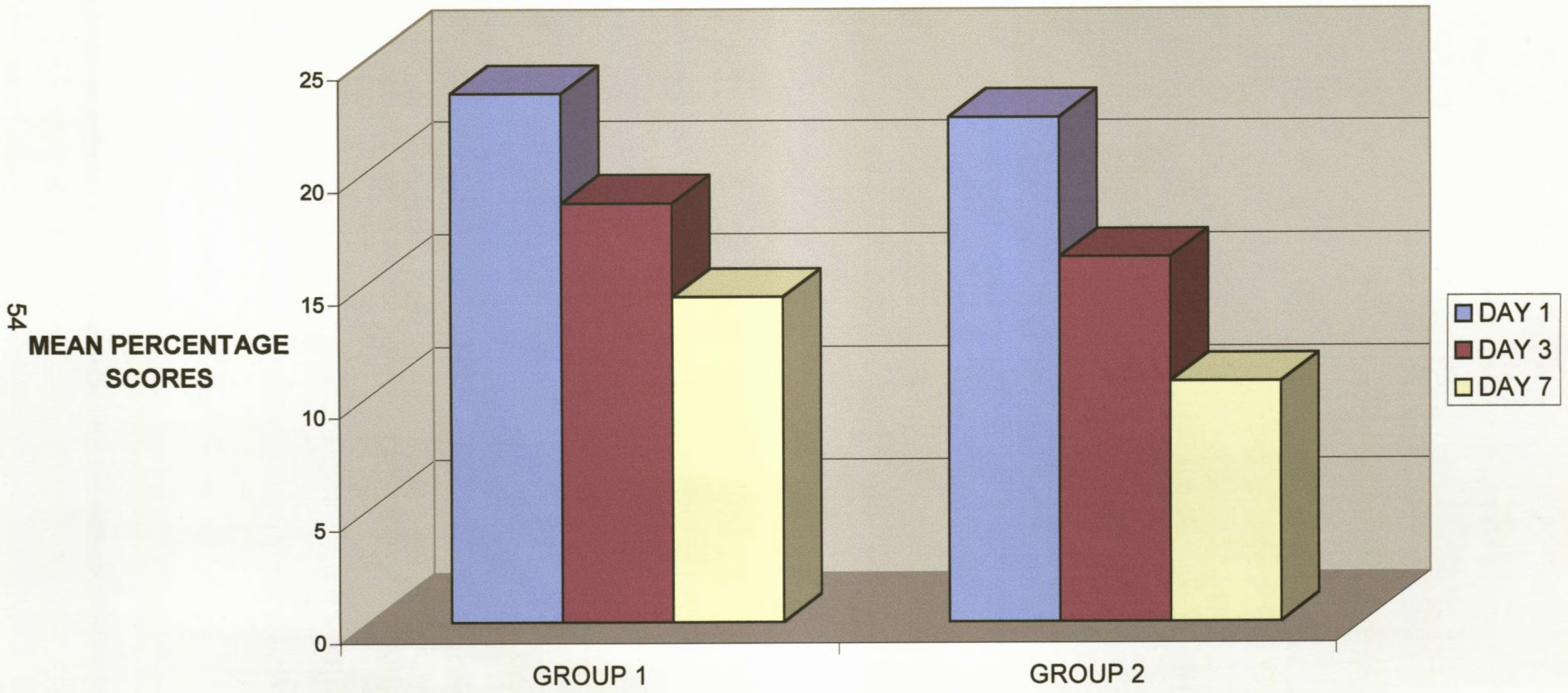
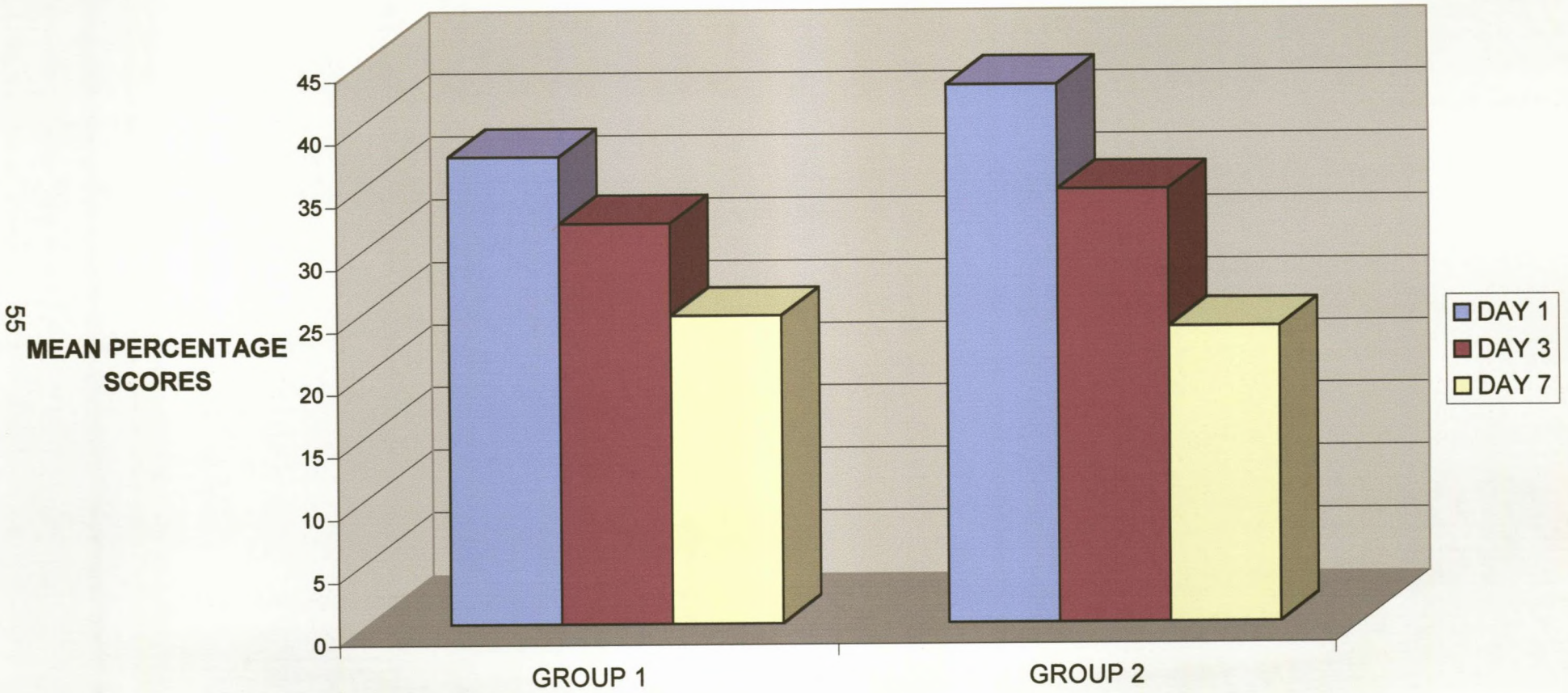


