THE EFFICACY OF COMBINED DICLOFENAC THERAPY AND SPINAL MANIPULATION COMPARED TO COMBINED PLACEBO THERAPY AND SPINAL MANIPULATION IN THE TREATMENT OF MECHANICAL LOW BACK PAIN

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I, Rowan Harvey White do declare that this dissertation is representative of my own work.

Signed: _____ Date: 23.11.2001

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DEDICATION

This dissertation is dedicated to my parents, Dexter and Sally, who instilled in me the motivation, perseverance and determination to fulfill my dreams.

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ABSTRACT

There are many non-surgical treatments that are available to patients with low back pain but few have been proven effective in controlled clinical trials. Arguably, the treatments with the greatest evidence for efficacy are nonsteroidal anti-inflammatory drugs (NSAIDs), some muscle relaxants and spinal manipulation (Deyo et al.(1983) and Shekelle et al.(1992). Non-steroidal anti-inflammatory drugs are the most widely used agents for musculoskeletal pain and inflammation. The widespread use of NSAIDs augments the impact not only of their benefits but also the risk of their adverse effects. The effectiveness of chiropractic management is now firmly established for most patients with acute and chronic low-back pain (Koes et al.1996).

The purpose of this study was to determine the relative efficacy of combined diclofenac sodium therapy and spinal manipulation compared to combined placebo therapy and spinal manipulation in the treatment of mechanical low back pain.

Sixty subjects were selected and randomly divided into two groups of thirty subjects. Subjects were treated four times over a two-week period, including a diclofenac or placebo medication course, taken three times daily for five days, starting from the first consultation.

The results of the Numerical Pain Rating Scale-101, Revised Oswestry Low Back Pain Disability Questionnaire, Orthopaedic Rating Scale and Algometer readings were taken before the first, third and fourth consultations. The statistical tests used were the parametric two-sample unpaired t-tests and the paired t-tests, and the nonparametric intra-group Friedman test, multiple comparison procedure, Wilcoxon Signed Ranks test and the inter-group Mann Whitney U-test at the 95% level of significance using the SPSS statistical package.

There was a statistically significant improvement in both treatment groups for both subjective and objective clinical findings, suggesting that spinal manipulation combined with either an NSAID or placebo medication will ultimately give relief to a patient suffering from lower back pain. The conclusions

of this study suggest that by virtue of lower doses of NSAIDs and including chiropractic treatment in the management of mechanical low back pain, that the adverse effects associated with the use of NSAID medication may well be reduced. This study recommends a more thorough interaction between allopathic and chiropractic practitioners, in order to establish more cost effective and safer treatment protocols for mechanical low back pain.

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DEFINITION OF TERMS

Acute mechanical low back pain

The duration of the complaint usually lasting less than six weeks (Koes et al. 1996:2861).

Chronic mechanical low back pain

The duration of the complaint usually having been present for more than six weeks (Koes et al. 1996:2861).

Efficacy

The ability of an intervention to produce the desired beneficial effect, in expert hands and under ideal circumstances.

Enteric-coated tablets

Enteric coating has long been used to reduce gastric effects from irritating substances. A good enteric coat should not release any drug in the stomach but should allow complete absorption when released into the intestine (Prescott and Nimmo, 1981:206).

Incidence

A rate which refers to the number of persons with new back pain occurring over a given time period among a known number of persons who were previously without back pain (Giles and Singer, 1997:18).

Mechanical low back pain

For the purpose of this study refers to posterior facet syndrome and sacroiliac syndrome or a combination of the two.

Motion palpation

Palpation of the human spine in the diagnosis of muscular, discal or articular mechanical changes used by some schools of osteopathy, chiropractic and occasionally medicine (Robert Alley 1983:97).

Placebo

An intervention which is believed to lack a specific effect i.e., an effect for which an empirically supported theory exists for its mechanism of action – on the condition in question, but which has been demonstrated to be better than no intervention.

Prevalence

The number of persons who have experienced back pain ever, even if they are not affected at present (Giles and Singer 1997:18).

Single blinding

The subject is unaware of the group that he/she is assigned to in the study (Haldeman, 1992:418).

Spinal Manipulation

A passive maneuver in which specifically directed manual forces are applied to vertebral or extravertebral articulations of the body, with the object of restoring mobility to restricted areas (Gatterman 1990:42).

CHAPTER ONE: INTRODUCTION

1.1. Introduction

Mechanical low back pain results from inherent susceptibility of the lumbar spine to static loads due to muscle forces, gravity forces and abnormal kinetic deviations. While no one therapeutic procedure is a panacea for all aetiological factors producing low back pain, a large percentage of disorders of the lumbar spine due to biomechanical lumbar spine disorders respond favourably to chiropractic management (Gatterman, 1990:129).

The prevalence of low back pain (LBP) is second only to the common cold (Weiner et al. 2000:451) and is the second most common cause of missed workdays in the United States, a statistic almost duplicated here in South Africa (Van der Meulen, 1997). Low back and spine problems remain the most frequent chronic conditions causing limitation of activity of persons under the age of 45. Acute episodes of LBP, starting around the age of 25, with the highest frequency of symptoms occurring between 35 and 55 (Gemmell and Jacobson, 1990:63).

Meade et al. (1990) compared chiropractic and physiotherapy hospital out patient management of patients with acute and chronic low back pain. In their study, Meade et al. (1990) randomly allocated 741 men and women, aged 18-65 years with low back pain in whom manipulation was not contraindicated, to a chiropractic clinic or hospital physiotherapy, to be treated. The trial was 'pragmatic' in that it allowed the therapists to treat patients as they would in day-to-day practice. The conclusion of the trial was that patients treated by chiropractic derive more benefit and long term satisfaction than those treated by hospitals.

A systematic review of randomized and double-blind controlled trials was performed by Van Tulder et al. (2000) to assess the effects of nonsteroidal anti-

inflammatory drugs in the treatment of nonspecific low back pain and to assess which type of anti-inflammatory drug is most effective. The review concluded that nonsteroidal anti-inflammatory drugs are effective for short-term symptomatic relief in patients with acute low back pain. Furthermore, there was no evidence that suggested that any one anti-inflammatory drug was clearly more effective than others were. Van Tulder et al. (2000:2512) suggested that there was a need for research evaluating the effectiveness of NSAID's in treating acute low back pain with sciatica, and chronic low back pain.

A systematic review of randomized clinical trials by Koes et al.(1996:2869) which assessed the efficacy of spinal manipulation for patients with low back pain concluded that the efficacy of spinal manipulation for patients with acute or chronic low back pain has not been demonstrated with well structured randomized controlled trials.

1.2. Objectives of the study

The purpose of this investigation was to evaluate the efficacy of combined diclofenac sodium therapy and spinal manipulation compared to placebo drug therapy and spinal manipulation in the treatment of mechanical low back pain, in terms of subjective and objective clinical findings, in order to determine a more effective treatment protocol for the management of mechanical low back pain.

The first objective was to evaluate diclofenac sodium therapy combined with spinal manipulation in the treatment of mechanical low back pain in terms of subjective clinical findings in order to establish the efficacy of this treatment approach in the management of mechanical low back pain.

The second objective was to evaluate placebo therapy combined with spinal manipulation in the treatment of mechanical low back pain in terms of objective

clinical findings in order to establish the efficacy of this treatment approach in the management of mechanical low back pain.

CHAPTER 2: REVIEW OF THE RELATED LITERATURE

2.1 Introduction

Low back pain (LBP) is a significant public health problem that has had a major impact on quality of life and on health care costs (Weiner et al. 2000).

Chiropractic management combines various treatment protocols including – manual therapies, electrotherapies, education, and exercise programs, orthotics/pelvic belts/other supports – but places primary emphasis on spinal manipulation (Chapman-Smith 2000:1).

Spinal manipulative therapy is said to realign spinal structures, increase joint range of motion, to initiate muscular relaxation through stimulation of reflex pathways and to initiate the release of anti-inflammatory agents within the body (Hertzog et al. 1992:1206). A systematic review of all trials up to September 1995 concluded that there was strong evidence of the effectiveness of manipulation for patients with chronic low-back pain (Van Tulder et al.1997:2128). The widespread use of NSAIDs for LBP indicates the impact not only of their benefits but also of their well-known side effects (Gabriel 1997:39). Deyo et al.(1983) and Shekelle et al.(1992) found that the treatments with the strongest evidence for efficacy are nonsteroidal anti-inflammatory drugs, some muscle relaxants, and spinal manipulation. It is the author's opinion that a combination of two effective treatment protocols may establish safer and more effective management programs for mechanical LBP. This study will serve to establish insight as to whether more beneficial results may be achieved by combining spinal manipulation with NSAID's.

2.2 Prevalence of mechanical low back pain

Musculoskeletal complaints are among the most common medical conditions, with impairments to the back and spine being the more frequent disorder (Praemer et al.1999:5). In people older than 18 reporting back pain, lower back pain was the primary site in 56%; the middle back, 11%; the upper back, 8% and multip[le sites,25% (Praemer et al.1999:7). People who have low back pain and associated conditions experience significant restrictions on their activities (Weiner et al.2000:450). There is an approximate 50% recurrence rate in the year following the initial complaint (Anderson, 1997:93). Patients often incur financial costs, including treatment, disability expenses and lost wages (Weiner et al.2000:450). Low back pain is a clinical problem as well, occurring in association with heavy physical work, stationary work postures, vibration, psychosocial work factors, smoking, obesity and even height (Weiner et al. 2000:450).

An epidemiological investigation by Van der Meulen (1997) indicated that the lifetime incidence of low back pain in a black South African township was 57.6% and the lifetime prevalence was 53.1%.

2.3 The effectiveness of various treatments for low back pain

Meade et al. (1990) compared chiropractic and physiotherapy hospital out patient management of patients with acute and chronic low back pain. The trial was 'pragmatic' in that it allowed the therapists to treat patients as they would in day-to-day practice. In their study, Meade et al. (1990) randomly allocated 741 men and women aged 18-65 years with low back pain in whom manipulation was not contraindicated, who initially referred or presented either to a chiropractic clinic or in hospital physiotherapy, to be treated either by a chiropractor or in hospital. The conclusion of the trial was that patients treated by chiropractic derive more benefit and long term satisfaction than those treated by hospitals.

