

# **THE EFFECTIVENESS OF SPINAL MANIPULATION AND INTERFERENTIAL CURRENT THERAPY VERSUS ORAL MELOXICAM AND INTERFERENTIAL CURRENT THERAPY IN THE TREATMENT OF ACUTE MECHANICAL LOW BACK PAIN**

**BY**

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I, Carla Bekker-Smith, do hereby declare that this dissertation is representative of  
my own work.

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## **DEDICATION**

I would like to dedicate this work to my family. Dad, Nan, Mom, Mike, Kathrine, Michael. It has been a long, seemingly never-ending road to this final great goal. Only you who have been there through the tears, fears, parties and hardships can understand what it takes to accomplish something like this. Without your love and endless support throughout the years I would never have managed to finish this. To Marc, I dedicate this work and all that the future holds for us. I know that there will be many good times. Dad, thank you for all the financial support that you have given without question. Words can never thank-you enough, I will always love all of you.

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## **ABSTRACT**

Low back pain is one of the largest known causes of disability in western society. The purpose of this study was to evaluate the relative effectiveness of combined spinal manipulation and interferential current therapy versus combined oral meloxicam and interferential current therapy in the treatment of acute mechanical low back pain. This prospective randomised clinical trial consisted of sixty voluntary subjects, diagnosed with acute or acute on chronic mechanical low back pain. The patients were randomly divided into two groups of thirty, with Group 1 receiving chiropractic manipulative therapy and ten minutes of interferential current therapy for five treatments with one follow-up consultation, and Group 2 receiving 15mg oral meloxicam tablets once a day for ten consecutive days and ten minutes of interferential current therapy for five treatments with one follow-up consultation. Both groups were treated within two to three weeks. Capturing of the subjective and objective data for both groups took place on the first, third and sixth consultations. Subjective data was captured using the Numerical Pain Rating Scale-101 and the Revised Oswestry Back Disability Questionnaire. Objective data was gathered using the Orthopaedic Pain Rating Scale.

Statistical Analysis was completed under the guidance of a statistician from Technikon Natal. Mann-Whitney U-test and Friedman's T-test's were used for inter-group and intra-group analysis. The data was analysed at the 95% level of confidence i.e.  $p < 0.05$ . This data was presented in the form of tables and figures.

According to the subjective readings from the Numerical Pain Rating Scale and Revised Oswestry Back Disability Questionnaire there was no improvement within both groups subjectively. According to the objective data there was an improvement within both groups but Group 1 showed better improvement overall.

The results of the study concur with the literature review and other studies on low back pain, in that both groups did respond to their treatment protocols. Based on the objective findings, the spinal manipulation and interferential current therapy group responded better than the oral meloxicam and interferential current group, which is significant because of the reduced side effects associated with Group 1's treatment compared to Group 2.

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**DEFINITIONS**

## SPINAL ADJUSTMENT

Specific form of direct articular manipulation utilizing either long or short leverage techniques with specific contacts, characterised by a dynamic thrust of controlled velocity, amplitude and direction. (Gatterman 1990:405)

## CHIROPRACTIC

A science of applied neurophysiologic diagnosis based on the theory that health and disease are life processes related to the function of the nervous system: irritation of the nervous system by mechanical, chemical or psychic factors is the cause of disease; restoration and maintenance of health depend on the normal function of the nervous system. (Saunders 1995:312)

## CONTRAINDICATION

Any condition, especially any disease conditions that renders one particular line of treatment improper or undesirable. (Gatterman 1990:407)

## FIXATION

The absence of motion of a joint in a position of motion, usually at the extremity of such motion. (Gatterman 1990:408)

## JOINT DYSFUNCTION

Joint mechanics with areas of disturbed joint function. (Gatterman 1990:409)

## MANIPULATION

A passive manoeuvre in which specifically directed manual forces are applied to the vertebral joint, with the object of restoring mobility to the restricted areas.  
(Gatterman 1990:410)

#### OBJECTIVE CLINICAL FINDINGS

Refers to procedures utilized by the practitioner that objectively assess the patient's condition. This is achieved through passive range of motion assessment and tests.

#### SUBJECTIVE CLINICAL FINDINGS

Diagnostic procedures, as completed by the patient that subjectively assesses the condition of the same patient. This was achieved through the use of the Numerical Pain Rating Scale-101 and Oswestry Low Back Disability Index.



# CHAPTER ONE: INTRODUCTION

## 1.1. THE PROBLEM SETTING.

Low back pain (LBP) is one of the largest single known causes of disability in western society, with estimates predicting that 60 to 80% of the population suffer from LBP at one point in their lives (Koes 1991). The lifetime incidence of LBP in Indian and Coloured communities in South Africa, was found to be 78.2% and 76.6% respectively (Docrat 1999), whilst in the formal black settlement of Chesterville the lifetime incidence of LBP was found to be 57,6% (van der Meulen 1997). With such a high lifetime incidence of LBP in South Africa, as in the rest of the world, research into the effective management of the condition is required.

Chiropractic manipulation is recognised as an effective means of treating mechanical LBP, with respect to both Lumbar Facet Joint Syndrome (LFS) and Sacro-iliac Joint Syndrome (SIS) (Assendelft et al.1992 and Koes et al.1996). Meade et al. (1990) in a randomised, controlled study of 711 LBP patients for whom spinal manipulation therapy (SMT) was not contra-indicated, compared hospital outpatient management with that of chiropractic management. The group treated by chiropractors achieved more favourable results with respect to disability and patients' satisfaction. A weakness of this study is that there was no control over the manipulation techniques used by chiropractors in the study.

Interferential current (IFC) therapy is often applied clinically to control pain, yet there is no conclusive evidence as yet to justify its use (Goats 1990:91). IFC is clearly widely used around the world, especially for the control of patients' pain. There is scant scientific research to demonstrate its proposed effects and even less evidence defining which frequencies and dosages to use to produce the different effects. Much of the textbook information on IFC usage is anecdotal and protocols are often based on the trial and error of the individual therapist (Johnson, 1999: 294).

Doctors prescribe anti-inflammatory drugs worldwide as the primary treatment for LBP, regardless of possible side effects and the option of alternate treatment methods (van Tulder et al. 2000). “NSAIDs are the classical treatment for LBP and sometimes the basic therapy.” According to an opinion survey carried out in Belgium among general practitioners (Szpalski and Hayez 1994), NSAIDs were also found to be the most frequently prescribed medication for LBP, according to the survey. In a global analyses of clinical trials, meloxicam (Mobic®) 7.5mg and 15mg, had a better gastro-intestinal (GI) safety profile in comparison with diclofenac 100mg, piroxicam 20 mg and naproxen 750-1000mg. Although the above research involved different conditions, the pathophysiology still points to inflammation causing the pain. Meloxicam was therefore chosen for this study to help ensure the safety of the patients on the research trial.

Limited research is available on the combined effectiveness of commonly used treatments in both chiropractic and allopathic medicine. Although studies have shown NSAIDs to be no more effective than spinal manipulation for acute LBP, it is still a common treatment used (van Tulder et al. 2000). Practically, health care professionals treat LBP patients with a variety of modalities including manipulation, IFC and NSAIDs. SMT and IFC therapy are commonly used together to treat LBP by the chiropractor, as are NSAIDs with IFC therapy used by the general practitioner in combination with a physiotherapist. Research is needed to determine which of the above treatment protocols is more effective.

## **1.2. THE STATEMENT OF THE PROBLEM.**

The purpose of this study was to evaluate the relative effectiveness of combined SMT and IFC therapy versus combined oral meloxicam and IFC therapy, in the treatment of acute mechanical LBP.

### **1.2.1. The First Sub-problem.**

The first objective was to determine the relative effectiveness of combined SMT

and IFC therapy compared to combined oral meloxicam and IFC therapy, in the management of acute mechanical LBP, in terms of subjective clinical measures.

### **1.2.2. The Second Sub-problem.**

The second objective was to determine the relative effectiveness of combined SMT and IFC therapy compared to combined oral meloxicam and IFC therapy in the management of acute mechanical LBP, in terms of objective clinical measures.

## **1.3. HYPOTHESIS.**

### **1.3.1. The First Hypothesis.**

It is hypothesised that combined SMT and IFC therapy will be more effective than combined oral meloxicam and IFC therapy in the treatment of acute mechanical LBP, in terms of subjective clinical findings.

### **1.3.2. The Second Hypothesis.**

It is hypothesised that combined SMT and IFC therapy will be more effective than combined oral meloxicam and IFC therapy in the treatment of acute mechanical LBP, in terms of objective clinical findings.

## **1.4. THE BENEFITS OF THE STUDY.**

This research project aims to evaluate the relative effectiveness of combined SMT and IFC therapy versus combined oral meloxicam and IFC therapy in the treatment of acute mechanical LBP. This should enhance future treatment of this commonly treated condition by increasing doctors' awareness of the implications and results of combined therapies.

It is anticipated that this study will provide much needed clarity between chiropractors and doctors in the treatment of acute mechanical LBP. It will allow for better-informed decisions about the relative benefits of these treatment

protocols. Additionally, better practical guidelines can be developed regarding future treatment, which will help diminish patient risk and cost.

Thus this research may contribute to a more unified treatment protocol for acute LBP. By helping to determine whether either of these treatment protocols is more effective, could contribute to a more unified approach to the management of acute mechanical LBP.

# CHAPTER TWO: REVIEW OF THE RELATED LITERATURE

## 2.1. INTRODUCTION.

In reviewing the current literature it is intended that an overview of the incidence, aetiology and pathophysiology of LBP will be provided. Evidence of the efficacy of SMT, IFC therapy and oral meloxicam will all be investigated through a review of the related literature.

There is no universal consensus concerning the treatment of LBP (Meade et al. 1990:1431). SMT is theorized to reduce LBP in patients by releasing the mechanical stress on the posterior facet joints (Shekelle, 1994: 858). IFC therapy is widely regarded as a useful form of therapy in reducing pain. There is however a lack of sufficient clinical evidence to support this (Goats 1990:91). Recent guidelines for the management of LBP in primary health care have been published in the United Kingdom, New Zealand and the Netherlands. These guidelines have recommended the prescription of NSAIDs, as one option for symptomatic relief of acute LBP (van Tulder 2000). This is however the first study of its kind to compare the effectiveness of SMT to NSAIDs with the combination of treating both groups with IFC. I believe this gives the study an advantage over others as it helps to eliminate the biasing of results caused by applying different treatments to different groups.