FIG. 4.4 NRS-101 PAIN SCALE



5. DISCUSSION

5.1 INTRODUCTION

This chapter is concerned with discussing the information presented in the previous chapter. When objective measures are referred to they include the goniometer, algometer and motion palpation, while the subjective measures are the CMCC Neck Disability Index and the NRS-101 Pain Scale.

5.2 DEMOGRAPHIC DATA

The gender distribution was similar in the two groups, there were, however, more than twice as many females as males (Table 4.2). This agrees with the male: female ratio found in a similar trial by Williamson (1998). This may suggest a greater number of females suffering from cervical facet syndrome. Williamson's trial, however, did not restrict entrance to only those cases that were acute and hence no further insight can be obtained as to a female predilection for the acute condition. It should be noted that the larger number of females in both studies may be due to their greater availability during the open hours of the Technikon Natal Day Clinic

The mean ages for each group were similar (Table 4.3). The 15-25 years of age category held the largest number of patients. This may be due to the fact that eleven of the patients in the study were students, who would generally fit into this age group. This may further be explained by the fact that the research was run in

the Chiropractic Day Clinic on the campus of Technikon Natal and the awareness of the trial was perhaps greater amongst students.

When referring to Table 4.4 it can be seen that students have been put in a separate category. The reason for this is that the amount of computer work done by these students is difficult to judge. The remaining patients show that 24 were in occupations that required computer work. This further supports the findings of Williamson (1998) and may be of note in terms of future aetiology of acute cervical facet syndrome.

Twenty-four patients in total had experienced previous trauma involving the cervical spine, nineteen of which were motor vehicle accidents (Table 4.5). Group 1 had four patients more than Group 2 with previous neck trauma. Since nearly half of the patients in the study had experienced previous neck trauma it is reasonable to consider that this may be a predisposing factor to cervical facet syndrome.

Of the complications / side effects reported by the patients, to have arisen while taking the medication from either group, only headache is a documented side effect (piroxicam).

5.3 WITHIN-GROUP COMPARISONS

The comparison of the results from day 1 to those from day 3 was used to see if a rapid improvement resulted from taking either of the medications. Comparing results from day 3 and day 7 was used to detect an improvement that occurred

after day 3. Results from comparing day 1 to day 7 represent the overall improvement.

5.3.1 OBJECTIVE DATA

5.3.1.1 CERVICAL RANGE OF MOTION

The data for these variables may be found in Tables 4.10 to 4.15 . When comparing day 1 with day 3, and day 3 with day 7 no significant increase in range of motion occurred in any direction in either group. The results from comparing day 1 with day 7 showed an overall significant improvement in Group 1 in flexion and left and right lateral flexion, however no significant improvement occurred in the piroxicam group (Group 2) over the same period.

In summary, the intra-group analysis suggests that neither piroxicam nor Traumeel S showed a rapid improvement in range of motion. The Traumeel S group however showed significant improvement by the end of the seven days in some directions while none was observed in the piroxicam group.

5.3.1.2 ALGOMETER READINGS

Both groups showed improvement in algometer readings between day 1 and day 3, however neither of these were statistically significant. Neither group showed significant improvement between day 3 and day 7. There was a significant overall improvement in the piroxicam group. (Tables 4.10 to 4.15 and Figure 4.1.)

5.3.1.3 MOTION PALPATION

An improvement in motion palpation findings indicates that a specific joint, which was palpated on the first day of the comparison and was found to be fixated was no longer fixated on the next day being used for comparison. This was scored as a one for a fixation, and a zero for no fixation. The means for these scores on each day of assessment were used for statistical comparison. Group 1 showed a statistically significant improvement in motion palpation findings from day 1 to day 3. Over the period from day 3 to day 7 only Group 2 showed statistically significant improvement. Both groups showed very significant improvement in motion palpation findings when comparing days 1 and 7. It should be noted that although both medication groups had an overall improvement, the Traumeel S group showed a more rapid improvement than the piroxicam group. (Tables 4.10 to 4.15 and Figure 4.2.

5.3.2 SUBJECTIVE DATA

5.3.2.1 CMCC NECK DISABILTY INDEX

Both groups showed statistically significant improvement when comparing days 1 and 3, days 3 and 7 and days 1and 7. (Tables 4.10 to 4.15 and Figure 4.3.)

5.3.2.2 NRS-101 PAIN SCALE

Group 1 showed no statistically significant improvement between day 1 and day 3. Group 2 showed a significant improvement over the same time period. Group 2 had

a further significant improvement between day 3 and day 7. When looking at the overall improvement both groups exhibited significant improvements in subjective pain perception. Group 2 exhibited a strongly significant improvement ($p < 0.0001$). (Tables 4.10 to 4.15 and Figure 4.4)

5.4 BETWEEN-GROUP COMPARISONS

5.4.1 OBJECTIVE AND SUBJECTIVE DATA

None of the objective variables (ranges of motion, algometer readings and motion palpation findings), or subjective variables (CMCC Neck Disability Index and NRS-101 Pain Scale), when compared between groups on either of the three days showed any significant differences. This suggests that the medians (means in the case of motion palpation) for both groups started off on day 1 at similar levels and improved to similar levels on day 3 and day 7. This can be seen from the medians (means in the case of motion palpation) in Table 4.16 and 4.17. When looking at the graphs of the median (means in the case of motion palpation) values it is important to take note of the scales used so as to understand the similarities mentioned above.