Giles and Muller (1999) criticised the Meade et al. (1990) study claiming that although it was important, this trial "tested what happens in day-to-day practice and in which details of the type, frequency and duration of intervention were at the discretion of the treating physician", it failed to identify the exact component of the treatment that was responsible for the improvement. In their trial, Giles and Muller (1999) randomly assigned patients into three 'separate and clearly defined intervention protocols: needle acupuncture alone or in conjunction with low voltage electrical stimulation, chiropractic manipulation and non-steroidal anti-inflammatory (NSAID's) medication. The purpose of the above trial was to compare the above treatments for adult patients (18 years or more) suffering from chronic spinal pain. Pain was in the low-back and/or upper back and/or neck. Patients in the acupuncture and medication groups had no significant improvement during the trial, whereas the patients in the chiropractic manipulation group improved significantly. The findings of Giles and Muller's study are supportive of chiropractic as an effective treatment approach in managing mechanical LBP. However, combinations of medication and chiropractic have not yet been demonstrated prior to the findings of this report.

Van Tulder et al.(1997) reviewed randomized controlled trials for all common non-surgical treatments-not only spinal manipulation but also exercise therapy, back schools, bed rest, analgesics, NSAIDs, muscle relaxants, anti-depressants, epidural steroid injections, TENS, traction, behaviour therapy, orthoses, electromyographic biofeedback and acupuncture. They concluded that there was 'moderate evidence' for effectiveness of NSAIDs and 'strong evidence' for equivalency among NSAIDs. Furthermore, they also found that there is 'strong evidence' that manipulation is effective and that there is 'moderate evidence' that manipulation is more effective for chronic low back pain than "usual care by the general practitioner, bed rest, analgesics and massage.

2.4 The lumbar spine

2.4.1 Anatomy of the lumbar facet joints

The *facet joints* are composed of articular processes arising from adjacent vertebrae. The articular processes project superiorly and inferiorly from the junction of the pedicles and the laminae. They form true synovial joints with synovial fluid (a superior facet below with an inferior facet above), their purpose being to stabilize the motion between two vertebrae with respect to both translation and torsion while allowing sagittal plane flexion and extension. A fibrous capsule encloses each facet joint. Rudimentary invaginations of the joint capsule known as menisci, project into the joint space. The menisci provide stability and distribute loads over greater articular areas (Borenstein et al. 1995:3-9).

Lumbar facets joints have slightly sloped surfaces as opposed to a single plane angle observed in the cervical and thoracic spines. The convex laterally facing inferior facets and the medially facing concave superior facets of respective upper and lower vertebrae, form a true diarthrodial joint complete with a joint capsule (Giles and Singer 1997:72). The facet angles vary from mediolateral (L1) to anteroposterior (L5) and lie in the sagittal plane (Schafer and Faye 1990:198), and this contributes to the mechanism of injury to the L4-L5 and L5-S1 segments as discussed in the following section.

2.4.2 Mechanism of injury

Rotational strains and compressive forces, particularly in flexion, may cause injury to the posterior facet joints. The L4-L5 joint is particularly susceptible to rotational stresses and strains due to the alignment of the posterior facets and due to the fact that the L5-S1 joint is protected by bony architecture and strong ligaments. Falls directly onto the buttocks may result in compressive forces applied to the L5-S1 joint resulting in circumferential and radial tears to the disc

as well as capsular laxity and subluxation of the posterior facet joints (Kirkaldy-Willis 1992:55).

2.4.3 The three joint complex

The intervertebral disc and the posterior facet joints make up a three joint complex. Any changes that may affect the posterior facet joints could possibly affect the disc and vise versa. Degeneration in an intervertebral joint can be divided into a number of phases, namely dysfunction, instability (the unstable phase) and stabilization. During the dysfunction phase (phase 1), function of the joint may be interrupted due to injury. During the unstable phase (phase 2) there may an abnormally increased movement of the joint, and as degeneration progresses (phase 3, stabilization phase), the unstable segment becomes more stable, however, there is no definite distinction between any of the phases, and a patient's condition may alternate or pass from one phase to the next. After a recurrent episode of trauma, a patient in the dysfunction phases may pass into the unstable phase, and during a recovery period may pass back to the dysfunction phase (Kirkaldy-Willis 1992:55).

2.4.4 The posterior facet syndrome

The posterior facet syndrome often presents as unilateral pain (Gatterman, 1990:138), it may be referred to the groin, to the region of the greater trochanter, and to the posterior thigh as far as the knee; rarely below the knee (Kirkaldy-Willis,1992:106). The pain may be relieved by rest and aggravated by certain movements (Kirkaldy-Willis 1992:106), particularly extension and lateral bending away from the painful side (Gatterman, 1990:138). Flexion may be achieved, producing an inability to straighten without typically grabbing the back followed by walking the hands up the thighs and gradually straightening the low back(Minor's sign), to prevent further spasm of the paraspinal muscles (Gatterman,1990:138).

Examination usually reveals a restriction of spinal movement and tenderness at L4-L5 or L5-S1 (Peters 1984:89). Hyperextension in the prone or upright sitting positions may increase the pain, whereas flexion may reduce any discomfort (Gatterman 1990:162). Pressure applied to or springing of the affected facet is usually tender or painful (Facet joint challenge). There may be palpable muscle spasm over the affected facet with focal tenderness (Gatterman, 1990:162). Lateral bending in extension (Kemp's test) often produces pain (Peters, 1984:89).

2.5 The sacroiliac joint

2.5.1 Anatomy of the sacroiliac joints

The sacroiliac (SI) joint is an atypical synovial joint, possessing a synovial fluid filled joint space and synovial lined capsule. The synovial articulation between the surfaces of the sacrum and ilium comprise the SI joint (Giles and Singer 1997:174). The articular surfaces on the ilia are covered by fibrocartilage, while the articulating surfaces on the sacrum are covered by hyaline cartilage (Norkin and Levangie, 1992:156). The SI joint has an auricular or C-shape, with a convexity that faces anteriorly and inferiorly (Gatterman 1990:112). SI joint surfaces have been demonstrated to have cartilage-covered ridges and depressions, which are complimentary on the auricular surfaces. These surfaces not only restrict movement, but contribute strength to the joint as weight is transmitted from the vertebral column to the lower extremities (Giles and Singer 1997:174)

Although some of the largest and most powerful muscles in the body surround the SI joint, none are known to directly influence its movement (David Cassidy: 1992:42). Ligaments surrounding the SI joint contribute to the stability of the joint. These include the anterior, the posterior and the interosseous sacroiliac ligaments. The anterior SI ligaments are thin, easily distended by intra-articular swelling, and palpable on rectal examination. The posterior SI ligament is so

thick and strong that violent trauma will usually produce a fracture on either side of the joint rather than a dislocation. Furthermore, an additional superior intracapsular ligament, Illi's ligament, has been found in 75% of dissections (Hendler et al. 1995:169).

The stability of the SI joint is dependent not only on the interdigitation of the articular surfaces of the ilium and sacrum but also on several large accessory ligaments surrounding the joint. Ligaments attach the sacrum and ilium (*anterior, posterior* and *interosseous sacroiliac ligaments*), the sacrum and ischium (*sacrotuberous* and *sacrospinous* ligaments) (Borenstein et al. 1995:9).

2.5.2 The sacroiliac syndrome

Sacroiliac dysfunction or subluxation occurs when the ilium slips on the sacrum. An irregular prominence of one articular surface becomes wedged upon the prominence of an opposed aurticular surface. The ligaments are taut, and the reflex muscle spasm and pain may be intense, severe and continuous. The pain of subluxation is often relieved suddenly and dramatically by reduction of the subluxation by manipulation (Hendler et al. 1995:171).

The sacroiliac syndrome presents as pain over the back of the sacroiliac joint that varies in its degree of severity and referred in the groin, over the greater trochanter, down the back of the thigh to the knee, and occasionally, down the lateral or posterior calf to the ankle and foot. There is usually tenderness or pressure over the posterior superior iliac spine in the region of the sacroiliac joint or in the buttock. Movement of the joint is usually restricted. The diagnosis is usually confirmed by stressing the joint using Patrick Faber test, Gaenslen's test, Yeoman's test (Kirkaldy-Willis 1992:123-124) and the posterior shear test (Laslett and Williams 1994).

2.6.1 Neural mechanisms of lumbar pain

Back pain or any pain requires action potentials to ascend pain pathways. The pain pathway starts with the free nerve endings of the pain receptors (nociceptors). The generated action potentials continue up the axons of small C or A-delta fibres and into the dorsal horn of the spinal cord, where the first synapse is made. In the most prominent ascending pain pathway, the second order neuron continues the message across the spinal cord, up the white matter of the anterolateral spinothalamic tract to the thalamus, where another synapse is made. The third order neuron continues the message to the somatosensory cortex of the brain. Other ascending pathways that convey nociceptive information are the spinocervical tract, and the dorsal column (Jessel et al. 1991:386).

Low back pain may originate in the free nerve endings of pain fibres at tissue sites, such as disc annulus, facet joint or muscle. These peripheral nerve endings become sensitized by chemical mediators, which are released during tissue damage and inflammation (Cavanaugh, 1995:1804). These include neurogenic mediators, such as substance P, and eleven-amino acid neuropeptides released from C fibres. Substance P causes vasodilation, plasma extravasation, and release of histamine from mast cells. These are important in the inflammatory cascade, which can lead to pain. Other pain producing chemicals (non-neurogenic) released during tissue damage that activate or sensitize pain fibres include bradykinin, serotonin, histamine, potassium ions and prostaglandins (Rang et al. 1991:538). Substance P has been found in the facet joint of the rabbit (El-Bohy et al. 1988:380) and appears to play a role in the sensitization of pain fibres.

2.7 Nonsteroidal anti-inflammatory drugs

NSAID's are the most widely used medication for the treatment of musculoskeletal pain and inflammation (Gabriel and Fehring 1992:1041). NSAID's are helpful in making patients comfortable while their low back injury heals (Giles and Singer 1997:336). A review of 51 randomized and double-blind controlled trials and 6057 patients (Van Tulder et al. 2000), attempted to assess the effects of NSAID's in the treatment of nonspecific low back pain with or without radiation, and to assess which type of NSAID was most effective. The evidence from the review suggested that NSAID's are effective for short-term symptomatic relief in patient's with acute low back pain. Furthermore, there did not seem to be any anti-inflammatory drug that was clearly more effective than others. The use of diclofenac sodium in this trial is supported by the results of the above-mentioned review, and the results of this trial may possibly be interpreted as NSAID's collectively, in assessing their effects in treatment of mechanical low back pain.

NSAIDs are also associated with various adverse side effects, related to inhibition of cyclooxygenase. All NSAIDs inhibit the enzyme cyclooxygenase (COX), which mediates the conversion of arachidonic acid to prostaglandins. The enzyme occurs in two distinct forms or isoenzymes:

- **COX-1** is found in most tissues and involved in the physiological production of prostaglandins such as protective prostaglandins found in the stomach.
- **COX-2** induced at sites of inflammation by cytokines, mitogens and endotoxins.