## **2.2. THE INCIDENCE AND PREVALENCE OF LOW BACK PAIN.**

Incidence is the rate at which healthy people in a given population develop a disease or symptom over a specified period of time. Lifetime incidence therefore reflects the number of people who develop a condition at sometime in their lives. Prevalence is defined as a measure of the number of people in a certain population group, who have a symptom or disease at a specific time (Borenstein et al.1995: 22).

The lifetime incidence of LBP in western society is 60-80% of the population (Koes 1991). The prevalence rises after the age of 25 to a peak at 55 years old (Cox 1990:339). South Africa's lifetime incidence of LBP in Indian and Coloured communities was in keeping with Koes (1991) findings, where it was found to be 78.2% and 76.6% respectively, and the prevalence was 45% and 32.6% respectively (Docrat 1999). In the formal black South African settlement of Chesterville the prevalence of LBP was found to be 53.1%, while the lifetime incidence was 57.6% (van der Meulen 1997). Both these studies recommended larger sample sizes in the future, and more extensive epidemiological studies to be done in Africa.

## **2.3. THE AETIOLOGY OF MECHANICAL LOW BACK PAIN.**

There are commonly three diagnoses associated with mechanical LBP (Schafer and Faye 1989:195):

1. Lumbar Facet Syndrome (LFS)
2. Sacroiliac Syndrome (SIS)
3. Lumbar Radicular Syndrome (discogenic or mechanical in origin, LRS)

These syndromes may be caused by:

1. sprain/strain
2. poor posture

3. disuse
4. overuse
5. developmental abnormalities
6. joint dysfunction (fixation / hypermobility)
7. degenerative changes
8. combination of any of the above (Schafer and Faye 1989:195).

For the purpose of this study only patients with unilateral LFS and/or unilateral SIS were included in the research.

#### **2.4. THE PATHOGENESIS OF MECHANICAL LOW BACK PAIN.**

Movement between adjacent vertebrae takes place between the intervertebral disc and paired zygapophysial joints. This is known as the three joint complex (White and Punjabi 1990:45). Although movement between individual vertebra is slight, together the spine can produce a wide range of movements. The absence of movement at a single facet joint does not greatly reduce the range of motion of the entire spine but it does have more far reaching reflexogenic effects, which influence muscle tone and the excitability of the stretch reflexes in all the striated muscles. In order to fully understand the pathogenesis of LBP, one must understand the three joint complex, and that any alteration to its structure leads to the disruption of a kinematic chain between the joints, causing pain (Gatterman 1990:137).

According to Kirkaldy-Willis (1988:49-55) three further aspects must be considered when looking at the origins LBP. These include:

1. Emotional Factors -anxiety, depression, fear, tension and resentment
2. Changes in Muscle - impaired local circulation, sustained muscle contraction, vasoconstriction, structural muscle changes and abnormal contraction

3. Changes in the three joint complex - strains, synovitis, Facet Joint Syndrome, degeneration and disc degeneration

The pathogenesis of LBP can be categorised into three separate phases of degeneration namely: **Dysfunction, Instability and Stabilisation** (Kirkaldy-Willis 1988:117-131). For the purpose of this study only patients in stage one have been included, to avoid the complication of comparing the recovery of different stages of LBP.

### **Stage 1: Dysfunction**

Pathogenesis of this stage includes rotational sprains, synovitis and associated nipping of the facet joint synovial fringe, para-spinal muscle spasm resulting in joint dysfunction and entrapment of the facet joint meniscoids. These lead to the slow degeneration of the articular cartilage and intra-articular adhesions. The intervertebral discs are also affected as it develops circumferential tears within the annulus fibrosis. These tears coalesce to form larger radial tears, weakening the disc and predisposing it to bulges and herniations of the inner nucleus pulposis.

Symptoms of stage 1 are as follows:

1. Facet joint inflammation resulting in inflammatory metabolites, which stimulate pain sensitive nociceptors.
2. Muscle spasm, which results in ischemia, and thus pooling of the inflammatory metabolites. This leads to chemical irritation of pain sensitive nerve endings.
3. Joint dysfunction, which further perpetuates the pain cycle by disturbing the proprioception and gate-control mechanisms and thus increases the pain cycle. This is sclerogenous pain and may thus be referred or localised.
4. Disc pathology, if severe enough may result in nerve root compression leading to radicular symptoms.

These are the pathological lesions seen in the posterior facet joints and sacro-iliac joints, which leads to LFS and SIS.



## **Stage 2: Instability**

A continuation of the degenerative process of stage one leads to gross disc disruption. With a loss of disc height and the circumferential bulging of the annulus, hyper laxity of the facet joint capsule and increased degeneration of the facet cartilage ensues. There is also osseous erosion and ultimately the formation of osteophytes. The final outcome is excessive intersegmental motion leading to subluxation and lateral canal entrapment.

The symptoms of stage 2 are as follows:

1. Coalescence of the radial tears results in disc herniation, causing nerve root entrapment or compression and consequently muscle weakness, reduction in tendon reflexes and dermatomal hypoaesthesia.
2. Inflammatory response, which leads to pain.
3. Increased movement leads to intermittent lateral nerve root entrapment at one level with radicular patterns of pain referral aggravated by flexion, extension and rotational movements.

## **Stage 3: Stabilization**

Continuation of this degenerative process leads to enlargement of the superior and inferior facets, osteophyte formation, loss of articular cartilage and periarticular fibrosis. Disc tissue is replaced with fibrous tissue, causing substantial loss of disc height. There is also osteophyte formation and some degree of ankylosis.

The symptoms of stage 3 are as follows:

1. Fixed lateral canal entrapment due to subluxation, osteophytes and disc fibrosis, which leads to muscle weakness, reduced tendon reflexes and dermatomal hypoaesthesia.
2. Central canal stenosis due to enlarged facet joints and osteophyte formation.

The classical LFS and SIS demonstrate these degenerative changes of the three joint complex in the dysfunctional phase and predispose the patient to disc herniation, degeneration and strains of the low back (Gatterman 1990:399).

Whatever the cause of LBP, the resultant pain is due to chemical irritation of nociceptors (Wyke 1985). There is neither a single cause nor an easy answer to the development of LBP; rather the related literature points to the result of long-term degeneration and tissue failure as the cause. This excludes all cases of severe trauma where the mechanism of LBP is obvious.

## **2.5. SPINAL MANIPULATION.**

Manual therapy has proven to be one of the most successful treatment protocols for mechanical LBP (Koes et al. 1992). In a critical review of related literature Di Fabio (1992) found 11 well-designed studies demonstrating the efficacy of manipulation in treating LBP. These studies showed particularly good symptomatic short-term relief of pain, and improvements in pain, flexibility and disability status in the patient.

The treatment goals of the dysfunction phase when considering the pathology found, should aim at reducing pain and increasing segmental mobility to restore normal functioning. Preference has been given to treatment protocols that restore the loss of mobility. This points to manipulative techniques to treat mechanical LBP (Di Fabio 1992).

Carey, Garret et al.(1995) conducted a prospective study of 1 555 patients with acute LBP, who presented to various practitioners (chiropractors, orthopaedic surgeons and health maintenance organizations). The patients who sought treatment from the chiropractors reported “excellent” results in 42.5% of the cases. Those who visited other practitioners only reported “excellent” results in 26.5% of the cases. In this study, patients who were treated by chiropractors took an average of 0.7 prescription medications during their treatment time, compared to 1.9 prescription medications taken by patients who consulted other practitioners.

In a study comparing chiropractic treatment to hospital outpatient management for LBP over an extended period of time, Meade et al. (1995) found that out of 741 patients, aged 18-64, presenting with LBP, at the end of a 3 year follow-up period, the patients treated by chiropractors reported a 29% higher level of improvement in pain and disability, compared to the hospital outpatients. This study suggests that chiropractic care of LBP lead to greater relief from symptoms than standard hospital outpatient management.

The possible effects of manipulation according to Calliet (1981: 129-130) are as follows:

1. A facet joint is temporarily immobilized by an acute synovial reaction and adherence of the joint surfaces takes place at the facets. The passive separation of these joints during manipulation frees the surfaces.
2. Manipulation allows for possible entrapped menisci to be released.
3. Similarly the joint capsule that may be lodged between adjacent articular surfaces will be released.
4. The abrupt movement of the manipulation will desensitise the joint mechano-receptors, and eliminate the reflex spasm that hindered joint movement.
5. The spindle fibres of the adjacent muscles are stimulated by the dynamic thrust of the manipulation and cause reciprocal relaxation of the extrafusal muscle fibres.
6. Centre of gravity is restored by the correction of the segmental mal-alignment.

Lopes (1993), suggests that the adjustment be designed to reduce the dyskinesiologic position of a spinal segment. This normalises the axis of motion around which joints move and decreases tension in the stressed soft tissue. The normalisation of the position of individual segments may have an effect on the position of the lumbar spine as a whole, thus restoring normal biomechanics and function to the spine.

### **Contra-indications to spinal manipulation:**

This study included only patients with acute mechanical LBP (six weeks, Koes et al. 1996), particularly in the dysfunction stage. Further exclusion was made of the more ominous conditions where the indiscriminate application of spinal manipulation would have had an adverse effect on the patient (Haldeman et al. 1993: 170-172).

Gatterman (1990:67) lists the contra-indications as follows:

1. traumatic injury (e.g. fractures and instability)
2. inflammatory conditions (e.g. ankylosing spondylitis)
3. bone infections (e.g. TB, osteomyelitis)
4. abdominal aneurysm
5. prostate or bone tumours
6. neurological disorders (e.g. space occupying lesions)
7. metabolic disorders (e.g. clotting disorders)
8. psychological disorders (e.g. malingering)

### **2.6. INTERFERENTIAL CURRENT THERAPY.**

Electrical stimulation is a commonly used and effective modality for the reduction of pain. In some acute cases, short-term use of the appropriate electrotherapeutic modalities can be beneficial for some patients who might otherwise be unresponsive to care (Plaughter 1993:525).