5.5 SUMMARY DISCUSSION

According to the between group statistics, neither of the two groups were better than the other in treatment of the condition. The within group comparisons show an overall improvement of median (means in the case of motion palpation) values in all variables for both groups. The statistical tests show significant overall improvement

for both groups in pain perception (NRS-101), disability (CMCC Neck Disability Index) and motion palpation findings. The piroxicam group showed a rapid significant improvement in pain perception while the Traumeel S group did not. The Traumeel S group however showed rapid significant improvement in resolution of fixations (motion palpation findings). Both groups showed significant early and continuing improvement in terms of disability. The piroxicam group was the only one of the two to exhibit significant overall improvement in pressure pain threshold (algometer readings). The Traumeel S group was the only one of the two to show significant overall improvement in cervical range of motion (goniometer data), this occurred in flexion and left and right lateral flexion.

5.6 STUDY LIMITATIONS

The baseline characteristics of both groups were similar. This was fortunate as the groups were not intentionally stratified in terms of gender distribution and computer-related occupations, which may play aetiological roles in cervical facet syndrome. The use of the questionnaires may not have been as reliable as one might have hoped. This could be due to patients, who having had the trial explained to them and deducing that the questionnaires were a measure of improvement, may not have been entirely honest in their responses in order to please the researcher. This may also have occurred to a lesser degree with respect to use of the goniometer and algometer. For example on the patients' first visit they are introduced to the goniometer, a foreign piece of equipment to most. On the second consultation the new confidence and lack of apprehension may manifest in allowing ranges of motion to be exaggerated before responding to the researcher, hence affecting

results. In some cases the position, shape and size of patients' ears and noses as well as the shape of some patients heads and hair type and styles made it difficult to firmly secure the CROM instrument. There was slight movement of the goniometer itself on the patient's head while moving through range of motion, which would obviously affect the measurements. It is also questionable if patients performed the movements required for range of motion in an identical fashion on each of the assessment days. Although the researcher guided and observed these actions, slight differences in coupled motion utilised by the patients may have affected results in rotation and lateral flexion.

Human error with respect to the algometer may come in upon repeating exact placement of the instrument on second and third consultations. In addition it is the researcher's opinion that the angle at which the algometer is held may affect the amount of pressure needed to be applied in order to reach threshold. Furthermore, the tenderness of overlying musculature may interfere with direct measurement of tenderness over the facet joint itself. If the overlying musculature is shifted aside in order to place the algometer more precisely over the facet joint in question, the angulation of the instrument may be difficult to repeat. Research needs to be done to determine how reliable algometer readings are for testing pressure pain threshold over facet joints specifically.

The fact that the motion palpation was done by a relatively inexperienced intern instead of a practitioner with many years of experience may well be criticised. However, this seems of little significance in the light of Lakhani's (1999) study in which a significant correlation was found between motion palpation findings of an

intern of similar experience to the researcher, and a vastly more experienced practitioner.

Each patient completed a Patient Medication Diary, which was used to check that all the medication had been taken according to the recommended dosage. This however, was no guarantee that the Patient Medication Diaries were representative of the truth. Another concern is that the homoeopathic medication has special requirements (see Patient Medication Diary, Appendix G) and compliance with these could not be judged.

Stress is something that was not taken into account. Patients may have high stress occupations or be involved in daily stressful activities which may have impeded or masked any improvement occurring as a result of the medication. Emotional stress was also not taken into account and it is the researcher's strong opinion that this would influence results. Particularly in terms of pain perception and tenderness and to a lesser degree in decreased range of motion due to increased muscle tightness.

Patients in this study were not asked their opinion as to which group they thought they were in. Analysis of this would have given an idea of how successful the blinding procedure had been. It is the researchers opinion that the blinding methods were sound.

This study was limited by the lack of a placebo group. Creating a third group, which under the same conditions as the other two groups, received placebo medication,

would have allowed direct comparison to the treatment groups , and allow stronger deductions to be drawn.

However , the data generated by this study needs to be interpreted with caution due to the relatively small sample size. The small sample size is evident as a limitation through the power analysis results, which show a high possibility of making a Type II error (incorrectly accepting -the null hypothesis).

5.7 COMPARISON WITH OTHER STUDIES

There have been no studies up to this point on the treatment of acute cervical facet syndrome. Consequently, comparison to other studies seems, to a large extent, futile. However, comparison shall be drawn with two recent studies having similarities to this study in other areas.

Williamson (1998) compared spinal manipulative therapy to spinal manipulative therapy in conjunction with NSAIDs in the treatment of cervical facet syndrome. Patients received six treatments over two weeks. Comparisons will be drawn between the first and sixth consultations' results. The afore mentioned study is perhaps the better of the two to use in comparing results because it has a treatment period duration which is nearest to that, of this study.

Kavonic (1999) compared adjusting the ipsi-lateral side of a fixated joint, to adjusting the contra-lateral side in cervical facet syndrome. Patients received a

maximum of eight treatments over a period of four weeks. Results from comparing the first and eighth consultations shall be utilised.

In terms of range of motion, both of Williamson's groups achieved significant improvement in more directions of motion than the groups in this study. The Traumeel S group was similar in number of directions of cervical motion that improved significantly to those which improved in Williamson's (1998) adjustment plus placebo group. Neither of Kavonic's (1999) groups showed significant improvement of range of motion.

Piroxicam from this study and both of Williamson's (1998) groups had similar significant improvements in algometer readings. Kavonic (1999) found neither adjustment group to have any significant effect on pressure-pain threshold. Both of Kavonic's (1999) groups are in essence the same as Williamson's (1998) adjustment plus placebo group. This brings the reliability of algometer use for testing facet joint tenderness into question. Decreased reliability in the measurement of a variable, increases the likelihood of making a type II error (incorrectly accepting a null hypothesis)

The results from both groups in this study and both groups in each of the other two studies mentioned above showed similar significant improvement in terms of the CMCC Neck Disability Index and the NRS-101 Pain Scale results.