It is hypothesized that the therapeutic action of NSAIDs is dependent on inhibition of COX-2, while gastrointestinal side effects are related to the inhibition of COX-1.The mechanism of action of COX-2 inhibitors therefore appears to be due to inhibition of prostaglandin synthesis, primarily via inhibition of COX-2

without any clinically significant inhibition of COX-1 at the doses required to achieve anti-inflammatory and analgesic effects.

Prostaglandins mediate such varied processes as platelet aggregation, inflammation and pain. They also decrease gastric acid secretion, increase gastroesophageal sphincter tone, regulate renal blood flow and dilate the blood vessels. NSAID-related side effects can occur anywhere that prostaglandins are produced and most commonly involve the gastrointestinal (GI), renal, hepatic and haematologic systems (Gabriel 1997:39).

The potential for adverse effects can possibly be reduced, by giving the lowest effective dosage of NSAIDs, and in some cases concomitantly administering a prostaglandin analog H2-receptor antagonist, or acid-blocking agent (Gabriel 1997:39).

2.7.1 Gastrointestinal effects and risk factors

Adverse GI effects associated with NSAIDs include minor dyspepsia and gastritis, as well as more serious reactions such as ulceration, haemorrhage, perforation and death. There have also been reported cases of NSAID-induced enteropathy involving small and large bowel strictures, ulcerations and perforations, as well as villous atrophy (Robinson et al. 1995:317). These effects are believed to cause a specific NSAID-associated gastric syndrome that directly results from local depletion of prostaglandins, which have a protective effect on the gastric mucosa (Gabriel 1997:40).

Risk factors for GI complications during NSAID therapy include age over 60 and high dosage. The duration of therapy is also a determinant. There is evidence showing that GI events occur in 1% to 2% of patients who use NSAIDs for 3 months and in 2% to 5% of those who use them for a year (Clements et al. 1997:723). Previous peptic ulcer disease, GI bleeding and cardiovascular disease also predispose a patient to adverse outcome during NSAID treatment.

2.7.2 Renal effects and risk factors

A variety of renal conditions may be associated with NSAIDs. These include acute renal failure/prerenal azotemia, renal vasoconstriction, allergic interstitial nephritis, nephritic syndrome/minimal-change disease, hyperkalemic/ hyporeninemic hypoaldosteronism, sodium retention/diuretic resistance, and hyponatremia/enhanced antidiuretic hormone effect (Carson et al. 1993:246). Epidemiologic studies examining the renal effects of NSAIDs indicate, however, that the risk of renal dysfunction is modest.

Conditions of decreased renal perfusion, such as congestive heart failure, cirrhosis, renal insufficiency, volume depletion, shock or advanced age, increase the risk of acute ischaemic renal injury during NSAID therapy. Patients with mild renal failure and low baseline prostaglandin concentration are at increased risk for acute renal failure during NSAID therapy because of a decreased capacity to compensate for further reduction to prostaglandin levels (Whelton et al. 1990:572).

2.7.3. Haematologic effects and risk factors

Aplastic anaemia, agranulocytosis and thrombocytopaenia occur seldom but are serious enough to cause death in some patients. If haematologic abnormalities occur during the course of NSAID therapy, the drug certainly should be considered as a possible cause. A large, case controlled population-based study that assessed the risk of agranulocytosis and aplastic anaemia relative to analgesic drug use found that indomethacin, diclofenac and the butazones (phenylbutazone and oxyphenbutazone) were significantly associated with aplastic anaemia (Strom et al.1993)

Patients who are elderly and those with clotting disorders are at special risk during NSAID therapy. Caution is also advised for patients with thrombocytopaenia or existing haematologic conditions (Gabriel 1991:43).

2.7.4. Hepatic effects and risk factors

All NSAIDs have been reported to cause hepatic toxicity, which may be evident only as an elevation in liver function test (aspartate aminotransferase and alanine aminotransferase) values. The risk appears to be greater in association with aspirin, acetaminophen, diclofenac, sulindac and phenylbutazone, and lower with ibuprofen and ketoprofen (Clements et al. 1997:730). Hepatitis is a well recognized albeit rare, complication associated with NSAIDs. Cases of fatal fulminant hepatitis, especially during diclofenac therapy, have been reported. A recent report, which summarized data from five population based studies, showed that symptomatic hepatic side effects attributable to most NSAIDs are extremely rare and are usually mild (Velo et al. 1990:43). In that review, patients taking diclofenac showed no higher incidence of liver disease than did patients taking other NSAIDs.

Risk factors for hepatic toxicity include renal compromise, prolonged or high-dose NSAID therapy, multiple drug use, and advanced age. Patients with juvenile rheumatoid arthritis and systemic lupus erythematosus are also at increased risk, furthermore people with early stage liver disease and those who drink (alcohol) heavily (Gabriel 1997:47).

2.7.5 Hypersensitivity and dermatologic reactions and risk factors

Hypersensitivity to NSAIDs is quite common and can take the form of such respiratory and systematic reactions as vasomotor rhinitis, bronchial asthma, laryngeal oedema, severe bronchoconstriction, hypotension, shock and complete

respiratory and vasomotor collapse. Dermatologic reactions include rashes, erythema multiforme and its variants, aspirin-induced urticaria, benign morbilliform eruptions and anaphylactoid vasculitis (Velo et al. 1990:44).

Patients who use NSAIDs intermittently are the group most at risk for hypersensitivity. This is probably because intermittent use allows adequate time for full sensitivity to develop, setting the stage for anaphylaxis on subsequent rechallenge. Patients with the combination of bronchial asthma, vasomotor rhinitis, and nasal polyposis can experience acute exacerbation of asthma when taking NSAIDs and therefore should not receive NSAID's (Gabriel 1997:47).

2.8 Diclofenac sodium

When compared with placebo, diclofenac provided consistently superior relief of symptoms (Kantor 1986:64). Comparisons with other anti-inflammatory drugs or with opioids, such as pentazocine or Spasmofen, demonstrate that symptom relief with diclofenac was either comparable to or better than that obtained with these agents (Kantor 1986:64). Diclofenac has been established as a leading nonsteroidal anti-inflammatory drug in worldwide studies, and has been used successfully for acute as well as chronic or relapsing syndromes marked by pain and inflammation (Kantor 1986:64).

2.8.1 Pharmacological action

Diclofenac sodium is a non-steroidal compound, a phenylacetic acid derivative with analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium inhibits the biosynthesis and release of prostaglandins, known to be implicated in the pathogenesis of inflammation, pain and fever. Adco-diclofenac tablets are enteric-coated so that absorption occurs in the gastrointestinal tract to give peak plasma concentrations approximately two hours after ingestion. There is at least

99% binding to plasma-proteins and excretion of metabolites is mainly in the urine (Adco-Diclofenac package insert)(Appendix A)

2.8.2 Indications

Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, ankylosing spondylitis, osteo-arthrosis, painful post-operative and post-traumatic inflammation, and swelling, and dysmenorrhoea (Adco-Diclofenac package insert).

2.8.3 Contra-indications

Diclofenac sodium is contra-indicated in patients with known hypersensitivity to diclofenac and in patients who respond to aspirin and aspirin-type drugs with sensitivity reactions like asthma, acute rhinitis and urticaria. Diclofenac sodium is absolutely contra-indicated in patients with peptic ulceration or a history of such ulceration, and should be used with caution in patients with renal or hepatic insufficiency (Adco-Diclofenac package insert).

2.8.4 Dosage and directions for use

Usual adult dose: 25 mg to 50 mg taken three times daily. The tablet must be taken whole during or after meals (Adco-Diclofenac package insert).

2.8.5 Side effects and special precautions

Gastric or intestinal ulceration with associated bleeding has been reported, Adco-Diclofenac therapy should be discontinued immediately in such cases. Skin rashes and gastro-intestinal disturbances may occur. Headache, dizziness, oedema, nervousness, pruritus, tinnitus, insomnia, blurred vision and other ocular reactions, peripheral oedema, malaise, jaundice, elevated transaminase

with prolonged therapy with Adco-Diclofenac as blood dyscrasias have been reported. The safe use of Adco-Diclofenac in pregnancy has not been demonstrated. Blood concentrations of lithium are increased when Adco-Diclofenac is administered concomitantly. Adco-Diclofenac should be given with care to patients with bleeding disorders, cardiovascular disease, and in those who are receiving coumarin anticoagulants. Patients who are sensitive to aspirin generally should not be given Adco-Diclofenac (Adco-Diclofenac package insert).

2.8.6 Identification

50 mg tablet: Tan coloured, round, enteric-coated tablets
(Adco-Diclofenac package insert).

2.9 Folic acid

Folic acid was selected as a placebo medication because this tablet closely resembled the diclofenac tablet. Folic acid is found naturally in food sources such as green vegetables, beans, whole grains and orange juice. Some refined grain products are now fortified with folic acid. Folic acid can be taken at any time of the day, with or without food. In the body, folic acid is utilized to make blood cells, heal wounds, build muscle and any function that requires cell division. Folic acid is critical to DNA and RNA formation and makes sure that cells duplicate normally (Shepherd 1999). A literature review found no evidence to suggest that folic acid would have any therapeutic effect for mechanical low back pain.

2.10 Conclusion

Anti-inflammatory medication has been proven effective for patient's suffering from mechanical LBP (Kantor 1986:64), however the risks of NSAID usage are well documented (Gabriel 1997:39-48). This study does not attempt to discredit the benefits NSAID usage but rather to incorporate its use with spinal manipulation; a treatment that has minimal side effects and that is proven to be effective in treating LBP (Van Tulder et al. 1997). A combination of manipulation

with an initial anti-inflammatory medication of lower dosage or duration may reduce some pain and discomfort experienced by the patient, particularly during the acute phase of an injury or an acute exacerbation of a chronic condition, and possibly enhance the recovery time of a patient suffering from mechanical LBP.

CHAPTER THREE: MATERIALS AND METHODS

3.1 Introduction

This chapter gives a detailed description of the design, primary and secondary data, the subjects and interventions utilized. An overview of each questionnaire 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 combined Diclofenac medication and spinal manipulation and the other combined placebo medication and spinal manipulation.

3.2 The data

The data consisted of primary and secondary data.

3.2.1 The primary data

1. Patient's response to the Numerical Pain Rating Scale-101(Appendix B) on their perception of change in the level of pain.

2. Patient's response to the Revised Oswestry Low Back Disability Questionnaire (Appendix C) on their perception of change of their disability.

3. Clinical observation of change in their condition as observed through objective measurement using the algometer pain/pressure meter (Appendix D).