IFC therapy utilises two medium-frequency alternating currents that vary from 0-150 Hz. One circuit is set at 4000 Hz while the other oscillates between 4000 and 4150 Hz. The electrodes are placed so that the two currents intersect each other and cause interference, which forms a beat frequency over the intended treatment area. It is a low-frequency, alternating current (Gatterman 1990:352). This was a scientific break through because before, only direct current or low-frequency currents were tested, but they encountered high electrical resistance from the skin causing treatment to be very painful (Ganne 1976:109 and

Goats 1990:87). The sweep function, as described in the Dynatronics Operators Manual (1994:60), moves the point of interference inward and outward in a spiral pattern, bathing about 80% of the treatment area with the beat frequency.

The mechanisms of pain control and analgesia by IFC are not fully understood. The short duration of pulse frequency at 100Hz stimulates large diameter nerve fibres, which are known to inhibit the transmission of nociceptive stimulation via the smaller diameter fibres. This relates to the gate control theory of pain pathways and mediation of pain (De Domenico 1982, Forster and Palastanga 1985 and Goats 1990).

IFC can also activate the descending pain suppression system by stimulating the small diameter fibres. This causes the release of endogenous opiates (endorphins and enkephalins) at the spinal level, thus reducing the patients' perception of pain (Goats 1990, Forster and Palastanga 1985).

The increase in local circulation helps to remove nociceptive chemicals from the area, thus reducing pain (Forster and Palastanga 1985). It is also thought that the removal of these pain producing substances has a depressing effect on the A delta and C fibre activity. Sympathetic fibres innervate the muscle wall of the small arterioles of the body and a depressive effect on this system thus produces an increased blood flow through that blood vessel. Vasodilatation could occur in the damaged part of the blood vessel by inhibition of the sympathetic stimulation of the muscle wall of the arteriole. This leads to the relaxation of the vessel walls and thus an increase in the diameter. This leads to increased blood flow to the area and will flush out pain producing substances and improve healing (De Domenico 1982).

For the purpose of this study a sweep frequency was used on the patients to encompass all of the above-mentioned benefits, of the different frequencies of IFC therapy.

In a clinical trial by Hogenkamp (1987), it was found that the application of IFC near the vertebral column effectively treated local pain, hypertonia of the erector trunci muscles and aided in restoring disturbances in the neurovegetative balance (Hogenkamp 1987:21). By stimulating large-nerve fibers at the thoraco-lumbar level, segmentally, corresponding tissues such as internal organs, circulation to the cranium and lower and upper extremities are vegetatively influenced. An inhibition of the sympathetic reflex activity occurs, so that symptoms in the skin, muscles and internal organs due to an extensively high spontaneous activity of the sympathetic nervous system are counteracted (Hogenkamp 1987:21).

Nelson (1981) conducted a study in the physiotherapy department of the Sydney Hospital, from November 1977 to August 1978. The study included 100 patients with musculo-skeletal conditions who were treated with IFC therapy of varying frequencies, intensities and treatment times. The patients were divided into three groups according to the chronicity of their condition. Group one presented with symptoms for more than six months, group two from two weeks to six months, and group three less than two weeks. The conditions included pain of spinal origin, which was not responding to chiropractic or acupuncture treatment, osteoarthritis, joint pain, bursitis, tendonitis and muscle strains. The treatment times varied from 12-20 minutes and therapy was either given every day or twice a day in acute cases. If there was no change in three treatments the therapy was discontinued. There were varied results, from worse to complete recovery; Group 1 (> 6 months), 47% showed complete recovery, 31% slight to moderate improvement and 22% no change. Group two (2 weeks to 6 months) 76.9% showed complete recovery, 7.7% slight to moderate improvement and 15.4% no change. Group three (2 weeks), 100% showed complete recovery.

The results of this study are encouraging yet no conclusive deductions can be drawn due to the absence of a control group as well as the size of each group being small. Further ambiguity was caused by the variety of conditions, which were treated. Each condition has its own natural history (the time it takes to spontaneously resolve); thus treating them all for the same length of time may give skewed results.

Although several physiological effects undoubtedly occur during IFC therapy, reliable clinical studies proving the therapeutic benefits are inconclusive (Goats 1990:91).

**Contra-indications to interferential current therapy:**

According to Forster and Palastanga (1985:111) the only real danger of IFC therapy is an electrical burn if the bare electrode touches the skin of the patient, allowing the current to pass between the electrodes rather than through the deeper tissue. The apparatus must not be too close to any other type of electro medical apparatus, due to a shock risk.

Goats (1990:87-92) lists the contra-indications as follows:

1. inflammation in the area
2. fever
3. tumour or malignancy
4. thrombosis
5. pregnancy
6. cardiac pacemaker

## **2.7. NONSTEROIDAL ANTI-INFLAMMATORIES: MELOXICAM.**

### **2.7.1. Introduction.**

Over the past twenty-five years, many NSAIDs have come onto the market, gradually replacing aspirin as the main treatment for all kinds of inflammatory aches and pains.

### **2.7.2. Meloxicam.**

Meloxicam

[4-hydroxy-2-methyl-*N*-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide; U.H.A.C. 62 XX, Boeringer Ingelheim 2001], is a new enolic acid class of NSAID (Turck et al. 1996:13).

It is not clear why different agents cause varying gastro-intestinal side effects, while displaying similar anti-inflammatory potency. The discovery of two isoforms of the C.O.X. enzyme, C.O.X.-1 and C.O.X.-2, has helped to explain this further. Recent findings suggest that the anti-inflammatory actions of NSAIDs are primarily mediated through the inhibition of the inducible enzyme C.O.X.-2, whereas the toxic side effects, such as renal and gastric toxicity are due to the inhibition of C.O.X.-1 and C.O.X.-2 activity, which are necessary to protect the stomach, kidney and possibly other organs against damage (Distel et al. 1996:68). Meloxicam's good tolerability, particularly with respect to the gastro-intestinal tract, is thought to be due to its preferential inhibition of C.O.X.-2 over C.O.X.-1 (Turck et al. 1996:13).

Most NSAIDs are highly protein bound to albumin; meloxicam is no exception, being 99% bound. Meloxicam is mostly eliminated by metabolic degradation. There is roughly equal renal and faecal elimination, with less than 0.25% excreted unchanged in the urine and 1,6% of the parent compound present in the faeces. Oral meloxicam has a total clearance of 0.42-0.48 l/h. In comparison with other NSAIDs of the same class, meloxicam has a relative half-life (T<sub>1/2</sub>) of ~20 hours. This value allows for once-a-day dosage, without the need for a slow release



formulation. In comparison the relative half-life of piroxicam and tenoxicam are ~53 hours and 65-70 hours respectively. Additionally, a steady state is achieved within 3-5 days with meloxicam whereas 1-2 weeks is necessary for other NSAIDs. The absolute bioavailability of meloxicam is 89% for oral capsules after a single 30mg dose, and maximum plasma concentrations are achieved after 5-6 hours when administered after breakfast. The pharmacodynamics of NSAIDs may be affected by hepatic or renal insufficiency. For meloxicam there is no relevant influence of hepatic insufficiency or renal dysfunction on the drugs pharmacodynamics (Turck et al. 1996:13).

Meloxicam is indicated for:

1. The symptomatic relief from rheumatoid arthritis (RA)
2. The symptomatic treatment of osteoarthritis (OA)
3. The symptomatic treatment of ankylosing spondylitis (Mobic® package insert)

The pathogenesis of arthritis is primarily inflammation of the joints. As Mobic® is indicated for such extreme uses in arthroses, it is clear that it too has a place in treating acute mechanical LBP, which has a lower grade inflammatory reaction.

Barner (1996:29) showed in a review of clinical trials that doses of 7.5mg and 15mg daily, of meloxicam were comparable to the efficacy of other NSAIDs, such as diclofenac, piroxicam and naproxen in both OA and RA. While adverse effects of meloxicam cannot be excluded, it does appear that there is a distinct advantage in gastro-intestinal tolerability and other side effects, when compared to equipotent doses of other NSAIDs.

### **2.7.3. Toxicity of NSAIDs: meloxicam.**

The more frequent side effects of Mobic® in the gastro-intestinal (G.I.) system are; dyspepsia, nausea, abdominal pain, vomiting, diarrhoea, constipation and flatulence. In the haematological system anaemia may occur. There might be skin irritation or a rash. The onset of asthma, light-headedness and headaches, as well as swelling (oedema), may occur (Mobic® package insert 2001).

The major side effects of most NSAIDs are: G.I. ulceration and bleeding, hepato-renal dysfunction and organ failure. Large case studies have shown that these risks are greatly affected by the age of the patient, with elderly patients being at greatest risk, and increased risk with increased doses. The highest risk is an elderly patient with a previous history of such events and those treated with concomitant corticosteroids (Distel et al. 1996:68).

Complications include G.I. bleeding from platelet dysfunction and the cumulative effect on various other lesions, regardless of the aetiology but including erosions and ulcers. Many of these ulcers are in fact peptic ulcers that bleed because of irritation by the NSAIDs but are not initially caused by them. The now impaired healing of the tissue due to NSAID use may also aggravate them.

G.I. adverse effects occur in roughly 12.9% and 12.7% of meloxicam 7.5 mg and 15 mg patients respectively. Many patients discontinue treatment of these drugs prematurely due to adverse side effects; 5% and 6.7% for 7.5 mg and 15 mg respectively (Barner 1996:30).

### **2.7.4. Safety and Efficacy of Meloxicam.**

In a study involving 4 175 patients over the age of 65, with the majority of the patients suffering from O.A. and R.A., Distel et al. (1996:75) compared the safety and tolerability of meloxicam 7.5 mg and 15 mg. The data shows a better G.I. tolerability and safety profile for meloxicam compared to diclofenac 100 mg, piroxicam 20 mg and naproxen 750-1 000 mg. When considering all the G.I.

adverse effects, and specific categories of G.I. effects, both doses of meloxicam were significantly better than the comparative NSAIDs in most cases. The discontinuation of treatment due to adverse effects was least in meloxicam 7.5 mg, followed by meloxicam 15 mg. Both doses of meloxicam showed statistically significant decrease in the incidence of perforations, ulcers and bleeding over piroxicam and naproxen.