Every variable compared above showed no significant difference when between-group tests were run within the respective studies.

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSION

The results of this study show that both medications were effective in treating cervical facet syndrome. The piroxicam group, however, had no significant effect on improving range of motion, while the Traumeel S group had no significant effect on improving pressure pain threshold. It should, however, be noted that the piroxicam group provided earlier pain relief, while early resolution of fixated facet joints occurred only in the Traumeel S group. Neither group was statistically better than the other in overall improvement, in terms of disability, pain perception and resolution of fixations.

Four of the variables tested in this study were also tested by Williamson (1998). Three of these variables showed similar significant improvements in each group in both studies. All test groups except piroxicam significantly improved range of motion. It should be noted at this point that no group was significantly superior in improvement to the other in any variable in either this study or Williamson's study. From Williamson's study it seems as though spinal manipulative therapy is as effective as spinal manipulative therapy combined with an NSAID. This study shows that the use of piroxicam is as effective as using Traumeel S in the treatment of acute cervical facet syndrome, although each have areas in which the improvement seen, was greater, or occurred earlier than in the other group. The use of piroxicam, Traumeel S, spinal manipulative therapy and spinal manipulative therapy in combination with an NSAID are similarly effective in the treatment of cervical facet syndrome. It is the opinion of the researcher that when treating the

acute type of this condition, if a type of medication is to be used in conjunction with spinal manipulative therapy, it should be Traumeel S. The simple reason is that it eliminates the risk of complications associated with NSAIDs. If the patient is in extreme pain as a result of cervical facet syndrome, the use of piroxicam should be considered due to its rapid pain reducing action.

6.2 RECOMMENDATIONS

A larger sample size would make the sample more representative of the population from which it was taken. It would also decrease the chance of making a type II statistical error during analysis of the results. When choosing a sample for future tests on cervical facet syndrome researchers should ensure homogeneity in terms of age, chronicity, gender distribution and computer-related occupations. The last point should be enquired about at the beginning of the study for each patient. Taking note of the number of hours a patient spends working at a computer every day, and analysis of their workstation ergonomics may reveal some interesting trends.

Stress is a point of interest, which may be studied by questioning patients at the end of the treatment period (specifically with regards to stress experienced during the trial period), or devising a questionnaire for this purpose. It is the opinion of the researcher that the mental state of patients has possibly far greater importance in cervical facet syndrome than is given credit for. Anxious or stressed and depressed patients appear to have decreased pain thresholds. In a few cases this seemed to manifest itself in patients having decreased ranges of motion (CROM readings)

until the same level of discomfort was reached as previously. A similar effect appeared to have occurred when taking algometer readings i.e. pressure pain threshold was diminished in patients who were stressed or mentally depressed on the day of assessment. Although in this study no comparison could be made between the subjective measurements and patients' mental state it stands to reason that there may be an even greater impact in these areas. If mental state proves to be as important as it seems in cervical facet syndrome, and for that matter in other chiropractic conditions not considered here, it may provide some important guidelines for chiropractic care in the future. This may be in the form of including some simple stress management techniques into chiropractic patient education. It must be said that these alone may help patients but are unlikely to solve their problems entirely. Hence, the importance of a multidisciplinary approach to treating these patients becomes evident. Working together with psychologists, counsellors or other professionals trained in these areas may prove more effective as a holistic treatment of patients. This would seem to reinforce the wellness practice claimed by chiropractic

Further studies using NSAIDs could benefit by using the protocol utilised in this study to screen patients who were at risk of developing side effects. The number of patient s in this study who developed side effects, which could be attributed to the NSAID, were minimal, namely headaches. None of the dangerous complications were experienced.

The recommendation, which for the researcher, is of the greatest importance is the lack of information in the literature in terms of the natural history of cervical facet

syndrome. It is the opinion of the researcher that chiropractors fill this gap in their own knowledge through experience, however no documented studies or literature on the topic could be found at the time of this study's literature search. Studies need to be done on cervical facet syndrome in terms of the natural history of acute, sub-acute, chronic and acute exacerbations of the chronic condition.

REFERENCES

Amlie, E., Weber, H. and Holme, I. 1987. Treatment of Acute Low-back Pain with Piroxicam: Results of a Double-Blind Placebo-controlled Trial. Spine, **12**(5): 473-476.

Aoki, T., Kuroki, Y., Kageyama, T., Irimajiri, S., Mizushima, Y. and Yamamato, K. 1983. Multicentre Double-blind Comparison of Piroxicam and Indomethacin in The Treatment of Lumbar Diseases. European Journal of Rheumatology and Inflammation, **6**(3): 247-52.

Aprill, C. and Bogduk, N. 1992. The Prevalence of Cervical Zygapophyseal Joint Pain. Spine, **17**(7): 744-747.

Arky, R.1997. Physicians Desk Reference. 51st ed. Montvale: Medical Economics.

Bergmann, T.F., Peterson, D.H. and Lawrence, D.J. 1993. Chiropractic Technique – Principles and Procedures. New York, U.S.A.: Churchill-Livingston Inc.

Bland, J.H. 1994. Disorders of the Cervical spine: Diagnosis and Medical Management. Pennsylvania, U.S.A.: W.B. Saunders Company.

Böhmer, D.and Ambrus, P. 1992. Sports Injuries and Natural Therapy: A Clinical Double-Blind Study with a Homeopathic Ointment, Biological Therapy, **X**(4): 290-300.

Bolton, J.E. & Wilkinson, R.C. 1998. Responsiveness of Pain Scales: A Comparison of Three Pain Intensity Measures in Chiropractic Patients. Journal of Manipultive and Physiological Therapeutics. 21(1): 1-7.

Bosch, H.C., Sigmund, R. & Hettich, M. 1997. Efficacy and Tolerability of Intramuscular and Oral Meloxicam in Patients with Acute Lumbago: A Comparison with Intramuscular and Oral Piroxcam. Current medical Research and Opinion, 14(1): 29-38.