4. Clinical observation using an Orthopaedic Rating Scale (Appendix E), 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 Sample

Subjects were recruited from the greater Durban area by means of advertisements placed at local sports clubs, local schools, gyms and tertiary institutions, as well as advertising in local newspapers and in newsletters. Sixty subjects were selected from those who responded, using convenience sampling (Willemse, 1990:14). Patients were telephonically questioned or examined in person in terms of exclusion or inclusion criteria and either included or excluded accordingly. No stratification of the subjects took place and they were accepted regardless of gender, occupation, race, severity or chronicity of the condition. 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 lumbar facet and sacroiliac tests. An Indemnity Form was signed (Appendix I).

3.4 Inclusion and exclusion criteria

a) Due to the increased risk of NSAID side effects in the elderly, only subjects 18-65 (Meade et al. 1990:1431) were accepted for the trial.

b) Any active or latent myofascial trigger point involvement (Travell and Simons 1983) associated with but secondary to sacroiliac or lumbar facet

syndrome were assessed and noted in the low back regional examination and Orthopaedic Rating Scale, but no treatment for these conditions were administered.

c) Subjects presenting with conditions that are contra-indicated to manipulation as stated by Kirkaldy-Willis and Burton (1992:291) i.e. destructive lesions of spine, ribs and pelvis, healing fracture or dislocation, gross instability, cauda equina syndrome, large abdominal aneurysm or visceral referred pain, were excluded from the study. These were excluded on the grounds of clinical history and examination, and no further investigations were performed (e.g. radiographs or scans).

d) Any additional low back treatment received during the treatment period of the trial resulted in exclusion of the subject. This included the use of any other drugs, analgesics, anti-inflammatory medication or muscle relaxants due to drug actions and interactions that may have influenced the outcome of the trial.

e) Any subjects with obvious biomechanical abnormalities, previous lumbar surgery or examination findings indicating radiological examination were excluded from the trial.

f) Any subject who developed side effects to diclofenac sodium therapy, were withdrawn from the study immediately. Side effects included gastric bleeding or intestinal ulceration with associated bleeding, skin rashes and gastro-intestinal disturbances headaches, dizziness, oedema, nervousness, pruritis, tinnitus, insomnia, blurred vision and other ocular reactions, peripheral oedema, malaise, jaundice, elevated transaminase levels, drowsiness and hypersensitivity reactions (e.g. Bronchospasm) (Adco-Diclofenac package insert).

3.5 Ethical considerations

- The rights and welfare of the subject were protected.
- Informed consent was obtained (Appendix J).
- The subject was not coerced into participating in the study.
- Information was given to the subject in an understandable language.
- The research involved no more than minimal risk.
- Confidentiality was maintained.
- Participation was voluntary and did not involve financial benefit.
- The subject was free to withdraw from the study at any time (Pak and Adams 1994:34).

3.6 Measurements

3.6.1 Subjective measurements

Subjective measurements were recorded from two questionnaires completed by the patients in writing. The questionnaires used were the Numerical Pain Rating Scale-101 (Jenson et al. 1986) and the Revised Oswestry Low Back Pain Disability Questionnaire (Hsieh et al. 1992; Haas and Jacobs 1995). The Numerical Pain Rating Scale-101 and the Revised Oswestry Low Back Pain Disability Questionnaires were completed before the first, third and fourth treatments.

3.6.1.1 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). The Numerical Pain Rating Scale-101 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 be'. The two values recorded were firstly the pain intensity when it is at it's worst and secondly the pain intensity when it is at it's least. The average between these two figures is an indication of the subject's pain level.

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

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

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

A more recent study by Bolton and Wilkinson (1998) on seventy-nine chiropractic patients compared three pain scales, including the Visual Analogue Scale, the Verbal Rating Scale and the Numerical Pain Rating Scale-101. The authors found the Numerical Pain Rating Scale-101 to be the most responsive and recommended this questionnaire for most types of outcome studies.

3.6.1.2 The Revised Oswestry Low Back Disability Index

The original Oswestry Questionnaire was developed in the 1970's by Fairbank et al., in Oswestry, Shropshire, England. The original version has been altered by omitting a section on sex life because experience showed it was often unanswered or answered inaccurately as 'normal'. That section has been

replaced with one titled Changing Degree of Pain, giving more information on pain. Section 1 on Pain Intensity has been improved by incorporating information on variance and duration of pain. The original Oswestry simply asked about pain "at the moment". In various other sections the questions have been amended for clarity and ease of use. The Revised Oswestry Low Back Pain Disability Questionnaire (ROLBPQ), has been validated by chiropractic research studies by Hsieh et al. (1992) and Haas et al. (1995).

The ROLBPQ has ten sections of questions, including pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling and changing degree of pain. Each section was scored between 0 and 5, with 0 being no disability and 5 meaning the worst disability (Hsieh et al. 1992).

The subject ROLBPQ chose one from each section, where 0 (response 1) to 5 (response 6) were possible. Thus if all sections are completed a score of 50(100%) was possible.
The overall goal of assessment is to measure change in the subject's condition over time.

3.6.2 Objective measurements

Objective measurements were recorded from the results of algometer readings and the Orthopaedic Rating Scale, which comprised of orthopaedic tests specific for sacroiliac and lumbar facet syndromes, each of which were assigned points according to their specificity or accuracy. These measurements were recorded before the first, third and fourth consultations.

3.6.2.1 The Algometer

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

Fischer (1987) described the algometer pressure/pain threshold readings as the minimum pressure or force that induces pain or discomfort.

The algometer readings were taken over the most painful area of the symptomatic sacroiliac or lumbar facet joint. The patient was requested to indicate the point of pain or discomfort by saying 'now', and the reading taken at that point.

Measurements were taken by applying the force dial, to the most painful area of either one of the sacroiliac or respective lumbar facet joints. The force readings were measured in kilograms per square centimeter. The higher the reading the less tenderness was felt, indicating a higher tolerance to pain. The algometer tip was fitted with a one-centimeter square rubber disc, as Fischer (1986) considered this a more suitable way to assess tenderness in tendons, ligaments and joint capsules.

Fischer (1987) defines pressure threshold as the maximum pressure inducing pain or discomfort. The algometer can be used to quantify response to treatment such as manipulation and provides a means of measuring the patient's improvement (Fischer 1986:837).

The dial was set to zero before each reading, by pressing the rest button. The rubber disc was placed over the tenderest point of the sacroiliac joint or lumbar facet joint. The patient was instructed to say 'now' at the point when they first felt the sensation of pressure, change to a feeling of pain. The pressure was gradually increased at a rate of 1 kg/second (Fischer 1986) until the point of pain. The pressure was released and the reading was taken.

3.6.2.2 Orthopaedic Rating Scale

Specific orthopaedic tests were performed to determine the presence of sacroiliac or lumbar facet syndromes. The specific tests include: Kemp's test (Schafer and Faye 1990:208-209), facet joint challenge, hyperextension in the prone position (Gatterman 1990:162) and palpable muscle spasm with focal tenderness over the affected facet joint (Helbig and Casey 1988:61-64) for lumbar facet syndrome. Posterior shear or "thigh thrust test" (Laslett and Williams 1994), Patrick Faber test (Magee 1992:343), Gaenslen's test (Magee 1992:319) and Yeoman's test (Schafer and Faye 1990:271) for sacroiliac syndrome.

Each of the above tests was allocated a score on production of a positive result in order to establish an orthopaedic rating scale as an objective measure that may be statistically analysed. The presence of lumbar facet syndrome was determined: Kemp's test is the most commonly used test according to Schafer and Faye (1990:217) and often causes the most pain (Peters, 1984:89), Magee (1992:274) and Gatterman (1990:162) therefore it received a score of 4 when positive, while facet joint challenge, prone hyperextension (Gatterman 1990:162) and palpable muscle spasm with focal tenderness (Helbig and Casey 1988) each received a score of 2 when positive. The presence of sacroiliac syndrome was determined: The posterior shear test is the more sensitive test according to Laslett and Williams (1994) therefore it received a score of 4 when positive, while Patrick Faber test, Gaenslen's test and Yeoman's test each received a score of 2 when positive.

An orthopaedic assessment rating out of 10 for each syndrome 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 orthopaedic tests were positive for a diagnosis to be made. A change in the score gave an indication as to whether there was a difference in the patient's lumbar facet syndrome or sacroiliac syndrome.

3.6.2.3 Orthopaedic tests

1. Kemp's test: The patient is seated and supported by the examiner, who reaches around the patient's shoulders and upper chest from behind. The patient is directed to lean forward to one side and then around to eventually bend obliquely backward by placing the palm on the buttock and sliding it down the back of the thigh and leg as far as possible. If this compression causes or aggravates the pain in the thigh and leg, the test is positive (Schafer and Faye 1990:208-209).

2. Facet joint challenge: The patient is positioned prone. The examiner then stresses or "springs" the individual joints by exerting a posterior to anterior force to each of the spinous processes. The patient is instructed to indicate when there is an increase in pain or discomfort in the individual areas being tested, which would constitute a positive result (Gatterman 1990:84).

3. Prone hyperextension: The patient is positioned in the prone position. The patient is then requested to perform a 'press-up' while leaving the pelvis fixed on the examining table. Reproduction of the low back pain would constitute a positive test (Gatterman,1990:162).

4. Muscle spasm with focal tenderness over the affected facet joint: The patient is positioned prone. Palpation over the affected facet revealing muscle spasm and eliciting pain and tenderness would be a positive result (Gatterman,1990:162).

5. Posterior shear or "thigh thrust test": The patient is positioned supine. The examiner is positioned on the left side for a suspected right sacroiliac syndrome. The right hip and knee is flexed and slightly adducted. The examiner places the left hand under the right sacroiliac joint while exerting a posterior shearing force downward on the right knee through the femur, while feeling for excessive joint

motion with the opposite hand. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint (Laslett and Williams 1994).

6. Yeoman's (extension) test: The patient is positioned prone. The examiner places one hand under the right thigh above the knee on the affected side, to extend the right hip. The examiners other hand presses downward over the crest of the right ilium. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint (Kirkaldy-Willis,1992: 125).

7. Gaenslen's test: The patient is positioned supine. The examiner flexes the patient's left knee and hip, while pressing downward over the right thigh to hyperextend the right hip. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint (Kirkaldy-Willis,1992:125).

8. Patrick Faber test: The patient is positioned supine. The right leg, near the ankle is placed above the knee on the left thigh. The examiner places his right hand over the patient's left iliac crest, while the examiners left hand pushes downward on the medial aspect of the right knee. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint (Kirkaldy-Willis,1992:125).

The same tests were used to assess the patient's initial presentation and progress throughout the treatment period. The tests were performed bilaterally and scored a possible maximum of ten points. Points were recorded before the first, third and fourth treatments.
A negative result was recorded as zero points when the patient reported 'no pain'.