A more recent study was performed by Hawkey *et al.* (1998:937) using MELISSA (the Meloxicam Large-scale International Study Safety Assessment) comparing meloxicam with diclofenac. MELISSA was a large scale, double-blinded, randomised, international, prospective trial, conducted over 28 days and using 9232 patients with OA. Significantly more patients receiving meloxicam reported fewer adverse events. This was attributed to fewer G.I. adverse events (13%) compared to diclofenac (19%;  $P<0.001$ ). Of the most common G.I. adverse events, there was significantly less dyspepsia ( $P<0.001$ ), nausea and vomiting ( $P<0.001$ ) and diarrhoea ( $P<0.001$ ) with meloxicam compared to diclofenac. Adverse events caused withdrawal from the study in 5.48% of patients receiving meloxicam compared to 7.96% on diclofenac ( $P<0.001$ ) (Hawkey *et al.* 1998:937).

In a further review of over 51 current trials involving NSAIDs in the treatment of acute low back pain, van Tulder (2000:2501-2513) concluded that NSAIDs are effective for the short-term symptomatic relief in patients with acute LBP.

## **2.8. COMPARISON OF RESULTS FROM OTHER STUDIES.**

An open study was performed on 108 patients by Waterworth *et al.* (1985), comparing SMT, conservative therapy (e.g. shortwave diathermy, ultra sound and exercises) and NSAIDs (diflunisal), for acute mechanical LBP. The SMT was applied at the discretion of the therapist. There was a mean change in the pain intensity on a 4-point scale after 4-12 days: SMT group improved by 0.6, conservative group by 0.7 and the NSAIDs group by 0.6. There was no significant

change in pain or mobility between the groups.

In a study in Britain, Meade et al. (1995) compared the efficacy of chiropractic and hospital outpatient management for LBP over an extended follow-up period. The 741 patients (between the ages of 18 and 64) presenting with LBP, were randomly allocated into two groups. After a 3 year follow-up the patients were asked whether they thought their treatment had helped their LBP. The improvements were measured in terms of pain and disability levels and those treated by the chiropractors found a 29% higher satisfaction rate than the hospital outpatients, suggesting that chiropractic treatment for LBP is more successful than hospital outpatients' management, in terms of long-term satisfaction of the patient. The weakness in this study was the lack of specification of what the hospital out-patient management involved. Thus not allowing one to draw any scientific conclusion from this study.

In a prospective, randomised, clinical pilot study of 77 patients with chronic (>13 weeks) spinal pain syndrome Giles et al. (1999:22:376-81) compared needle acupuncture, medication (tenoxicam and ranitidine), and chiropractic spinal manipulation. The treatment period was 4 weeks and outcome measures were taken at the initial and after 4 weeks of treatment. The manipulation group displayed the most substantial improvements that were uniformly significant. In the other two groups there was not one significantly improved outcome measure. In conclusion of this pilot study it is evident that long-term studies with a 1-3 year follow-up are more beneficial, but the evidence is that in patients with chronic spinal pain syndromes, spinal manipulation, if not contraindicated, results in greater improvement than acupuncture and medication.

In a controlled randomised clinical trial of 60 patients White (2001), compared the efficacy of diclofenac therapy (NSAID) and SMT to combined placebo and SMT in the treatment of mechanical LBP. After a two to three week treatment period there was no significant difference between the two treatment groups. The researcher

deduced that with SMT in both treatment groups the patient recovery was so great that any additional improvement brought on by the NSAIDs was statistically insignificant. This implies that SMT is a successful modality of treatment for mechanical LBP.

## **2.9. CONCLUSION.**

Low back pain remains a complex and perplexing condition to treat regardless of the large amount of the effort and time that is invested in treating it. With a lifetime incidence of LBP between 57,6% and 78,2% in different communities, in South Africa (van der Meulen 1997, Docrat 1999), it is a condition that needs further research and consolidation of treatment protocols to be established.

SMT has been shown to be effective for acute mechanical LBP (Koes et al. 1992, Di Fabio 1992, Meade et al. 1995), as has the wide use of NSAIDs (Hawkey et al. 1998:937, van Tulder 2000). Although this research only deals with a small sample of the population, its application to the treatment protocol for LBP could be significant. This research gives us an indication of the validity of the two combinations of treatment, as well as which one is more effective.

## **CHAPTER THREE: METHOD**

### **3.1. INTRODUCTION.**

This chapter gives a detailed description of the design, primary and secondary data, the subjects and interventions utilized. An overview of each questionnaire is discussed as well as the methods of statistical analysis and the process of evaluation of the data. The study design chosen was a randomized, comparative, clinical trial. This involved two treatment groups, one group receiving IFC therapy and SMT and the second receiving IFC therapy and oral meloxicam for the treatment of acute mechanical LBP.

### **3.2. THE DATA.**

The data consisted of primary and secondary data.

#### **3.2.1. The Primary Data.**

1. The patient's response to the Numerical Pain Rating Scale-101 (NRS) (Appendix J), which gives their perception of the level of change in their pain.
2. The patient's response to the Revised Oswestry Low Back Disability Questionnaire (OSW) (Appendix I), which gives their perception of change in their disability.
3. Clinical observation using an Orthopaedic Rating Scale (ORS) (Appendix K), involving a point system allocated to various orthopaedic stress tests, to assess the objective change in their condition.

### **3.2.2. The Secondary Data.**

Relevant data obtained from various sources, including journal articles, books, Medline and the internet, using the relevant search engines.

### **3.3. THE SUBJECTS.**

Subjects were recruited from the greater Durban area by means of advertisements placed at local sports clubs, local schools, gymnasia and tertiary education institutions, as well as advertising in local newspapers and in newsletters. Sixty subjects were selected from those who responded, using convenience sampling . No stratification of the subjects took place and they were accepted regardless of gender, occupation, race or severity of their pain.

An initial telephonic interview was conducted and patients were only excluded from the study at this stage if they did not fit the age criteria or if they had any obvious contra indication to SMT and NSAIDs. A letter of information (Appendix A) was provided and a letter of informed consent was signed by all subjects (Appendix C). All subjects were evaluated by means of a case history (Appendix F), the relevant physical examination (Appendix G), low back regional examination (Appendix H) and orthopaedic pain rating scale tests (Appendix K). Additionally patients in Group 2 completed a screening questionnaire for NSAID's (Appendix E) to establish whether further investigation into their medical history was needed to ensure the safety of them taking oral meloxicam.

### **3.4. INCLUSION AND EXCLUSION CRITERIA.**

1. Only patients between the ages of 18 and 45 years of age were included in this study to avoid parental consent and to keep the LBP being researched within the dysfunctional phase (Kirkaldy-Willis 1992:105).
2. Only patients with acute (less than six weeks) LBP (Koes et al. 1996)

were included. This included patients with an acute exacerbation of chronic LBP.

3. Subjects presenting with conditions that were contra-indicated to manipulation as stated by Gatterman (1990:67), were excluded on the grounds of clinical history and examination, and no further investigations were performed (e.g. radiographs or scans).
4. Patients presenting with any contra-indications to IFC therapy as stated by Goat (1990:87-92), were excluded from the study.
5. Patients presenting with any contra-indications to meloxicam (Boehringer Ingelheim 2001), were excluded from the study.
6. Pregnant females were excluded from the study due to the associated hormone-induced ligament laxity and possible resultant instability of the sacroiliac joint.
7. Patients presenting with bilateral LBP were excluded.
8. Patients receiving workers compensation or disability insurance for LBP were excluded.
9. Patients already taking analgesic or anti-inflammatory medication (Myprodol, Mobic, Voltaren, Cataflam B, etc.) were required to stop for a flush-out period of three days before starting on the research. No other analgesic or anti-inflammatory medication was permitted during the course of the research for either group.
10. Patients were required not to change their lifestyle or activity levels during the research period to avoid biasing the results. Failure to comply, with these instructions resulted in exclusion from the trial.
11. Patients that received any other form of treatment for LBP during the research period, were excluded.

There were four patients who dropped out of the study. Three were due to transport restrictions getting to and from their appointments, and one was for personal reasons.



### **3.5. ETHICAL CONSIDERATIONS.**

1. The rights and welfare of the subject were protected.
2. Informed consent was obtained (Appendix I).
3. The subject was not coerced into participating in the study.
4. Information was given to the subject in an understandable language where possible.
5. The research involved no more than minimal risk.
6. Confidentiality was maintained.
7. Participation was voluntary and did not involve financial benefit.
8. The subject was free to withdraw from the study at any time.

### **3.6. SAMPLING.**

The sample population consisted of sixty patients, selected for the study according to the criteria defined above. Patients were randomly allocated into one of two groups without the use of stratification, depending on whether they chose a piece of paper out of a box with the number 1 or 2 on it, until each had thirty patients.

Group 1 was treated with IFC therapy for ten minutes and received SMT as required by the motion palpation findings.

Group 2 was treated with IFC therapy for ten minutes and took oral meloxicam 15mg, for ten days.

### **3.7. THE MEASUREMENTS.**

#### **3.7.1. Subjective Measurements.**

Subjective measurements were recorded from two questionnaires completed by the patients in writing. The questionnaires used were the NRS (Jenson, Karoly and Braver 1986:117) and the OSW Questionnaire (Hsieh et al. 1992:25; Haas and

Jacobs 1995:79). The NRS and the OSW Questionnaires were completed before the first and third treatments and at the sixth follow-up assessment.

#### **3.7.1.1. Numerical Pain Rating Scale-101.**

Subjective pain is still considered one of the most important measurements available to both researchers and clinicians (Jenson et al. 1986:117). The NRS is a questionnaire used to measure the intensity of pain experienced by the subject. The subject was required, prior to treatment, to indicate the intensity of pain by means of a percentage from 0 to 100, where 0 represents 'no pain' and 100 represents 'pain as bad as it could get'. The two values recorded were firstly the pain intensity when it is at its worst and secondly the pain intensity when it is at its least. The average between these two figures is an indication of the subject's pain level.