Bourdillon, J.F., Day, E.A. & Bookhout, M.R. 1992. Spinal Manipulation. 5th ed. U.K.: Butterworth Heinemann Ltd.

Brunarski, D.J. 1984. Clinical Trials of Spinal Manipulation: A Critical Appraisal and Review of the Literature. Journal of Manipulative and Physiological Therapeutics, 7(4): 243-249.

Cassidy, J.D., Lopes, A.A. & Yong-Hing, K. 1992. The Immediate Effect of Manipulation versus Mobilization on Pain and Range of Motion in the Cervical Spine:A Randomized controlled Trial. Journal of Manipulative and Physiological Therapeutics, 15(9): 570-575.

Cassidy, J.D., Quon, J.A., Lafrance, L.J. & Yong-Hing, K. 1992. The Effect of Manipulation on Pain and Range of Motion in the Cervical Spine: A Pilot Study. Journal of Manipulative and Physiological Therapeutics, 15(8): 495-500.

Conforti, A., Bertani, H., Metelmann, H., Chirumbolo, S., Lussignoli, S. and Bellavite, P.(1997).Experimental Studies on the Anti-Inflammatory Activity of a Homeopathic Preparation. Biomedical Therapy. XV(1):28-31.

Dabbs, V. & Lauretti, W.J. 1995. A Risk Assessment of Cervical Manipulation versus NSAIDs for the Treatment of Neck Pain. Journal of Manipulative and Physiological Therapeutics, 18(8): 530-536.

Deyo, R.A. 1996. Drug Therapy for Back Pain. Which Drugs Help Which Patients? Spine, 21(24): 2840-2849.

DiPalma, J. R. and DiGregorio, G. J. 1994. Management of Low Back and Neck Pain by Analgesics and Adjuvant Drugs: An Update. The Mount Sinai Journal of Medicine, 61(3):193-196.

Dishman, R. 1985. Review of the Literature Supporting a Scientific Basis for the Chiropractic Subluxation Complex. Journal of Manipulative and Physiological Therapeutics, 8(3): 163-174.

Dishman, R.W. 1988. Static and Dynamic Components of the Chiropractic Subluxation Complex: A Literature Review. Journal of Manipulative and Physiological Therapeutics, 11(2): 98-107.

Dorland's Illustrated Medical Dictionary. 26th ed. 1985. Pennsylvania: W.B. Saunders company.

Drews, E.R. 1995. A Study of Demographic and Epidemiological Factors of Private Chiropractic Practices and a Chiropractic Teaching Clinic. Masters Dissertation, Chiropractic, Technikon Natal, Durban.

Dwyer, A., Aprill, C. & Bogduk, N. 1990. Cervical Zygapophyseal Joint Pain Patterns I: A Study in Normal Volunteers. Spine, 15(6): 453-457.

Edwards, C.R.W. & Bouchier, I.A.D. (ed.) 1993. Davidson's Principles and Practices of Medicine. 16th ed. U.K: Churchill Livingston.

Englert, R., Fontanesi, G., Muller, P., Ott, H., Rehn, L. and Silva, H. 1996. Piroxicam Fast Dissolving Dosage Form in the Treatment of Patients with Acute Low Back Pain. Clinical Therapeutics, 18(5): 843-852.

Faye, L.J. and Wiles, M.R. Manual Examination of the Spine. In: Haldeman, S. 1992. Principles and Practice of Chiropractic. 2nd Ed. U.S.A.: Appleton and Lange.

Fischer, A.A. 1987. Pressure Algometry over Normal Muscles. Standard values, validity and reproducibility of pressure threshold. Pain, 30: 115-126.

Fitz-Ritson, D. 1990. The Chiropractic Management and Rehabilitation of Cervical Trauma. Journal of Manipulative and Physiological Therapeutics, 13(1): 17-25.

Foreman, S.M. & Croft, A.C. 1995. Whiplash Injuries: The Cervical Acceleration Deceleration Syndrome. 2nd ed. Baltimore: Williams & Wilkins.

Gatterman, M.I. 1990. Chiropractic Management of Spine Related Disorders. Baltimore: Williams & Wilkins.

Gifford, L.S. Influence of Circadian Variation on Spinal Examination. In; Grieve, G.P. 1994. Grieve's Modern Manual Therapy: The Vertebral Column. 2nd ed. Edinburgh: Churchill Livingston.

Giles, L.G.F. & Müller R. 1999. Chronic Spinal Pain Syndromes: A Clinical Pilot Trial Comparing Acupuncture, a Nonsteroidal Anti-inflammatory Drug, and Spinal Manipulation. Journal of Manipulative and Physiological Therapeutics, 22 (6): 376-371.

Goodman, T.A. and Simon, L.S. 1994. Minimizing the Complications of NSAID Therapy. Journal of Musculoskeletal Medicine. 2: 33-46.

Gore, D.R., Sepic, S.B., Gardner, G.M. & Murray M.P. 1987. Neck Pain. A Long-term Follow-up of 205 Patients. Spine, 12(1): 1-5.

Grieve, G.P. 1988. Common Vertebral Joint Problems. 2nd ed. U.K.: Churchill Livingston.

Haldeman, S. 1992. Principles and Practice of Chiropractic. 2nd Ed. U.S.A.: Appleton and Lange.

Heel. 1989. Routine Therapy. 5th ed. Baden-Baden, West Germany: Biologische Heilmittel Heel GmbH.

Howe, D.H., Newcomb, R.G. & Wade, M.T. 1983. Manipulation of the Cervical Spine: A Pilot Study. Journal of the Royal College of General Practitioners, **33**: 574-579.

Insel, P.A. Analgesic, Antipyretic and Anti-inflammatory Agents, In: Gilman, A.G. 1990. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 8th ed. New York: Penguin Press Inc.

Jensen, M.P., Karoly, P. and Braver, S. 1986. The Measurement of Clinical Pain Intensity: A comparison of six methods. Pain, **27**: 117-126.