3.7 Interventions

Each subject who was accepted for the trial attended four consultations over a two-week period. Group A received combined spinal manipulation and Diclofenac medication, in the form of three 50mg Diclofenac tablets daily with meals for five consecutive days. Group B received a combination of spinal manipulation and placebo medication, in the form of three 5mg folic acid tablets daily with meals for five consecutive days.
Each patient was required to fill in a medication diary in order to improve patient compliance.

If any subject developed side effects such as gastric or intestinal ulceration with associated bleeding, skin rashes, gastrointestinal disturbances, headaches, dizziness, oedema, nervousness, pruritis, tinnitus, insomnia, blurred vision and other ocular reactions, peripheral oedema, malaise, jaundice, elevated transaminase levels, drowsiness and hypersensitivity reactions (e.g. bronchospasm), those patients were withdrawn from the study.

3.7.1 Spinal manipulative therapy

Both groups received spinal manipulative therapy, once the diagnosis of sacroiliac or lumbar facet syndrome was confirmed using the Orthopaedic Rating Scale (as discussed in section 3.6.2.2). The specific subluxations were determined by motion palpation, using the following listings; for the lumbar spine: extension, flexion, lateral flexion and rotation (Schafer and Faye 1990: 213-216), and for the sacroiliac joint: upper flexion, lower flexion, upper extension and lower extension (Schafer and Faye 1990: 260).

3.7.2 Motion palpation

Walker and Buchbinder (1997) conducted a survey of all registered chiropractors in Victoria, Australia and found that motion palpation was commonly used and considered the most reliable diagnostic method for detecting the spinal fixations that they manipulate. This study used motion palpation for a similar purpose, and only the fixated level was detected using this technique.

3.7.2.1 Motion palpation of the lumbar spine

Motion palpation of the lumbar spine was achieved with the subject (sitting) and the examiner (sitting obliquely behind) and fixations identified as a lack of a springy end feel at the end of specific ranges of motion, described by Schafer and Faye (1990:213-216).

a) Flexion: The examiner's thumb is placed between the spinous processes, while the subject's spine is passively flexed forward, while pushing anterosuperiorly on the superior spinous, checking for a springy end feel at the end of the flexion range of motion.

b) Extension: The examiner's thumb pushes anteriorly on the articular process of the superior segment of the motion unit, while the subject's spine is passively extended by a few degrees, checking for a springy end feel at the end of the extension range of motion.

c) Lateral flexion: To assess for left lateral flexion, the examiner's right thumb is placed against the left side of the spinous process of the superior segment, of the motion unit being evaluated. As the subject is passively laterally flexed to the left with the stabilizing arm, the examiner's right thumb pushes against the left aspect of the spinous process to produce a greater opening between the contralateral facets, checking for a springy end feel at the end of the lateral

flexion range of motion. The procedure is reversed for a right lateral flexion assessment.

d) Rotation: To assess for right rotation. The examiner's thumb is placed against the right inferior process of the superior segment of the motion unit. The subject is rotated to the right using the stabilizing arm while pushing anteriorly with the right thumb, checking for a springy end feel at the end of the range of motion. The procedure is reversed for a left rotation fixation assessment.

3.7.2.2 Motion palpation of the sacroiliac joint

Motion palpation of the sacroiliac joint is conducted using the Standing Flexed-Knee-Raising Test as described by Schafer and Faye (1990:260-261).

a) Superior Joint Motion Palpation: For a right sacroiliac joint assessment, the examiner's left thumb was placed on the sacral base and the right thumb on the PSIS. The subject was asked to raise the right flexed knee as if taking a high step, noting the separation of the thumbs. The sacral base would normally be seen and felt to arc anteriorly and inferiorly. The PSIS would normally move backward and downward for a left sacroiliac joint assessment. The test was repeated with the left knee raised. If the superior sacroiliac joint is locked, the sacrum and ilium would move as a unit and not separate appreciably.
b) Inferior Joint Motion Palpation: For a right sacroiliac joint assessment, the examiner's left thumb was placed on the sacral apex and the right thumb was placed on the ischial protuberance. The subject was requested to raised the right knee. Normally the ischium should be felt moving antero-superior and slightly lateral on the sacrum. If the inferior sacroiliac joint is locked, the ischium and the sacral apex move as a unit.

3.8 Statistical Analysis of the Data

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. The null hypothesis was rejected at the $\alpha = 0.05$ level of significance if $p < \alpha$ where p was the observed significance level or probability value. The null hypothesis was otherwise accepted at the same level.

3.9 The Use of Parametric and Non-Parametric Testing

Parametric tests were conducted to analyse the continuous variables ($n \geq 30$), while non-parametric tests were conducted to analyse the categorical variables ($n < 30$) (Fischer and van Belle 1993).

3.9.1. Parametric Testing

The continuous variables analysed included results from the Revised Oswestry Low Back Disability Questionnaire (Hsieh et al. 1992 and Haas et al. 1995), and the Numerical Pain Rating Scale-101 (Jenson et al. 1986). Medians, ranges and standard deviations were used for analysis.

Subjective and objective data from the results of the continuous variables were analysed using two sample unpaired t-test for inter-group comparison. This was in order to determine whether any significant difference existed between the median values within the control and experimental groups at the first, third and fourth consultations. Significance level was set at $\alpha = 0.05$.

Subjective and objective data from the continuous variables were also analysed using two sample-unpaired t-test for intra-group comparison. This was in order to determine whether any significant change occurred between the median values

within each group of the first, third and fourth consultations. Significance level was set at $\alpha = 0.05$.

3.9.1.1 Paired t-test (Intra-group)

The paired t-test was used to determine whether any significant improvement occurred within group 1 and group 2 between the initial and the third consultation, the initial and final consultation and the third and final consultation for each group. This parametric test was used, as the sample size was greater than or equal to 30 ($n \geq 30$).

Ho: There is no improvement between the consultations.

Ha: There is an improvement between the consultations.

$\alpha = \mathbf{0.05}$, one tailed test.

Decision rule:

If $p < \alpha$, reject Ho.

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

(1) $p = \frac{\text{reported p-value}}{2}$ If Ha is of form > and z is positive
If Ha is of form < and z is negative

(2) $p = 1 - \frac{\text{(reported p-value)}}{2}$ If Ha is of form > and z is negative
If Ha is of form < and z is positive

(The reported p-value is the SPSS print out value of p).

3.9.1.2 Unpaired t-test (Inter-group)

Unpaired t-test was used to determine whether there was any significant difference between the two groups at the time of the initial, second and final consultations. This parametric test was used, as the sample size was greater than or equal to 30 ($n \geq 30$).

Ho: There is no difference between the two groups.

Ha: There is a difference between the two groups.

$\alpha = \mathbf{0.05}$

Decision rule:

If $p < \alpha$, reject Ho.

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

Where p is the reported p-value.

3.9.2 Non-Parametric Testing

The categorical variables analysed included results from the orthopaedic rating scale and algometer readings.

Subjective and objective data from the Revised Oswestry Low Back Disability Questionnaire and the orthopaedic rating scale were analysed using the Mann-Whitney Unpaired Test for inter-group comparison. This was in order to determine whether any significant difference existed between the median values in the control and experimental groups at the first, third and fourth consultations. Significance level was set at $\alpha = 0.05$ (Fisher and Van Belle, 1993:315-319).

Subjective and objective data, from both categorical variables were analysed using the Wilcoxon Signed Rank Test for intra-group comparison. This was in order to determine whether any significant change occurred between the median values within each group, between the first, third and fourth consultations. Significance level was set at $\alpha = 0.05$ (Fisher and Van Belle, 1993:315-319).

3.9.2.1 Friedman Test (Intra-group)

This test is a nonparametric analog of the parametric two-way analysis of variance. Calculations are performed on ranks from the data. In the Friedman test, the observations within each block are ranked separately from smallest to largest. This was done between the initial, third and final consultations within both groups.

Ho: All three treatments yield identical results.

Ha: At least one treatment is different from the rest.

$\alpha = 0.05$

Decision rule:

$p < \alpha$, reject Ho.

$p \geq \alpha$, accept Ho.

If Ho is rejected, then we carry out the multiple comparison procedure to determine which of the three consultations is different.

Compute $|Ri - Rj|$

If $|Ri - Rj| \geq z\sqrt{\frac{bk(k+1)}{6}}$

b= number of patients

k= number of consultations

(Daniel W.W. 1978: 244 and 231).

3.9.2.2 Wilcoxon Signed Ranks Test (Intra-group)

The Wilcoxon Signed Ranks test was used at 5% level of significance. It was used to determine whether any statistically significant improvement occurred within group 1, and group 2 between the initial and the third consultation, the initial and final consultation and the third and final consultation.

One-tailed test.

Ho: There is no improvement between the consultations.

Ha: There is an improvement between consultations.

$\alpha = \mathbf{0.05}$

Decision rule:

If $p < \alpha$, reject Ho.

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

(1) $p = \frac{\text{reported p-value}}{2}$ If Ha is of form > and z is positive
If Ha is of form < and z is negative

(2) $p = 1 - \frac{(\text{reported p-value})}{2}$ If Ha is of form > and z is negative
If Ha is of form < and z is positive

(The reported p-value is the SPSS print out value of p).

3.9.2.3 Mann-Whitney U-test (Inter-group)

The Mann-Whitney U-test was used to determine whether any significant difference existed between group 1 and group 2 at the time of the initial, third and final consultations.

Ho: There is no difference between the two groups.

Ha: There is a difference between the two groups.

$\alpha = \mathbf{0.05}$

Decision rule:

If $p < \alpha$, reject Ho.

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

Where p is the reported p-value.

3.10 General Hypotheses

The null hypothesis (Ho) for objective one stated that within each group there was no improvement of the patient's condition in terms of subjective clinical findings.

The alternative hypothesis (Ha) for objective one stated that within each group there was an improvement of the patient's condition in terms of subjective clinical findings.

The null hypothesis (Ho) for objective two stated that there was no difference between group one and two in terms of objective clinical findings.

The alternative hypothesis (Ha) for objective two stated that there was a difference between group one and two in terms of objective clinical findings.

3.11 Summary Statistics

If the parametric or non-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 to identify the more effective treatment group. The standard deviation could then be used to measure the reliability of the mean by measuring the spread data around the mean. Both parametric and non-parametric tests used the median within the calculations.

CHAPTER FOUR: THE RESULTS

4.1 The Sample size

The size of the study was limited to 60 subjects, with 30 subjects allocated to each of the two treatment samples. Group A received a combination of nonsteroidal anti-inflammatory medication and spinal manipulation of the low back. Group B received a combination of placebo medication and spinal manipulation of the low back.

4.2 Demographics

Demographical data including age distribution, gender distribution, acute and chronic conditions, lumbar facet syndrome and sacroiliac syndrome are represented in the form of bar graphs. The total number of applicants for the trial and the subjects that dropped out of trial will be discussed in chapter five.