Jenson et al. (1986:117-126) conducted a study where six methods of evaluating pain intensity were compared according to five criteria:

1. Ease of administration of the scoring,
2. Relative rate of incorrect responding,
3. Sensitivity with regard to questions,
4. Sensitivity of statistical analysis,
5. Relationship to a combination of pain intensity indices.

The results of this study concluded that the NRS was superior to the other measures due to its simple and practical method of administering and scoring, which may be in written or verbal form and its results did not seem to be dependent on age.

A more recent study by Bolton and Wilkinson (1998:1-7) on seventy-nine chiropractic patients compared three pain scales, including the Visual Analogue Scale, the Verbal Rating Scale and the NRS. The authors found the NRS to be the

most responsive and recommended this questionnaire for most types of outcome studies.

### **3.7.1.2. Revised Oswestry Low Back Disability Index.**

The OSW Questionnaire has been validated by chiropractic research studies by Hsieh et al. (1992:4-9) and Haas et al. (1995:79-87). Fairbank and Pynsent (2000:2949) concluded that the OSW was a “valid and vigorous measure of condition-specific disability.”

The OSW (Appendix I) has ten sections of six statements, including pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, travelling and changing degree of pain. For each section of six statements, the total score is 5. If the first statement is marked the score = 0, if the last statement is marked, the score = 5. Intervening statements were scored according to rank. A total score out of 50 is multiplied by 100 to form a percentage (Fairbank and Pynsent, 2000:2944). The overall goal of assessment was to measure change in the subject’s condition over time.

### **3.7.2. Objective Measurements.**

Objective measurements were recorded from the ORS (Appendix K), which comprised orthopedic tests specific for LFS and SIS, each of which were assigned points according to their specificity or accuracy. These measurements were recorded before the first, before the third and at the sixth follow-up consultations.

#### **3.7.2.1. Orthopaedic Rating Scale.**

Specific orthopaedic tests were performed to determine the presence of LFS and/or SIS. The specific tests for LFS included: Kemp’s Test (Corrigan and Maitland 1990: 35), Facet joint challenge test, hyperextension in the prone position (Gatterman 1990: 84 and 162), and a palpable muscle spasm with focal tenderness over the facet joints (Helbig and Casey 1988:61-64). The specific tests for SIS include: Posterior shear or “thigh thrust test” (Laslett and Williams

1994:1244), Patrick Faber test (Broadhurst and Bond 1998: 342), Gaenslen's test (Magee 1992:319) and Yeoman's test (Magee 1992: 320).

The details of these tests are as follows;

**KEMPS TEST** (also called the quadrant test): This test is designed to place the facet joints under maximum stress. The patient is seated, unsupported with the examiner standing behind. The examiner then passively extends, rotates and laterally flexes the patient to one side. A positive test is indicated by pain localized over the facet joint (Corrigan and Maitland 1990: 35).

**FACET JOINT CHALLENGE:** With the patient lying prone, a posterior to anterior force is applied on each spinous process of the lumbar vertebrae, to 'spring' or approximate each joint. A positive test is indicated by pain over the joint being tested (Gatterman 1990:84).

**PRONE HYPEREXTENSION TEST:** With the patient lying prone and keeping their pelvis on the examination table, the patient pushes his/her self upwards with their arms thus extending the back. A positive test is indicated by pain in this position (Gatterman 1990: 162).

**PALPABLE MUSCLE SPASM:** With the patient prone the examiner applies gently manual pressure to the paraspinal muscles. A focal point of tenderness as indicated by the patient gives a positive test (Helbig and Lee 1988).

**POSTERIOR THIGH THRUST TEST:** With the patient in the supine position and the test leg raised to 90° of hip flexion with the knee bent. The femur is adducted to the midline and axial pressure is exerted along the line of the femur. A positive test is characterized by localized pain over the sacroiliac joint (Laslett and Williams 1994: 1244).

GAENSLENS TEST: With the patient supine and both legs drawn up to the chest, the test leg is then released and hyperextension over the end of the bed is created. Pain localized over the ipsilateral sacroiliac joint is a positive test (Magee 1992: 319).

PATRICK FABER TEST: With the patient supine and the test side leg with the foot on the knee and the hip externally rotated, the examiner stabilizes the pelvis with one hand while lowering the test leg into further abduction, towards the table with the other hand. A positive test is localized pain over the sacroiliac joint (Broadhurst and Bond 1998: 342).

YEOMAN'S TEST: With the patient prone, the examiner stabilizes the pelvis whilst grasping the knee of the test leg and pulling the hip into extension. A positive test is characterized by pain over the sacroiliac joint (Magee 1992: 320).

Each of the above tests were allocated a score on production of a positive result in order to establish an orthopedic rating scale as an objective measure that may be statistically analyzed. All tests received a score of 2 when positive. An overall percentage of 60% was needed to have a positive diagnosis.

An orthopedic assessment rating out of 10 was determined. Only subject's with a rating of 6 out of 10 or higher were included in the trial ensuring that at least two orthopedic tests were positive for a diagnosis to be made. A change in the score gave an indication as to the progress or regression of the syndromes.

### **3.8. INTERVENTIONS.**

Each subject who was accepted for the trial attended five consultations over a two to three-week period. Group 1 received unilateral manipulation of the symptomatic lumbar facet or sacroiliac joint, followed by ten minutes of IFC therapy. The IFC therapy was administered at Group 2 received meloxicam 15mg, for ten days and ten minutes of IFC therapy. If a patient became asymptomatic, in terms of subjective or objective clinical findings, before the sixth treatment, the patient continued evaluation for the remainder of the treatment period. They received no further manipulative therapy, but continued on their meloxicam medication and with the IFC therapy.

#### **3.8.1. Spinal Manipulative Therapy.**

Both groups received SMT, once the diagnosis of LFS and/or SIS was confirmed using the ORS (as discussed in section 3.7.2.1). The involved area was manipulated according to the Diversified Technique (Schafer and Faye 1989:241-269). The applicable side posture adjustment with the patient in the lateral recumbent position, with a thenar or hypothenar contact, was delivered to the affected joint/s.

#### **3.8.2. Interferential Current Therapy.**

In this research study, all patients lay prone with their lower backs exposed. The four electrodes of the Dynatron 550 IFC machine were placed diagonally opposite each other in a square formation. The pads were placed inside moistened fabric pouches to improve conductivity. Special care was taken to ensure the electrodes were correctly positioned on each patient at each consultation. They were aligned with the bottom of lumbar vertebra 1 and sacral vertebra 1, on each patient. This created consistent positioning through out the study. For each patient a sweep, beat frequency was used, to optimise the treatment. The intensity of the current was determined by the patient's comfort because the size and depth of the patient's low back affects the resistance of the current. Group 1 received this after

their SMT treatment, and Group 2 received it at each of their five consultations (Dynatron 550 Operator's Manual 1996: 58).

### **3.8.3. Meloxicam.**

All patients in Group 2 were screened for possible side effects to NSAIDs (Appendix E). When they were found to be clear of any potential adverse effects they were started on a course of one 15mg meloxicam, per day after a meal in the morning, for ten consecutive days. Within a two to three week period they also received five, ten-minute IFC treatments.

## **3.9. STATISTICAL ANALYSIS.**

Statistical analysis was conducted on the subjective and objective data using the SPSS version 9.0 statistical software programme (manufactured by SPSS Inc., 444N. Michigan Ave, Chicago, Illinois, 60611, USA) and was presented in the form of bar graphs and tables.

Parametric statistical methods were used as each group consisted of thirty patients and the level of significance was fixed at  $\alpha = 0.05$  for all tests. Decisions were made based on p-values (If  $p \leq 0.05$  the hypothesis was rejected; and if  $p \geq 0.05$  the hypothesis was not rejected).

### **3.9.1. Comparison between Independent Samples.**

The inter-group information between group 1 and group 2 was statistically analysed at the same intervals as above. The objective and subjective measurements were analysed by the Mann-Whitney U-test.

### **3.9.2. Comparison between Related Samples.**

The intra-group comparison was made between the first and third, first and sixth and third and sixth visits. Subjective (OSW and NRS 101) and objective (ORS) comparisons were made using Friedman's T-test.

### 3.9.3. Hypothesis Testing and the Decision Rule.

The null hypothesis (Ho) stated that there was no improvement between treatments. The alternative hypothesis (H1) stated that there was an improvement between the treatments.

$$\alpha = 0.05 \quad \text{Level of significance}$$

For a one tailed test;

Reject Ho if  $P < \alpha = 0.05$

Accept Ho if  $P \geq \alpha = 0.05$  where:

$P = (\text{reported p-value}) / 2$  if  $H_1$  is of form  $<$  and  $z$  is negative  
 $H_1$  is of form  $>$  and  $z$  is positive

$P = 1 - (\text{reported p-value} / 2)$  if  $H_1$  is of form  $<$  and  $z$  is positive  
 $H_1$  is of form  $>$  and  $z$  is negative

If the null hypothesis Ho was rejected for Friedman's T-test, then the multiple comparison procedure (Dunn's Procedure) was applied to determine after which treatments a significant difference occurred.

Summary statistics including the mean, standard deviation and standard error were obtained to support the data from the various tests. The results of these tests were used to draw conclusions as to which treatment protocol was better for LBP.

### 3.10. GENERAL HYPOTHESIS.

#### 3.10.1. Objective Findings.

The null hypothesis (Ho) stated that there was no difference between Group 1 and 2 in terms of objective clinical findings (ORS). The alternative hypothesis (H1) stated that there was a difference between Group 1 and 2 in terms of objective clinical findings.



### **3.10.2. Subjective Findings.**

The null hypothesis (Ho) stated that within each group there was no improvement of the patient's condition in terms of subjective clinical findings (OSW and NSR). The alternative hypothesis (H1) stated that within each group there was an improvement of the patient's condition in terms of subjective clinical findings.

### **3.11. SUMMARY STATISTICS.**

If the parametric tests determined by way of calculation that there was a significant difference between the two groups in terms of subjective or objective clinical findings, the mean was established to identify the more effective treatment group. The standard deviation could be used to measure the reliability of the mean by measuring the spread data around the mean. For non-parametric tests, comparisons were made using the medians and decisions made using the appropriate p-values.