Johnson, M.R., Schultz, M.K. & Ferguson, A.C. 1989. Comparison of Chiropractic, Medical and Osteopathic Care For Work Related Sprains And Strains. Journal of Manipulative and Physiological Therapeutics, **12**(5): 335-344.

Kahanovitz, N., Arnoczky, S.P., Levine, D.B. & Otis, J.P. 1984. The Efffects of Internal Fixation on the Articular Cartilage of Unfused Canine Facet Joint Cartilage. Spine. 9(3): 268-272.

Kavonic, B.G. 1999. The Relative Effectiveness of Adjusting the Ipsi-lateral Side of a Fixation versus Adjusting the Contra-lateral Side of a Fixation in the Management of Facet Syndrome of the Cervical Spine. Masters Dissertation, Chiropractic, Technikon Natal, Durban.

Koes, B.W., Bouter, L.M., van Mameren, H., Essers, A.H.M. Verstegen, G.M.J.R., Hofhuizen, D.M., Houben, J.P. & Knipschild, P.G. 1992. The Effectiveness of Manual Therapy, Physiotherapy, and Treatment by the General Practitioner for Nonspecific Back and Neck Complaints: A Randomized Clinical Trial. Spine, 17(1): 28-35.

Koes, B.W., Scholten, R.J.P.M., Mens, J.M.A. and Bouter, L.M. 1997. Efficacy of Non Steroidal Anti-Inflammatory Drugs for Low Back Pain: A Systematic Review of Randomized Clinical Trials. Annals of Rheumatic Diseases, 56: 214-23.

Lakhani, E. 1999. The Efficacy of Motion Palpation as a Post-Adjustive Assessment Tool in the Cervical Spine to Monitor Patient Progress. Masters Dissertation, Chiropractic, Technikon Natal, Durban.

Lantz, C.A. The Vertebral Subluxation Complex. In: Gatterman, M.I. 1995. Foundations of the Chiropractic Subluxation. St. Louis, Missouri: Mosby-Year Book Inc.

Lippit, A.B. 1984. The Facet Joint and Its Role in Spine Pain: Management With Facet Joint Injections. Spine, 9(7): 746-750.

Mennell, J.M.C.M. 1990. The Validation of the Diagnosis "Joint Dysfunction" in the Synovial Joints of the Cervical Spine. Journal of Manipulative and Physiological Therapeutics, 13(1): 7-12.

Mooney, V. & Robertson, J. 1976. The Facet Syndrome. Clinical Orthopaedics and Related Research, 115: 149-156.

Moran, M. 1990. An Observer-blind Comparison of Diclofenac Potassium, Piroxicam and Placebo in the Treatment of Ankle Sprains. Current Medical Research and Opinion, 12(4): 268-274.

Nansel, D.D., Peneff, A., Cremata, E. & Carlson, J. 1990. Time Course Considerations for the Effects of Unilateral Lower Cervical Adjustments with Respect to the Amelioration of Cervical Lateral-Flexion Passive End-Range Asymmetry. Journal of Manipulative and Physiological Therapeutics, 13(6): 297-304.

Nansel, D.D., Peneff, A. & Quitoriano, J. 1992. Effectiveness of Upper versus Lower Cervical Adjustments with Respect to Amelioration of Passive Rotational versus Lateral-Flexion End-Range Asymmetries in Otherwise Asymptomatic Subjects. . Journal of Manipulative and Physiological Therapeutics, 15(2): 99-105.

Nussbaum, E.L. & Downes, L. 1998. Reliability of Clinical Pressure-Pain Algometric Measurements Obtained on Consecutive Days. Physical Therapy, 78(2): 160-169.

Nyiendo, J., Phillips, R.B., Meeker, W.C., Konsler, G., Jansen, R. & Menon, M. 1989. A Comparison of Patients and Patient Complaints at Six Chiropractic College Teaching Clinics. Journal of Manipulative and Physiological Therapeutics, 12(2): 79-85.

Oberbaum, M. 1998. Experimental Treatment of Chemotherapy-induced Stomatitis using a Homoeopathic Complex Preparation: A Preliminary Study. Biologische Medizin, 3: 104-8.

Osterbauer, P.J., Derickson, K.L., Peles, J.D., Deboer, K.F., Fuhr, A.W. & Winters, J.M. 1992. Three-Dimensional Head Kinematics and Clinical Outcome of Patients with Neck Injury Treated with Spinal Manipulative Therapy: A Pilot Study. Journal of Manipulative and Physiological Therapeutics, 15(8): 501-511.

Panzer, D.M. Facet Subluxation Syndrome. In: Gatterman, M.I. 1995. Foundations of Chiropractic: Subluxation. St. Louis, Missouri: Mosby Year Book, Inc.

Peters, R.E. 1984. Facet Syndrome. European Journal of Chiropractic, **32**: 85-102.

Reggars, J.W. & Pollard, H.P. 1995. Analysis of Zygapophyseal Joint Cracking During Chiropractic Manipulation. Journal of Manipulative and Physiological Therapeutics, **18**(2): 65-71.

Reid, D.C. 1992. Sports Injury Assessment and Rehabilitation. U.S.A: Churchill Livingston Inc.

Roy, D.F., Fleury, J., Fontaine, S.B. and Dussault, R.G. 1988. Clinical Evaluation of Cervical Facet Joint Infiltration. Journal De Association Canadienne Des Radiologistes, **39**(6): 118-120.

Rubak, J.M., Poussa, M. & Ritsilä, V. 1982. Effects of Joint Motion on the Repair of Articular Cartlage with free Periosteal Grafts. Acta Orthopaedic Scandinavica, **53**: 187-191.

Schafer, R.C. & Faye, L.J. 1990. Motion Palpation and Chiropractic Technique – Principals of Dynamic Chiropractic. 2nd ed. Huntington Beach: The Motion Palpation Institute.

Sloop, P.R., Smith, D.S., Goldenberg, E. & Dore, C. 1982. Manipulation for Chronic Neck Pain. Spine, **7**(6); 532-535.