4.2.1 Age Distribution

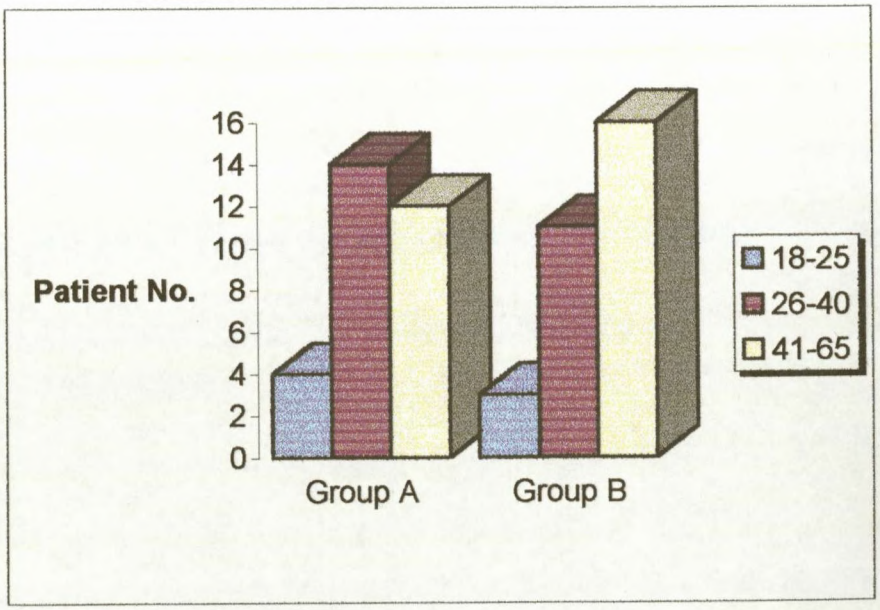


Figure 1: Age distribution

4.2.2.Gender Distribution

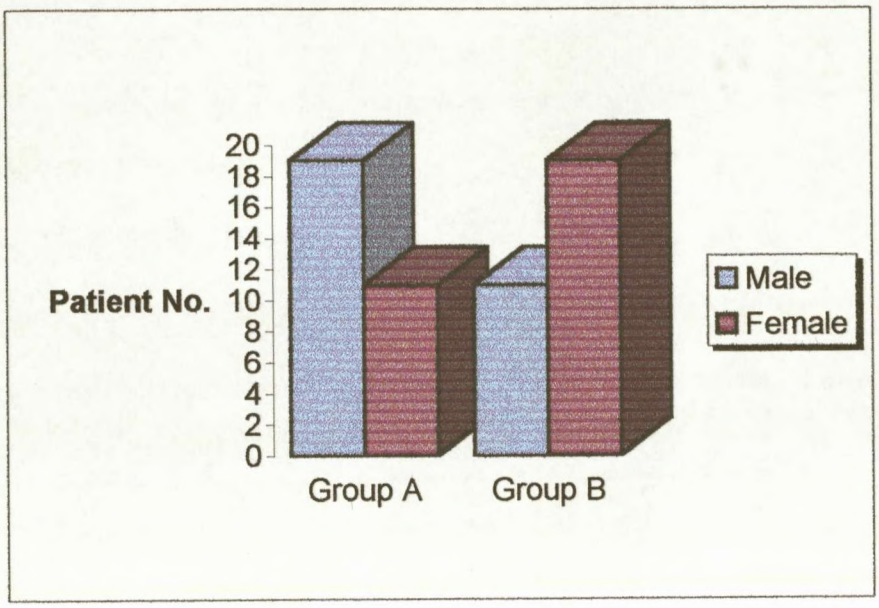


Figure 2: Gender distribution

4.2.3 Chronicity

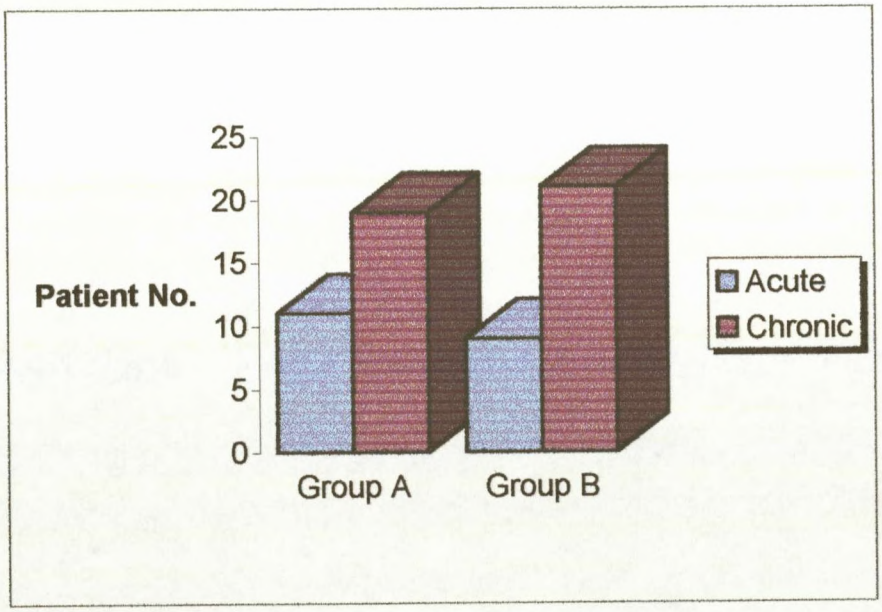


Figure 3: Chronicity

4.2.4 Sacroiliac and Lumbar facet syndrome

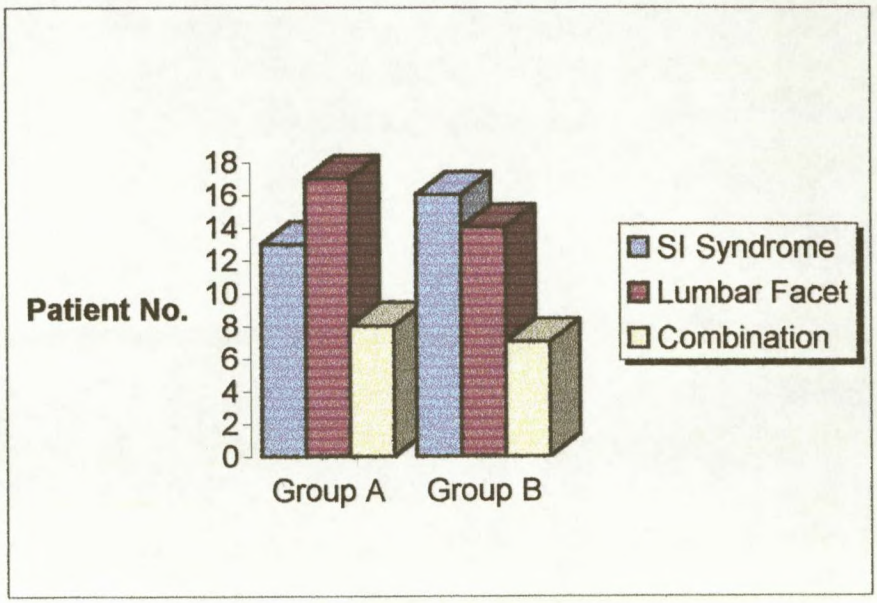


Figure 4: Sacroiliac and lumbar facet syndrome

4.3 Analysis of the data

Parametric and non-parametric testing was used in order to analyse the respective data. Parametric testing was used to analyse the continuous variables, namely the algometer readings, the Numerical Pain Rating Scale-101, and the Revised Oswestry Back Pain Disability Questionnaire, to establish a general trend for mechanical low back pain, as the sample size was 30 subjects ($n \geq 30$). Non-parametric testing was used to analyse results of the orthopaedic rating scale, including results of the Numerical Pain Rating Scale-101 and Revised Oswestry Low Back Pain Disability Questionnaire and algometer readings for sacro-iliac syndrome and lumbar facet syndrome specifically, as sample sizes were less than 30 subjects ($n < 30$). Furthermore, non-parametric testing was also used to analyse the results of the Numerical Pain Rating Scale-101, the Revised Oswestry Low Back Pain Disability Questionnaire and algometer readings for acute and chronic conditions, as sample sizes were less than 30 subjects ($n < 30$). The p-values for inter-group and intra-group

comparisons were set at $\alpha = 0.05$ level of significance. The p-values of the two-tailed unpaired t-tests and the Mann-Whitney tests for inter-group comparisons, as well as the Friedman test and Wilcoxon Signed Ranks tests for intra-group comparisons, were all set at $\alpha = 0.05$ level of significance.

4.4 Parametric testing: A comparison of continuous variables.

4.4.1 Inter-group analysis: Two-sample unpaired t-tests.

Table 1: Two-Sample unpaired t-test assessing mechanical low back pain in Group 1 and Group 2 for all subjective results.

	Consultation 1	Consultation 3	Consultation 4
NRS	0.728	0.032	0.550
Oswestry	0.519	0.128	0.650

The null hypothesis was accepted according to the defined decision rule, indicating no difference between consultation 1, consultation 3 and consultation 4 between group 1 and group 2. However, the null hypothesis was rejected for all NRS 101 results in consultation 3 indicating a difference between group 1 and group 2.

Figure 5: Inter-group mean for all NRS-101 results.

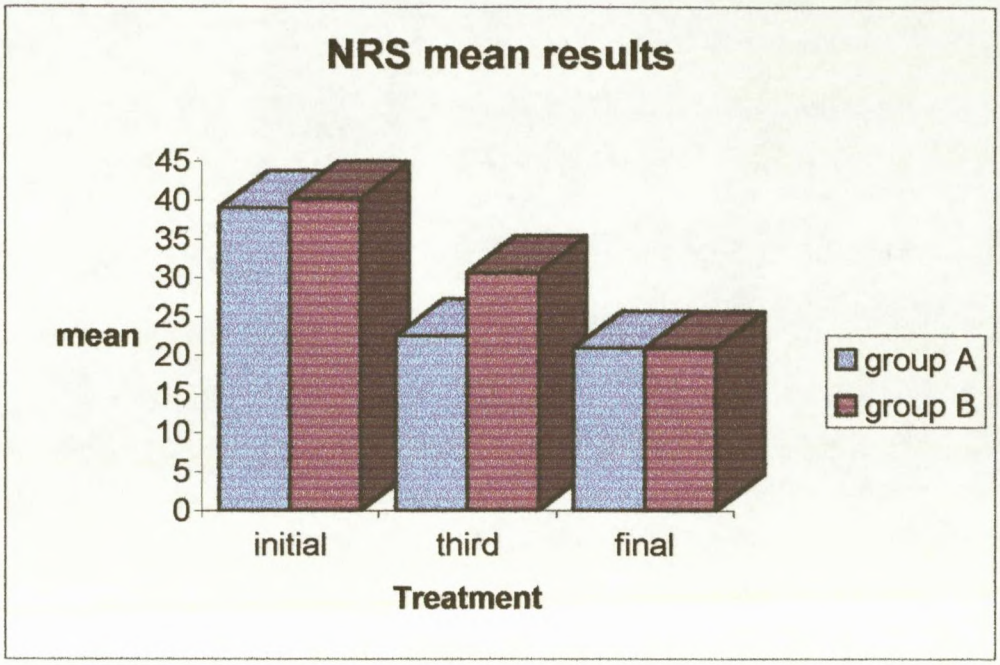


Figure 6: Inter-group mean for all Oswestry results.