## CHAPTER FOUR: RESULTS

### 4.1. INTRODUCTION.

This chapter will present the results obtained from the clinical trial. The first set of data is the demographic data, followed by the statistical analysis of the results from the subjective and objective data, from the patients. The subjective data being analysed includes the NRS Questionnaire and the OSW Questionnaire. The objective data includes the ORS.

The results are tabulated to display the mean, the standard deviation, the standard error and the probability value. The level of significance for inter-group and intra-group analysis is  $\alpha = 0.05$  for all the tests.

## 4.2. DEMOGRAPHIC DATA.

### 4.2.1. Gender Distribution.

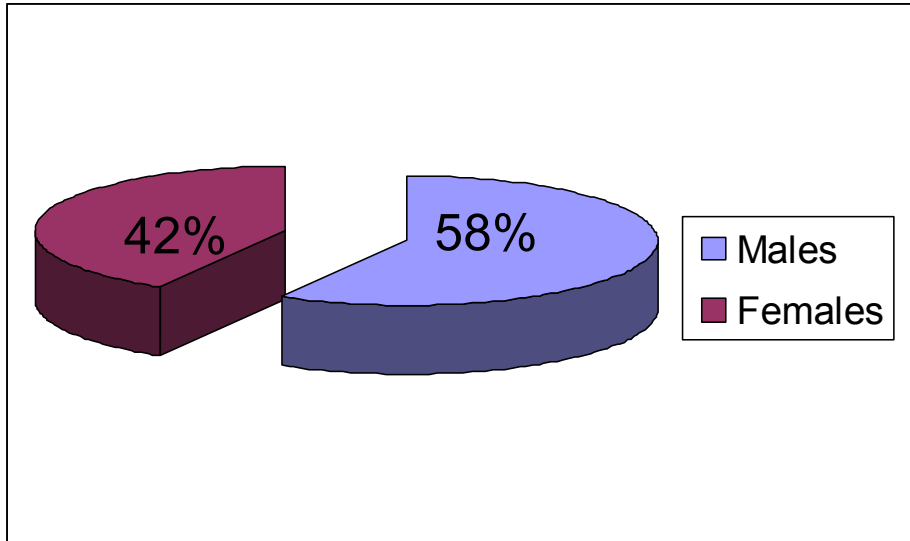


Figure 1: Male to Female Ratio within the sample population (n= 60)

### 4.2.2. Age Prevalence and Distribution.

Table 1: Age Prevalence and Distribution within the sample population (n=60)

Age	Group 1 (n=30)	Group 2 (n=30)	Total (n=60)
18-24	5 (16%)	11 (36%)	16 (26.6%)
25-34	21 (70%)	10 (33%)	31 (51.6%)
35-45	4 (13%)	9 (30%)	13 (21.6%)

### 4.2.3. Racial Distribution.

Table 2: Racial Distribution within the sample population (n=30)

Patients Racial Group	Group1 (n=30)	Group 2 (n=30)
Black	0 (0%)	1 (3%)
White	29 (96%)	24 (80%)
Indian	1 (3%)	4 (13%)
Coloured	0 (0%)	1 (3%)

### 4.3. TABLES TO CHARACTERIZE THE DISTRIBUTION BETWEEN LFS AND SIS.

Table 3: Percentage of LFS, SIS and combined LFS with SIS at initial consultation

	LFS	SIS	Combination
Group 1 (n=30)	8 (26.6%)	7 (23.3%)	15 (50%)
Group 2 (n=30)	14 (46.6%)	11 (36.6%)	5 (16.6%)

Table 4: Percentage of LFS, SIS and combined LFS with SIS at final consultation

	LFS	SIS	Combination	Resolved
Group1 (n=30)	1 (3.3%)	11 (36.6%)	0 (0%)	18 (60%)
Group2 (n=30)	16 (53.3%)	12 (40%)	2 (6%)	0(0%)

In **Group 1**, there was a change in the diagnoses from the initial to the final consultation for LFS was from 26.6% - 3.3%, for SIS from 23.3% - 36.6%, and for a combination from 50% - 0%. This shows that there was an overall improvement in the diagnoses for Group 1, with **60%** of cases resolved. In **Group 2**, the change in diagnoses for LFS was from 46.6% - 53.3%, for SIS from 36.6% - 40% and for a combination from 16.6% - 6%. The total percentage of resolved cases was **0%**. This is not statistical data, yet it is of interest to note the change in positive diagnostic cases of LFS, SIS and the combinations thereof, from the initial to the final consultations for Group 1 and 2.

## **4.4. STATISTICAL ANALYSIS.**

### **4.4.1. Abbreviations**

Group 1	= Spinal manipulation and IFC
Group 2	= Meloxicam and IFC
NRS-101	= Numerical Pain Rating Scale-101 Questionnaire
Osw	= Revised Oswestry Back Disability Questionnaire
ORS	= Orthopaedic Pain Rating
$\alpha$	= Level of significance of a test
P-value	= Observed significance level of a test
S.D.	= Standard deviation
S.E.	= Standard error
Con 1	= Consultation one
Con 3	= Consultation three
Con 6	= Consultation six
LFS	= Lumber Facet Syndrome
SIS	= Sacro-iliac Syndrome

### **4.4.2. Analysis of the Data.**

Parametric testing was used in order to analyse the respective data. Parametric testing was used to analyse the continuous variables, namely the NRS, and the OSW Questionnaire, to establish a general trend for mechanical LBP, as the sample size was 30 subjects ( $n \geq 30$ ). The p-values for inter-group and intra-group comparisons were set at  $\alpha = 0.05$  level of significance. The p-values of the Mann-Whitney U-tests for inter-group comparisons, as well as the Friedman's T-test, with the Dunn Procedure for intra-group comparisons, were all set at  $\alpha = 0.05$  level of significance.

## 4.5. PARAMETRIC TESTING: A COMPARISON OF CONTINUOUS VARIABLES.

### 4.5.1. Comparison of Continuous Variables.

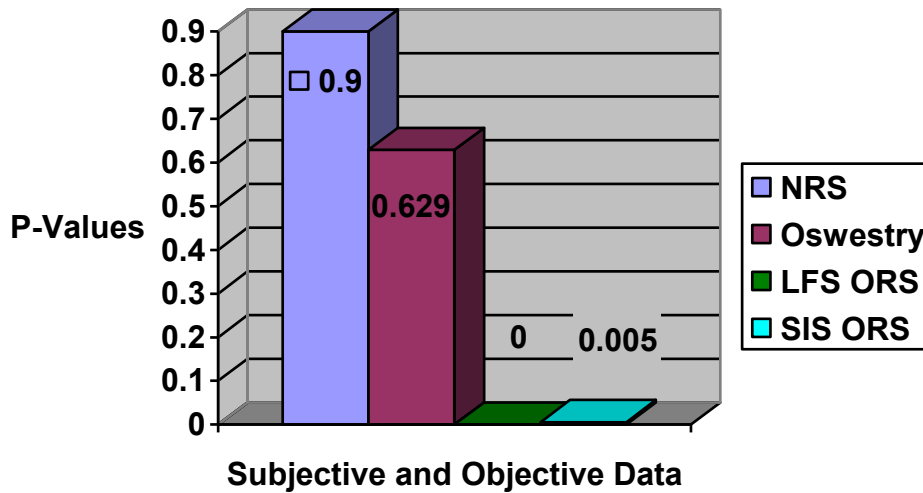


Figure 2: Mann-Whitney U-test assessing Low Back Pain at consultation 6 in Group 1 and Group 2

The null hypothesis was accepted according to the defined decision rule indicating no difference between treatments for the subjective data (NRS and OSW). The null hypothesis was rejected according to the decision rule for the objective data (ORS), thus showing an improvement for group 1 and group 2.

#### 4.6. NON-PARAMETRIC HYPOTHESIS TESTING.

##### 4.6.1. Intragroup Analysis: Friedman's T-test.

##### 4.6.2. Analysis of Objective Data in Group 1.

Table 5: The results of Friedman's T-test comparing the ORS readings at the initial, third and sixth consultations, for LFS and SIS in Group 1

GROUP 1							
Cons 1			Cons 3		Cons 6		P-value
	Mean	SD	Mean	SD	Mean	SD	
LFS	85.8333	26.0001	54.1667	22.8218	21.6667	14.2837	0.000 (<0.001)
SIS	55.3333	31.3746	32.000	26.0503	9.3333	12.5762	0.000 (<0.001)

Table 6: Mean Rank of ORS for Group 1

	Cons 1	Cons 3	Cons 6
LFS Mean Rank	2.88	2.00	1.12
SIS Mean Rank	2.80	2.00	1.20

For both LFS and SIS the null hypothesis is rejected and one can conclude that at the 5 % level of significance, there was an improvement between consultations one, three and six. The S.D. shows the spread of data around the mean value. In the above cases the S.D. values were similar enough to render the data reliable and consistent.

#### 4.6.3. Analysis of the Subjective Data in Group 1.

Table 7: The results of Friedman’s T-test comparing the NRS and OSW readings at the initial, third and sixth consultations, for LFS and SIS

GROUP 1							
Cons 1			Cons 3		Cons 6		
	Mean	SD	Mean	SD	Mean	SD	P-value
NRS	41.700	15.283	34.35	19.549	26.63	18.866	0.000 (<0.001)
OSW	16.266	8.399	13.866	10.224	9.4	8.853	0.000 (<0.001)

Table 8: Mean Rank of NRS and OSW, for Group 1

	Cons 1	Cons 3	Cons 6
NRS	2.53	1.98	1.48
Osw	2.5	2.08	1.42

For NRS and OSW readings, the null hypothesis was rejected which means that at the 5 % significance level, there was an improvement between consultations one, three and six. The S.D. values show the spread of data around the mean. In the above instance, the values are similar enough to render the data reliable and consistent.