Snyman, J.R.ed. 2000. MIMS Medical Specialities. vol 40(3). Pretoria, South Africa: MIMS, a division of Times Media Limited.

Stock, W. 1988. Latest Clinical Results with Traumeel Ointment in Sports Injuries. Biological Therapy, VI(4): 73-78.

Takala, J., Sievers, K. & Klaukka, T. 1982. Rheumatic Symptoms in the Middle Aged Population in South Western Finland. Scandinavian Journal Rheumatology Supplement, 47: 15-29

Terret, A.C.J. & Vernon, H. 1984. Manipulation And Pain Tolerance: A Controlled Study of the Effect of Spinal Manipulation on Paraspinal Cutaneous Pain Tolerance Levels. American Journal of Physical Medicine, 63(5): 217-225.

Thiel, W. and Borho, B. 1994. The Treatment of Recent Traumatic Blood Effusions (Hematomas) of the Knee Joint. Biological Therapy, XII (4): 242-8.

Vernon, H.T.and Mior, S. 1991. The Neck Disability Index: A Study of Reliability and Validity. Journal of Manipulative and Physiological Therapeutics, 14(7):409-415.

Wilcox, M.C., Karen, A., Shalek, R.N. & Cotsonis, G. 1994. Striking Prevalence of Over-the-Counter Nonsteroidal Anti-Inflammatory Drug Use in Patients With Upper Gastrointestinal Hemorrage. Archives of Internal Medicine, 154: 42-46.

Williamson, A.R. 1998. The Relative Effectiveness of Spinal Manipulative Therapy versus Spinal Manipulative Therapy in conjunction with the Administration of Nonsteroidal Anti-Inflammatory Drugs in the Treatment of Cervical Facet Syndrome. Masters Dissertation, Chiropractic, Technikon Natal, Durban.

Yeomans, S.G. 1992. The Assessment of Cervical Intersegmental Mobility before and after Spinal Manipulative Therapy. . Journal of Manipulative and Physiological Therapeutics, 15(2): 106-114.

Youdas, J.W., Carey, J.R. and Garret, T. R. 1991. Reliability of Measurements of Cervical Spine Range of Motion – Comparison of Three Methods. Journal of Physical Therapy, 71(2): 98-106.

Zell, J., Connert, W.D., Mau, J and Feuerstake, G. 1989. Treatment of Acute Sprains of the Ankle: A Controlled Double-Blind Trial to Test the Effectiveness of a Homoeopathic Ointment. Biological Therapy, VII (1): 1-6.

Appendix A

PATIENT INFORMATION LETTER

Dear patient,

Welcome to this research study. You have been selected to participate in a clinical trial comparing two forms of anti-inflammatory medication for your neck pain. You have a common condition seen by chiropractors , which is known as Cervical Facet Syndrome. Inflammation is believed to play a role in cervical facet syndrome, hence the need to determine how effective anti-inflammatory medications are in its treatment.

There will be 2 groups containing 30 patients each. One group will be treated with Adco piroxicam, a non-steroidal anti-inflammatory drug and the other with Traumeel S, a homeopathic complex. You will be assigned to a group but will not know which of the 2 medications you are receiving.

The medication must be taken daily for 7 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 assessed on days 1, 3 and 7.

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 changes 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 piroxicam which are listed in the attached copy of the Adco piroxicam package insert. For your protection you will undergo a screening procedure in the form of a questionaire 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.

Thank You.

Sincerely,

Stuart Hepburn.
(6th year chiropractic resident)

Appendix B

SCHEDULING STATUS: S3

PROPRIETARY NAME
(and dosage form):

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

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

PHARMACOLOGICAL CLASSIFICATION:
A. 3.1. Antirheumatics (Anti-inflammatory agents)

PHARMACOLOGICAL ACTION:
ADCO-PIROXICAM has analgesic, anti-inflammatory and antipyretic properties, and is used in the treatment of rheumatoid arthritis and other rheumatic disorders. Piroxicam acts as an inhibitor of prostaglandin biosynthesis.
ADCO-PIROXICAM is completely absorbed after oral administration: peak concentrations in plasma occur within two to four hours. Neither food nor antacids alter the rate or extent of absorption.
After absorption, piroxicam is extensively (99%) bound to plasma proteins, and has a long plasma half-life of approximately thirty-five to forty-five hours. At steady state, (eg. after seven to ten days) concentrations of piroxicam in plasma and synovial fluid are approximately equal.
Piroxicam is metabolised in the liver by hydroxylation of the pyridyl ring of the piroxicam side chain followed by conjugation with glucuronic acid and urinary elimination. Less than 10% of the drug is excreted in the urine unchanged.