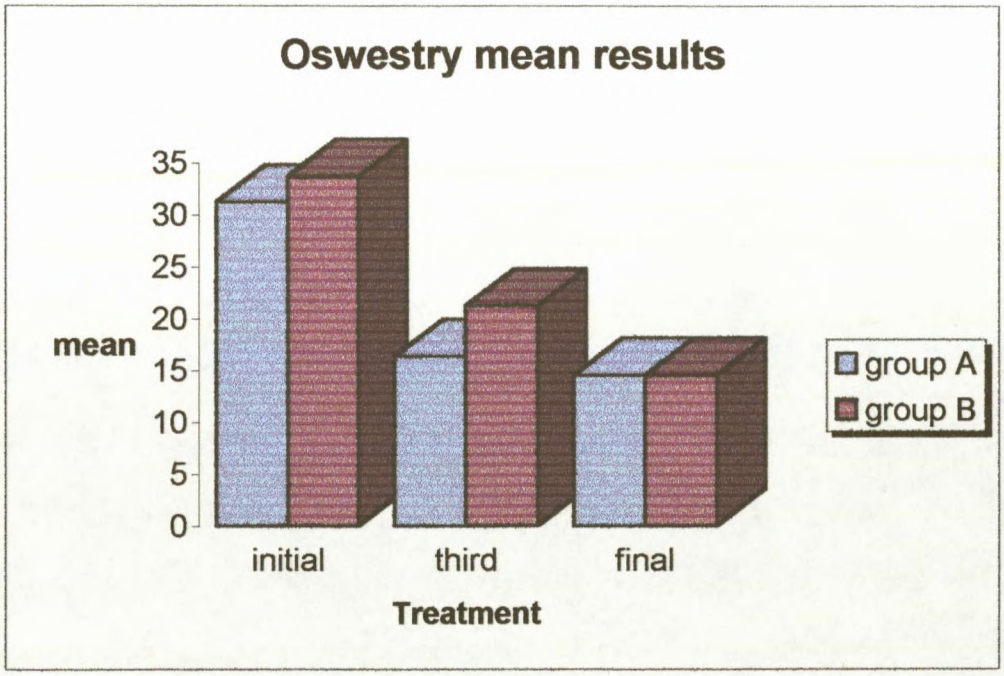
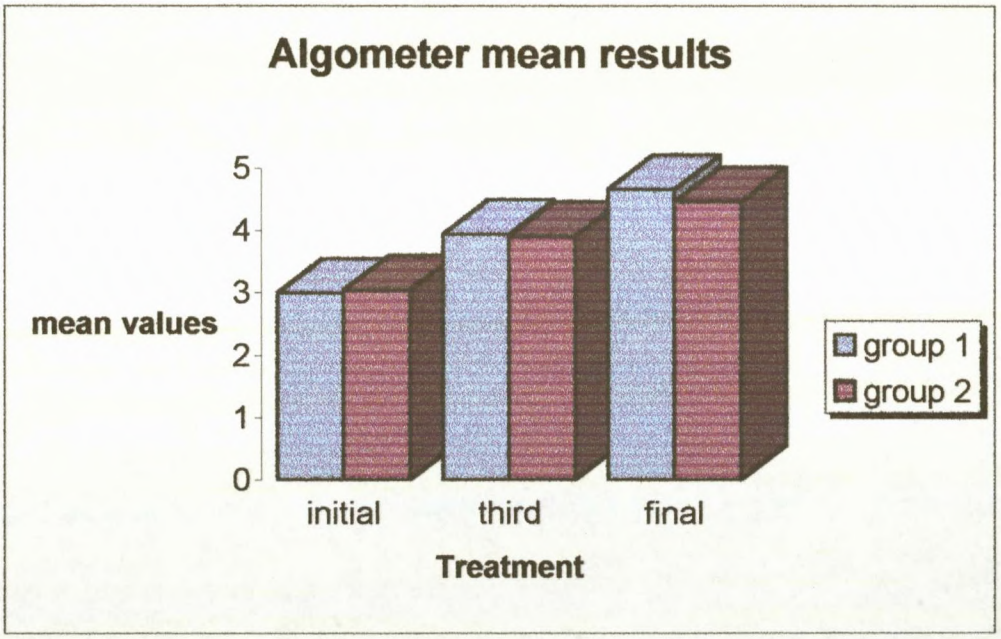


Table 2: Two-Sample unpaired t-test assessing mechanical low back pain in Group 1 and Group 2 for all objective results.

	Consultation 1	Consultation 3	Consultation 4
Algometer	0.750	0.924	0.533

The null hypothesis was accepted according to the defined decision rule, indicating no difference between consultation 1, consultation 3 and consultation 4 between group 1 and group 2.

Figure 7: Inter-group mean for all algometer results.



4.4.2 Intra-group analysis: Paired t-tests

Table 3: Two-Sample Paired t-Tests assessing mechanical low back pain for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.000	0.000	0.145
Oswestry	0.000	0.000	0.028

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4. The null hypothesis was rejected for all Oswestry Low Back Disability Questionnaire results, indicating an improvement between consultation 3 and consultation 4. The null hypothesis was accepted for the NRS 101, indicating no improvement between consultation 3 and 4 for all NRS 101 results.

Table 4: Two-Sample Paired t-Tests assessing mechanical low back pain for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all algometer results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Algometer	0.000	0.000	0.001

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4 and consultation 3 and consultation 4 for all algometer results in Group 1.

Table 5: Two-Sample Paired t-Tests assessing mechanical low back pain for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.002	0.000	0.001
Oswestry	0.000	0.000	0.008

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4 and consultation 3 and consultation 4 for all subjective results in Group 1.

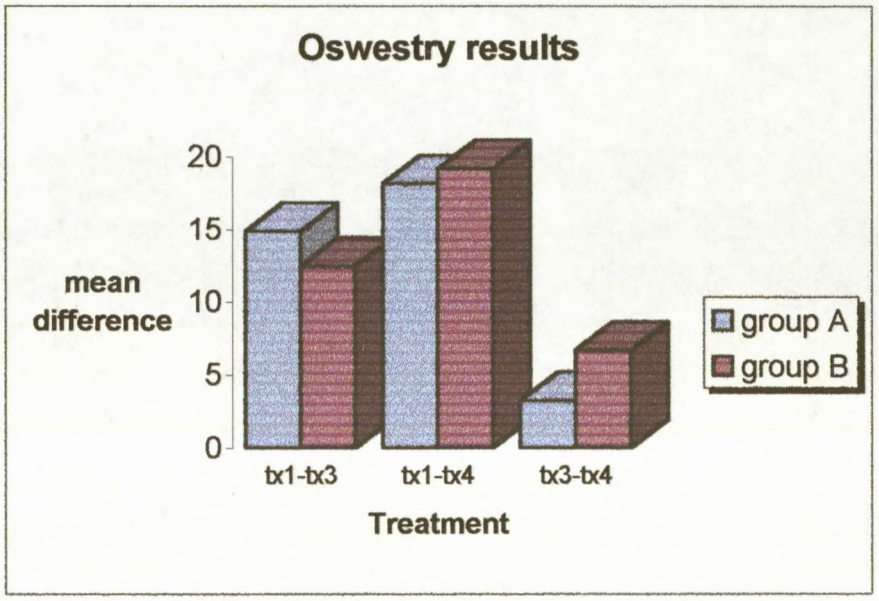
Table 6: Two-Sample Paired t-Tests assessing mechanical low back pain for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all algometer results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Algometer	0.000	0.000	0.003

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4 and consultation 3 and consultation 4 for all algometer results in Group 1.

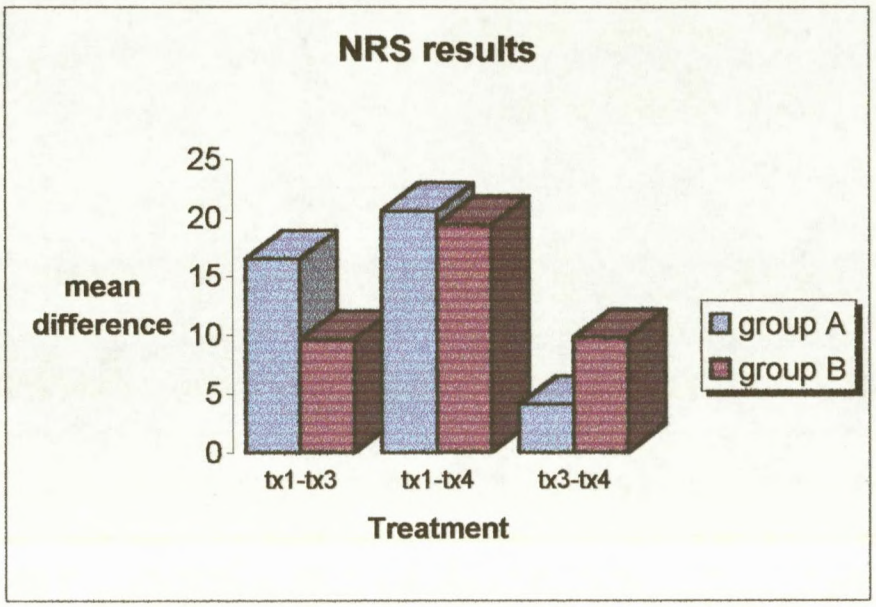
4.4.3. Intra-group mean differences

Figure 8: Intra-group mean differences for all Oswestry results.