#### 4.6.4. Analysis of Objective Data in Group 2.

Table 9: The results of Friedman's T-test comparing the ORS readings at the initial, third and sixth consultations, for LFS and SIS in Group 2

GROUP 2							
Cons 1			Cons 3		Cons 6		
	Mean	SD	Mean	SD	Mean	SD	P-value
LFS	81.667	24.5066	76.667	27.016	65.000	28.314	0.000 (<0.001)
SIS	60.667	38.050	43.000	30.529	32.667	31.6155	0.000 (<0.001)

Table 10: Mean rank of ORS for Group 2

	Cons 1	Cons 3	Cons 6
LFS	2.38	2.12	1.50
SIS	2.63	1.92	1.45

For both LFS and SIS the null hypothesis was rejected and one can conclude that at the 5 % level of significance, there was an improvement between consultations one, three and six. The S.D. shows the spread of data around the mean value. In the above cases the S.D. values were similar enough to render the data reliable and consistent.

#### 4.6.5. Analysis of the Subjective Data in Group 2.

Table 11: The results of Friedman's T-test comparing the NRS and OSW readings at the initial, third and sixth consultations, for LFS and SIS

GROUP 2							
Cons 1			Cons 3		Cons 6		
	Mean	SD	Mean	SD	Mean	SD	P-value
NRS	42.8333	13.208	30.2333	14.001	27.733	18.497	0.000 (<0.001)
OSW	17.400	9.884	12.800	10.720	11.266	10.654	0.000 (<0.001)

Table 12: Mean rank of NRS and OSW for Group 2

	Cons 1	Cons 3	Cons 6
NRS	2.77	1.75	1.48
OSW	2.68	1.9	1.42

For NRS and OSW readings, the null hypothesis was rejected which means that at the 5 % significance level, there was an improvement between consultations one, three and six. The S.D. values show the spread of data around the mean. In the above instance, the values are similar enough to render the data reliable and consistent.

#### 4.7. THE DUNN'S PROCEDURE (MULTIPLE COMPARISON TEST).

The null hypothesis was rejected for the NRS, OSW and ORS. Multiple comparison procedure was performed to determine the significance of each treatment.

Let  $R_j$  and  $R_{j'}$  be the  $j$ th and  $j'$ th consultation rank totals.

Let  $\alpha$  be the experiment-wise error rate  $\alpha = 0.10$

(Experiment-wise error rate is usually higher than  $\alpha$  and it depends on the sample size.)

**Decision Rule:**

$$|R_j - R_{j'}| \geq z \sqrt{\frac{bk(k+1)}{6}}$$

In the above formula:

$b$  = the number of blocks

$k$  = the number of consultations

$z$  = value in the inverse normal distribution corresponding to  $\{1 - [\alpha/k(k-1)]\}$

In order to compute the consultation rank totals, the values in each block were ranked and

then the sum of the ranks for each consultation was computed

In this case  $k = 3$ ,  $\alpha = 0.10$ ,  $z = 2.12$ ,  $b = 30$

#### 4.7.1. Objective Measures.

##### 4.7.1.1. Dunn's Procedure for the ORS for Group1 for LFS.

Table 13: Dunn's Procedure for the ORS for Group1 for LFS

	Rank Total	Difference	Rank Total	
R.1	86.4	26.4	60	R.3
R. 1	86.4	52.8	33.6	R.6
R. 3	60	26.4	33.6	R.6

$R1 - R3 = 26.4 \geq 16.42$ , therefore between consultations **1 and 3**, the result is declared **statistically significant**.

$R1 - R6 = 52.8 \geq 16.42$ , therefore between consultations **1 and 6**, the result is declared **statistically significant**.

$R3 - R6 = 26.4 \geq 16.42$ , therefore between consultations **3 and 6**, the result is declared **statistically significant**.

This implies that a significant improvement exists between consultations 1, 3 and 6, in terms of objective data for LFS for Group 1.

#### 4.7.1.2. Dunn's Procedure for the ORS for Group 2 for LFS.

Table 14: Dunn's Procedure for the ORS for Group 2 for LFS

	Rank Total	Difference	Rank Total	
R.1	71.4	7.8	63.6	R.3
R. 1	71.4	26.4	45	R.6
R. 3	63.6	18.6	45	R.6

$R1 - R3 = 7.8 < 16.42$ , therefore between consultations **1 and 3**, the result is declared **statistically insignificant**.

$R1 - R6 = 26.4 \geq 16.42$ , therefore between consultations **1 and 6**, the result is declared **statistically significant**.

$R3 - R6 = 18.6 \geq 16.42$ , therefore between consultations **3 and 6**, the result is declared **statistically significant**.

This implies that a significant improvement exists between consultations 1 and 6, and 3 and 6, but no improvement can be demonstrated between consultation 1 and 3 in terms of objective data for LFS for Group 2.

#### 4.7.1.3. Dunn's Procedure for ORS for Group 1 for SIS.

Table 15: Dunn's Procedure for ORS for Group 1 for SIS

	Rank Total	Difference	Rank Total	
R.1	84	24	60	R.3
R. 1	84	48	36	R.6
R. 3	60	24	36	R.6

$R1 - R3 = 24 \geq 16.42$ , therefore between consultations **1 and 3**, the result is declared **statistically significant**.

$R1 - R6 = 48 \geq 16.42$ , therefore between consultations **1 and 6**, the result is declared **statistically significant**.

$R3 - R6 = 24 \geq 16.42$ , therefore between consultations **3 and 6**, the result is declared **statistically significant**.

This implies that a significant improvement exists between consultations 1, 3 and 6, in terms of objective data for LFS for Group 1.

#### 4.7.1.4. Dunn's Procedure for the ORS for Group 2 for SIS.

Table 16: Dunn's Procedure for the ORS for Group 2 for SIS

	Rank Total	Difference	Rank Total	
R.1	78.9	21.3	57.6	R.3
R. 1	78.9	35.4	43.5	R.6
R. 3	57.6	14.1	43.5	R.6

$R1 - R3 = 21.3 \geq 16.42$ , therefore between consultations **1 and 3**, the result is declared **statistically significant**.

$R1 - R6 = 35.4 \geq 16.42$ , therefore between consultations **1 and 6**, the result is declared **statistically significant**.

$R3 - R6 = 14.1 < 16.42$ , therefore between consultations **3 and 6**, the result is declared **statistically insignificant**.

This implies that a significant improvement exists between consultations 1 and 3, and 1 and 6, but no improvement can be demonstrated between consultation 3 and 6 in terms of objective data for SIS for Group 2.

## 4.7.2. Subjective Measurements.

### 4.7.2.1. Dunn's Procedure for the NRS Data for Group 1.

Table 17: Dunn's Procedure for the NRS Data for Group 1

	Rank Total	Difference	Rank Total	
R.1	75.9	16.42	59.4	R.3
R. 1	75.9	31.5	44.4	R.6
R. 3	59.4	15	44.4	R.6

$R1 - R3 = 16.42 \geq 16.42$ , therefore between consultations **1 and 3**, the result is declared **statistically significant**.

$R1 - R6 = 31.5 \geq 16.42$ , therefore between consultations **1 and 6**, the result is declared **statistically significant**.

$R3 - R6 = 15 < 16.42$ , therefore between consultations **3 and 6**, the result is declared **statistically insignificant**.

This implies that a significant improvement exists between consultations 1 and 3, and 1 and 6, but no improvement can be demonstrated between consultation 3 and 6 in terms of NRS data for Group 1.



#### 4.7.2.2. Dunn's Procedure for the NRS Data for Group 2.

Table 18: Dunn's Procedure for the NRS Data for Group 2

	Rank Total	Difference	Rank Total	
R.1	83.1	30.6	52.5	R.3
R. 1	83.1	38.7	44.4	R.6
R. 3	52.5	8.1	44.4	R.6

$R1 - R3 = 30.6 \geq 16.42$ , therefore between consultations **1 and 3**, the result is declared **statistically significant**.

$R1 - R6 = 38.7 \geq 16.42$ , therefore between consultations **1 and 6**, the result is declared **statistically significant**.

$R3 - R6 = 8.1 < 16.42$ , therefore between consultations **3 and 6**, the result is declared **statistically insignificant**.

This implies that a significant improvement exists between consultations 1 and 3, and 1 and 6, but no improvement can be demonstrated between consultation 3 and 6 in terms of NRS data for Group 2.

#### 4.7.2.3. Dunn's Procedure for the OSW Data for Group 1.

Table 19: Dunn's Procedure for the OSW Data for Group 1

	Rank Total	Difference	Rank Total	
R.1	75	12.6	62.4	R.3
R. 1	75	32.4	42.6	R.6
R. 3	62.4	19.8	42.6	R.6

$R1 - R3 = 12.6 < 16.42$ , therefore between consultations **1 and 3**, the result is declared **statistically insignificant**.

$R1 - R6 = 32.4 \geq 16.42$ , therefore between consultations **1 and 6**, the result is declared **statistically significant**.

$R3 - R6 = 19.8 \geq 16.42$ , therefore between consultations **3 and 6**, the result is declared **statistically significant**.

This implies that a significant improvement exists between consultations 3 and 6, and 1 and 6, but no improvement can be demonstrated between consultation 1 and 3 in terms of OSW data for Group 1.

#### 4.7.2.4. Dunn's Procedure for the OSW Data for Group 2.

Table 20: Dunn's Procedure for the OSW Data for Group 2

	Rank Total	Difference	Rank Total	
R.1	80.4	23.4	57	R.3
R. 1	80.4	37.8	42.6	R.6
R. 3	57	14.4	42.6	R.6

$R1 - R3 = 23.4 \geq 16.42$ , therefore between consultations **1 and 3**, the result is declared **statistically significant**.

$R1 - R6 = 37.8 \geq 16.42$ , therefore between consultations **1 and 6**, the result is declared **statistically significant**.

$R3 - R6 = 14.4 < 16.42$ , therefore between consultations **3 and 6**, the result is declared **statistically insignificant**.

This implies that a significant improvement exists between consultations 1 and 3, and 1 and 6, but no improvement can be demonstrated between consultation 3 and 6 in terms of OSW data for Group 2.

# CHAPTER FIVE: DISCUSSION OF THE RESULTS

## 5.1. INTRODUCTION.

This chapter will discuss all the results of the subjective and objective results as recorded from the NRS, the OSW Questionnaire and the ORS, all of which have been presented in chapter four.

**Intergroup Analysis** - The evaluation of the first consultations measurements, shows any changes in the subjective and objective data between the two groups, in terms of their original signs and symptoms. The comparison of the third and sixth consultations confirms which treatment is more effective.