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

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

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

DOSAGE AND DIRECTIONS FOR USE:
Rheumatoid arthritis, osteo-arthritis (arthrosis, degenerative joint disease), ankylosing spondylitis:
The usual daily dose for the relief of signs and symptoms of rheumatoid arthritis or osteo-arthritis is 20 mg given in single or divided doses. Since steady state concentrations in plasma are not reached for seven to ten days, maximal therapeutic responses should not be expected for two weeks. Long-term administration of doses higher than 30 mg carries an increased risk of gastrointestinal side-effects.
Acute musculoskeletal disorders:
Therapy should be initiated with 40 mg daily for the first two days, given in single or divided doses. For the remainder of the seven to fourteen day treatment period, the dose should be reduced to 20 mg daily.
Acute Gout:
Therapy should be initiated by a single oral dose of 40 mg to be followed on the next four to six days by 40 mg given in a single or divided daily dosage. ADCO-PIROXICAM is not indicated for the long-term management of gout.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Gastrointestinal symptoms are the most commonly encountered side-effects. Long-term administration of doses higher than 30 mg daily carries an increased risk of gastrointestinal side-effects.
Peptic ulceration and gastrointestinal bleeding have been reported with ADCO-PIROXICAM. Drug administration should be closely supervised in patients with a history of upper gastro-intestinal disease.
Other than the gastrointestinal symptoms, oedema, mainly ankle oedema, has been reported. Routine ophthalmoscopy and slit-lamp examination have revealed no evidence of ocular changes.
ADCO-PIROXICAM should not be used in patients on coumarin-type anticoagulants. Changes in different liver function parameters have been observed. Some patients may develop increased serum transaminase levels during treatment with ADCO-PIROXICAM.
Care should be exercised with the use of ADCO-PIROXICAM in patients with renal dysfunction. Blood urea nitrogen elevation has been observed in some patients. These elevations are not progressive over the course of treatment with ADCO-PIROXICAM, a plateau being reached which returns to or towards baseline levels if treatment is stopped. The rise in blood urea nitrogen is not associated with elevations in serum creatinine.
ADCO-PIROXICAM decreases platelet aggregation and prolongs bleeding time. This effect should be kept in mind.
Dermal hypersensitivity reactions, usually in the form of skin rash, have been reported. Stevens-Johnson syndrome may develop.
Decreases in haemoglobin and haematocrit, independent of gastrointestinal bleeding, have occurred. Thrombocytopenia and non-thrombocytopenic purpura (Henoch-Schönlein), aplastic anaemia, leucopenia and eosinophilia have been reported, and constitute indications for immediate withdrawal of ADCO-PIROXICAM.
It should be assumed that ADCO-PIROXICAM will precipitate bronchoconstriction in those patients who are hypersensitive to aspirin. Central nervous system effects such as dizziness, headache, somnolence and vertigo have been reported. ADCO-PIROXICAM increases plasma lithium levels.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
In the event of overdosage with ADCO-PIROXICAM, supportive and symptomatic therapy is indicated.

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

PRESENTATION:
ADCO-PIROXICAM 10 mg Capsules : Securitainers of 50 capsules
ADCO-PIROXICAM 20 mg Capsules : Securitainers of 50 capsules

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

REGISTRATION NUMBERS:
ADCO-PIROXICAM 10 mg Capsules : [illegible]
ADCO-PIROXICAM 20 mg Capsules : [illegible]

ZIMBABWE ONLY
10 mg : [illegible]
20 mg

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
Adcock Ingram Limited (Pharmaceuticals Division)
[illegible] Commando Road
[illegible]ustina
Johannesburg
2093

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
[illegible] September 1997
[illegible] 9.96-A[illegible]

Adcock Ingram

[illegible]

Appendix C

DR D.R. MOODLEY

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

GENERAL MEDICAL PRACTITIONER & CLINICAL ANATOMIST

23 KLAARWATER RD
SHALLCROSS
4093
TEL : 491471
FAX : 491371

16 AUTUMN GROVE
MALVERN
4093
TEL : 4631162
CELL : 0824659742

VAT NO : 4560179642

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

QUESTIONNAIRE :

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

   YES _____
   NO _____

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

   YES _____
   NO _____

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

   YES _____
   NO _____

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

   YES _____
   NO _____

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

   YES _____
   NO _____

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

   YES _____
   NO _____

   DETAILS _____

7. Have you had any surgery previously ?

YES _____
NO _____

DETAILS_____

_____

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

YES _____
NO _____

REASON_____

_____

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

YES _____
NO _____

DETAILS_____

_____

_____

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

YES _____
NO _____

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

YES _____
NO _____

FEMALE PATIENTS:

1. Are you pregnant now ?

YES _____
NO _____

2. State the onset date of your last period_____

3. Are your periods regular ?_____

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

Patient_____ I.D._____

Parent if under 21_____ I.D._____

Appendix D

INDEMNITY

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

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

_____

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

_____

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

_____

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

_____

SIDE EFFECTS OF ANTI- INFLAMMATORY DRUGS :

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

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

_____

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

PATIENT: _____

PARENT : _____

DATE : _____

DECLARATION :

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

Cervical Facet Syndrome

AND MAY USE THE FOLLOWING DRUG

Piroxicam

DOSAGE

40mg/day for 2 days, 20mg/day for the next 5 dau

PATIENT :_____

PARENT :_____

RESEARCH STUDENT :_____

CLINICAL SUPERVISOR :_____

MEDICAL DOCTOR :_____

DATE :_____

Appendix F

INFORMED CONSENT FORM

(To be completed in duplicate by patient /subject)

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

Please Print in block letters:

Patient /Subject Name:_____ Signature:_____

Parent /Guardian Name:_____ Signature:_____

Witness Name:_____ Signature:_____

Research Student Name:_____ Signature:_____

Appendix G

PATIENT MEDICATION DIARY

Patient name : _____ File no : _____ No : __

	DAY1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
CAPSULE							
1st Powder							
2nd Powder							
3rd Powder							

The dosage is one capsule once a day and one powder three times a day, each spaced equally throughout the day.

Please record the time at which each medication was taken.

-The powders are to be dissolved under the tongue, and not taken with water.
-Take the powders away from meals at least half an hour before a meal or one hour after.

- The powders must be stored away from camphor (eg. Vicks products), light , heat, and electromagnetic radiation (TV, Computers etc.).
- Try to avoid the intake of coffee during treatment.

- **The capsules are to be swallowed.**

Appendix H

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

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

Section 3 - Lifting

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

Section 4 - 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 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 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 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 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 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 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.

Vernon/Hagino, modified from Foubister et al.,Physiotherapy, 1980

Numerical Rating Scale

Patients name _____

Please indicate on the line below the number between 0 and 100 that best describes the pain of your major problem at this point, *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.

0_____100

Please indicate on the line below, the number between 0 and 100 that best descrbes the pain of your major problem at this point, *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.

0_____100

Appendix J

Patient Objective Measures Information

Patient Name : _____ **File no :**_____ **No :** _____

MOTION PALPATION DATA

	DAY 1	DAY 3	DAY 7
LEVEL			
SIDE			
DIRECTION			

C.R.O.M. DATA

	DAY 1	DAY 3	DAY 7
FLEXION			
EXTENSION			
LEFT ROTATION			
RIGHT ROTATION			
LEFT LAT. FLEXION			
RIGHT LAT. FLEXION			

ALGOMETER DATA

	DAY 1	DAY 3	DAY 7
READING			