**Intragroup Analysis** - The evaluation of the intragroup data from the first, third and sixth consultations represents the relative effectiveness of the treatment protocols in the treatment of mechanical LBP.

## 5.2. DEMOGRAPHIC DATA.

The average age distribution of the patients between the two groups was very similar, with both averages being 28.7 and 30.8 respectively. The age prevalence in both groups from 18-24 was 26.6 %, from 25-34 was 51.6 % and from 35-45 was 21.6 % (Table 1). The gender distribution over all was 7:5 and between the two groups, Group 1 was 19: 11 and Group 2 was 16: 14 (Males: Females, Figure 1). The majority of the patients were white (Table 2), which is possibly due to the fact that chiropractic is a relatively unknown profession in the black community. Other contributing factors are that newspaper adverts were published in English only, and distributed in a majority of "white" areas. This may have a negative effect on the outcome of the study, as demographically, blacks and Indians make up a significant proportion of LBP sufferers in Kwa-Zulu Natal (van der Meulen 1997).

### **5.3. INTERGROUP ANALYSIS: MANN-WHITNEY U-TEST.**

#### **5.3.1. Objective Measurements.**

Orthopaedic Rating Scale.

The objective statistical results (Table 5), from the Mann-Whitney U-test, indicate a significant difference in the groups. This means that both groups improved in terms of their objective data. The null hypothesis was rejected according to the defined decision rule at  $p=0.05$  level of significance.

#### **5.3.2. Subjective Measurements.**

NRS-101 and OSW Questionnaire

The subjective statistical results (Table 5), from the Mann-Whitney U-test, indicate no difference between the treatments. The null hypothesis was accepted according to the defined decision rule at  $p=0.05$  level of significance.

### **5.4. INTRAGROUP ANALYSIS: FRIEDMAN'S T-TEST.**

#### **5.4.1. Objective Measurements.**

In **Group 1 (SMT and IFC)**, Friedman's T-test was performed and showed a difference between the first, third and sixth consultation for the LFS ORS data.

The mean difference between the 1st and 3rd consultations for LFS ORS data was 0.88 (consultation 1:2.88; consultation 3:2.00). At consultation 1 and 6 the mean difference was 1.76 (consultation 1:2.88; consultation 6:1.12), and between consultation 3 and 6 it was 0.88 (consultation 3:2.00; consultation 6:1.12). Dunn's procedure was then performed and proved this difference to be statistically significant for all three comparisons. Thus in **Group 1** there was an **improvement** in the objective measurements for LFS between the 1<sup>st</sup>, 3rd and 6th treatments. Other studies have shown SMT to be particularly good for short-term symptomatic relief of pain and improvements in flexibility and disability in patients (Di Fabio 1992).

In **Group 2 (NSAIDs and IFC)**, Friedman's T-test was performed and showed a difference between the 1st, 6th and 3rd and 6th consultation for the LFS ORS data.

With the Dunn's procedure applied, the mean difference between the 1st and 3rd consultations for LFS ORS data was 0.26 (consultation 1:2.38; consultation 3:2.12). This showed no statistically significant improvement between these two treatments. At consultation 1 and 6 the mean difference was 0.88 (consultation 1:2.38; consultation 6:1.50). The mean difference between consultation 3 and 6 was 0.62 (consultation 3:2.12; consultation 6:1.50). Dunn's procedure was then performed and proved this difference to be statistically significant.

In **Group 2** statistically there was **no improvement** between the 1st and 3rd consultations, but thereafter there was an **improvement** in the patients' objective data for LFS. Overall then it is clear that Group 1 responded better to the treatment than Group 2 for LFS. Similarly, these results were found by Giles et al. (1999), when he compared acupuncture, NSAIDs and SMT in chronic spinal pain patients.

In **Group 1 (SMT and IFC)**, Friedman's T-test was performed and showed a difference between the 1<sup>st</sup>, 3rd and 6th consultation for the SIS ORS data.

The mean difference between the 1st and 3rd consultations for LFS ORS data was 0.80 (consultation 1:2.80; consultation 3:2.00). At consultation 1 and 6 the mean difference was 1.60 (consultation 1:2.80; consultation 6:1.20), and between consultation 3 and 6 it was 0.80 (consultation 3:2.00; consultation 6:1.20). Dunn's procedure was then performed and proved this difference to be statistically significant for all three comparisons. Thus within Group 1 there was an **improvement** in the objective measurements between the 1<sup>st</sup>, 3rd and 6th treatments.

In **Group 2 (NSAIDs and IFC)**, Friedman's T-test was performed and showed a difference between the 1<sup>st</sup>, 6th and 3rd and 6th consultation for the SIS ORS data.

The mean difference between the 1st and 3rd consultations for LFS ORS data was 0.71 (consultation 1:2.63; consultation 3:1.92). At consultation 1 and 6 the mean difference was 1.18 (consultation 1:2.63; consultation 6:1.45). Dunn's procedure was then performed and proved this difference to be statistically significant. The mean difference between consultation 3 and 6 was 0.47 (consultation 3:1.92; consultation 6:1.45). Dunn's procedure showed **no improvement** between these two treatments.

In **Group 2** statistically there was improvement between the 1st and 3rd and 1st and 6th consultations, but thereafter there was **no improvement** in the patients' objective data for SIS. Overall then it is clear that Group 1 responded better to the treatment than Group 2 for SIS.

#### **5.4.2. Subjective Measurements.**

In **Group 1 (SMT and IFC)**, Friedman's T-test was performed and showed a difference between the 1st, 3rd and 6th consultation for the NRS data.

The mean difference between the 1st and 3rd consultations for NRS data was 0.55 (consultation 1:2.53; consultation 3:1.98) and between consultation 1 and 6 the mean difference was 1.05 (consultation 1:2.53; consultation 6:1.48). Dunn's procedure was then performed and proved this difference to be statistically significant. The mean difference between consultation 3 and 6 was 0.5 (consultation 3:1.98; consultation 6:1.48). Dunn's procedure showed **no improvement** between these two treatments.

In **Group 2 (NSAIDs and IFC)**, Friedman's T-test was performed and showed a difference between the 1st, 3rd and 6th consultation for the NRS data.

The mean difference between the 1st and 3rd consultations for NRS data was 1.02 (consultation 1:2.77; consultation 3:1.75) and between consultation 1 and 6 the mean difference was 1.29 (consultation 1:2.77; consultation 6:1.48). Dunn's

procedure was then performed and proved this difference to be statistically significant. The mean difference between consultation 3 and 6 was 0.27 (consultation 3:1.75; consultation 6:1.48). Dunn's procedure showed **no improvement** between these two treatments.

Therefore, statistically the two groups did not vary in their response to the treatments and improved equally. This can be attributed to the affect of the IFC therapy on both groups (Plaughter 1993), or the natural history of LBP.

In **Group 1 (SMT and IFC)**, Friedman's T-test was performed and showed a difference between the 1st, 3rd and 6th consultation for the OSW data.

The mean difference between the 1st and 3rd consultations for OSW data was 0.42 (consultation 1:2.50; consultation 3:2.08). When interpreted by the Dunn's procedure there was no difference between these two treatments. At consultation 1 and 6 the mean difference was 1.08 (consultation 1:2.50; consultation 6:1.42), and between consultation 3 and 6 was 0.5 (consultation 3:1.98; consultation 6:1.48). Dunn's procedure was then performed and proved this difference to be statistically significant for both.

In **Group 2 (NSAIDs and IFC)**, Friedman's T-test was performed and showed a difference between the 1st, 3rd and 6th consultation for the OSW data.

The mean difference between the 1st and 3rd consultations for OSW data was 0.78 (consultation 1:2.68; consultation 3:1.90) and between consultation 1 and 6 the mean difference was 1.26 (consultation 1:2.68; consultation 6:1.42). Dunn's procedure was then performed and proved this difference to be statistically significant. The mean difference between consultation 3 and 6 was 0.48 (consultation 3:1.90; consultation 6:1.42). Dunn's procedure showed no improvement between these two treatments.



Therefore, statistically the two groups responded differently in terms of the patients' perception of their disability in the two groups. **Group 1** initially found there to be **no difference** in their back disability but after the 3rd treatment **recovered significantly**. They recovered well over all six treatments. **Group 2** responded differently to Group 1, for the first three treatments (while they were taking meloxicam), they felt **less disability** compared to the last three treatments. They **did improve** subjectively overall.

## **CHAPTER SIX: RECOMMENDATIONS AND CONCLUSIONS**

### **6.1. RECOMMENDATIONS.**

It is my recommendation that South African studies should be more demographically balanced in order to give a fair and true reflection of what treatments work within a certain community. In South Africa we have a unique opportunity to do research within these different racial and economic groups, yet our focus tends to not be on the demographics of our patients.

A one-month follow up may be of interest to determine long-term benefits of the two different treatments. The true benefit of the chiropractic manipulation compared to the oral NSAID may only have become apparent after one month. This may not allow for patient compliance either because they are recovered or because the follow-up consultation does not offer the patient a treatment.

The experience and reliability of the undergraduate researcher in the field may lead to biased results or the failure to bring out the true results. This is due to their inexperience in both research methodology and chiropractic practise.

## **6.2. CONCLUSIONS.**

The results of this study conducted over a two to three week period showed an overall improvement in both the SMT and IFC and the NSAIDs and IFC treatment groups; subjectively and objectively. In the inter-group analysis (for the objective data), Group 1 improved better overall than Group 2. In terms of subjective data, Group 1 did not improve initially, but did overall, and Group 2 did respond initially but not over the last three treatments. This suggests that while Group 2 was on the medication (first ten days) they responded better than Group 1 until the medication stopped (after ten days) when their perception of pain increased again.

The results provide a strong case for the inclusion of SMT and IFC in place of NSAIDs and IFC in LBP management protocols, particularly in light of the reduced likelihood of side effects from SMT as compared to NSAIDs.

In conclusion, there will always be room to improve and expand on existing research. To compare two different treatment protocols within one research topic has been both rewarding and enlightening because different patients respond differently to treatments and as a healthcare provider one should never narrow ones treatment options, but rather expand and learn to appreciate what else is available and what really works for the patient. This open-minded approach allows us to be holistic professionals.

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