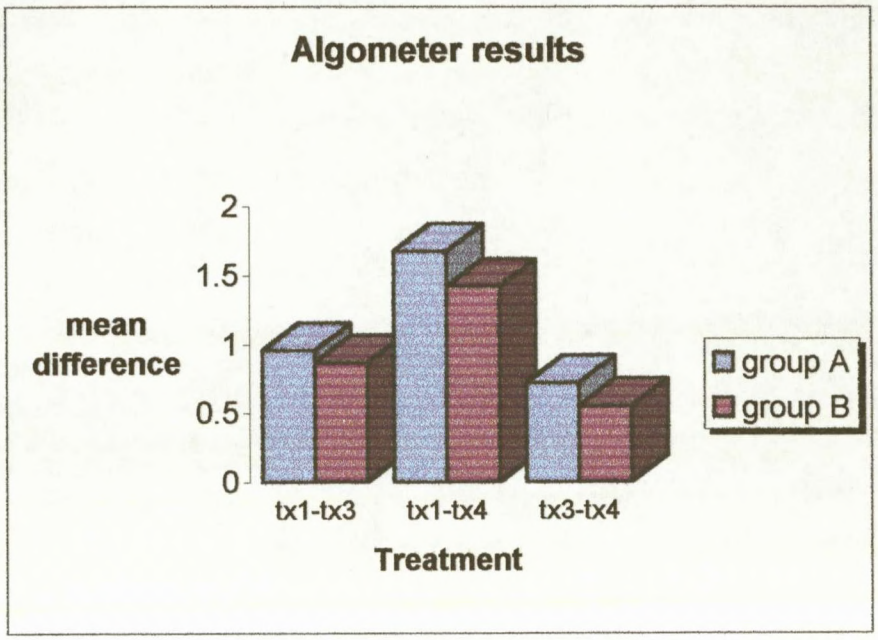
A greater improvement is evident between the 1st and 3rd treatments for group 1, however a greater improvement occurs between the 3rd and 4th treatments for group 2. A slightly greater overall improvement occurs for group 2 between the 1st and 4th treatments.

Figure 9: Intra-group mean differences for all NRS results.



A greater improvement is evident between the 1st and 3rd treatments for group 1, however a greater improvement occurs between the 3rd and 4th treatments for group 2. A slightly greater overall improvement occurs for group 1 between the 1st and 4th treatments.

Figure 10: Intra-group differences for all algometer results.



A greater improvement is evident in group 1 for all treatments.

4.5 Non-parametric testing: A comparison of categorical variables

4.5.1 Friedman test and multiple comparison procedure

Table 7: Friedman test assessing mechanical low back pain for all Oswestry Low Back Pain Disability Questionnaire results for group 1 and group 2

N = 30	Mean Rank group 1	Mean Rank group 2
OSWES 1	2.93	2.75
OSWES 2	1.73	1.85
OSWES 3	1.33	1.40
p-value	0.000	0.000

The null hypothesis was rejected according to the defined decision rule indicating that a difference existed between one of the consultations, therefore the multiple comparison procedure was conducted.

Table 7.1: Multiple comparison procedure assessing mechanical low back pain for all Oswestry Low Back Pain Disability Questionnaire results for group 1 and group 2

	Computed value Oswestry group 1	Critical value	Computed value Oswestry group 2
$\lvert R_1-R_3 \rvert$	36	18.59	27
$\lvert R_3-R_4 \rvert$	12	18.59	13.5
$\lvert R_1-R_4 \rvert$	48	18.59	40.5

From the above we conclude that a greater improvement occurred between the 1st and 4th consultations in both group 1 and group 2.

Table 8: Wilcoxon Signed Ranks test assessing mechanical low back pain for all Oswestry Low Back Pain Disability Questionnaire results for group 1 and group 2

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Oswestry 1	0.000	0.000	0.010
Oswestry 2	0.000	0.000	0.010

The null hypothesis was rejected according to the defined decision rule indicating that there was an improvement between all consultations for group 1 and group 2.

Table 9: Friedman test assessing mechanical low back pain for all NRS 101 results for group 1 and group 2

N = 30	Mean Rank group 1	Mean Rank group 2
NRS 1	2.77	2.67
NRS 2	1.82	1.97
NRS 3	1.42	1.37
p-value	0.000	0.000

The null hypothesis was rejected according to the defined decision rule indicating that a difference existed between one of the consultations, therefore the multiple comparison procedure was conducted.

Table 9.1: Multiple comparison procedure assessing mechanical low back pain for all NRS 101 results for group 1 and group 2.

	Computed value NRS 1	Critical value	Computed value NRS 2
$\lvert R_1-R_3 \rvert$	28.5	18.59	21
$\lvert R_3-R_4 \rvert$	12	18.59	18.1
$\lvert R_1-R_4 \rvert$	40.5	18.59	39

From the above we conclude that a greater improvement between the 1st and 4th consultations in both group 1 and group 2.

Table 10: Wilcoxon Signed Ranks test assessing mechanical low back pain for all NRS 101 results for group 1 and group 2

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS 1	0.000	0.000	0.023
NRS 2	0.003	0.000	0.001

The null hypothesis was rejected according to the defined decision rule indicating that there was an improvement between all consultations for group 1 and group 2.

Table 11: Friedman test assessing mechanical low back pain for all algometer results for group 1 and group 2

N = 30	Mean Rank group 1	Mean Rank group 2
ALG 1	**1.12**	**1.20**
ALG 2	**2.12**	**2.12**
ALG 3	**2.77**	**2.68**
p-value	**0.000**	**0.000**

The null hypothesis was rejected according to the defined decision rule indicating that a difference existed between one of the consultations, therefore the multiple comparison procedure was conducted.

Table 11.1: Multiple comparison procedure assessing mechanical low back pain for all algometer results for group 1 and group 2.

	Computed value NRS 1	Critical value	Computed value NRS 2
$\lvert R_1-R_3 \rvert$	30	18.59	27.6
$\lvert R_3-R_4 \rvert$	19.5	18.59	16.8
$\lvert R_1-R_4 \rvert$	49.5	18.59	44.4

From the above we conclude that a greater improvement occurred between the 1st and 4th consultations in both group 1 and group 2.

Table 12: Wilcoxon Signed Ranks test assessing mechanical low back pain for all algometer results for group 1 and group 2

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Algometer 1	0.000	0.000	0.001
Algometer 2	0.000	0.000	0.003

The null hypothesis was rejected according to the defined decision rule indicating that there was an improvement between all consultations for group 1 and group 2.

4.5.2 Inter-group analysis: Mann-Whitney U-tests

4.5.2.1 Lumbar facet syndrome

Table 13: Mann-Whitney U-test assessing lumbar facet syndrome for all subjective results in Group 1 and Group 2

	Consultation 1	Consultation 3	Consultation 4
NRS	0.340	0.013	0.264
Oswestry	0.874	0.486	0.486

The null hypothesis was accepted according to the defined decision rule indicating no difference between the 1st consultations and 4th consultations, between Group 1 and Group 2.

The null hypothesis was rejected indicating that a difference existed between Group 1 and Group 2 in the 3rd consultations for all NRS 101 results. The null hypothesis was also accepted, indicating that no difference existed between Group 1 and Group 2 in the 3rd consultation for all Oswestry Low Back Disability Questionnaire results.

Table 14: Mann-Whitney U-test assessing lumbar facet syndrome for all objective results in Group 1 and Group 2

	Consultation 1	Consultation 3	Consultation 4
Orth Scale	0.310	0.541	0.350
Algometer	0.251	0.936	0.889

The null hypothesis was accepted according to the defined decision rule indicating no difference between the 1st consultations, the 3rd consultations and 4th consultations for all objective results between group 1 and group 2.

4.5.2.2 Sacroiliac syndrome

Table 15: Mann-Whitney U-test assessing sacroiliac syndrome for all subjective results in Group 1 and Group 2

	Consultation 1	Consultation 3	Consultation 4
NRS	0.723	0.658	0.965
Oswestry	0.262	0.129	0.740

The null hypothesis was accepted according to the defined decision rule indicating no difference between the 1st consultations, the 3rd consultations and the 4th consultation for all subjective results between group 1 and group 2.

Table 16: Mann-Whitney U-test assessing sacroiliac syndrome for all objective results in Group 1 and Group 2

	Consultation 1	Consultation 3	Consultation 4
Orth Scale	0.924	0.660	0.896
Algometer	0.188	0.582	0.708

The null hypothesis was accepted according to the defined decision rule indicating no difference between the 1st consultations, the 3rd consultations and the 4th consultation for all objective results between group 1 and group 2.

4.5.2.3 Acute mechanical low back pain

Table 17: Mann-Whitney U-test assessing acute low back pain for all subjective results in Group 1 and Group 2

	Consultation 1	Consultation 3	Consultation 4
NRS	0.849	0.108	0.673
Oswestry	0.044	0.093	0.465

The null hypothesis was accepted according to the defined decision rule indicating no difference between the 3rd consultation and the 4th consultation, between Group 1 and Group 2.

The null hypothesis was accepted indicating that no difference existed between Group 1 and Group 2 in 1st consultations for all NRS 101 results. The null hypothesis was also rejected, indicating that a difference existed between Group 1 and Group 2 in the 1st consultation for all Oswestry Low Back Disability Questionnaire results.

Table 18: Mann-Whitney U-test assessing acute low back pain for all algometer results in Group 1 and Group 2

	Consultation 1	Consultation 3	Consultation 4
Algometer	0.535	0.444	0.517

The null hypothesis was accepted according to the defined decision rule indicating no difference between the 1st consultations, the 3rd consultations and the 4th consultation for all algometer results between group 1 and group 2.

4.5.2.4 Chronic mechanical low back pain

Table 19: Mann-Whitney U-test assessing chronic low back pain for all subjective results in Group 1and Group 2

	Consultation 1	Consultation 3	Consultation 4
NRS	0.531	0.073	0.550
Oswestry	0.597	0.957	0.817

The null hypothesis was accepted according to the defined decision rule indicating no difference between the 1st consultations, 3rd consultation and 4th consultations for all subjective results between group 1 and group 2.

Table 20: Mann-Whitney U-test assessing chronic low back pain for all algometer results in Group 1 and Group 2

	Consultation 1	Consultation 3	Consultation 4
Algometer	0.635	0.723	0.215

The null hypothesis was accepted according to the defined decision rule indicating no difference between the 1st consultation, 3rd consultation and 4th consultations for all algometer results between group 1 and group 2.

4.5.3 Intra-group analysis: Wilcoxon Signed Ranks Test

4.5.3.1 Lumbar facet syndrome

Table 21: Wilcoxon Signed Ranks test assessing lumbar facet syndrome for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.001	0.002	0.430
Oswestry	0.000	0.002	0.298

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4. The null hypothesis was accepted according to the defined decision rule indicating no improvement between consultation 3 and consultation 4.

Table 22: Wilcoxon Signed Ranks test assessing lumbar facet syndrome for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all objective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Orth Scale	0.000	0.000	0.084
Algometer	0.001	0.001	0.017

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4 and consultation 3 and consultation 4.

Table 23: Wilcoxon Signed Ranks test assessing lumbar facet syndrome for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.012	0.004	0.049
Oswestry	0.008	0.002	0.325

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, and consultation 1 and consultation 4 for all subjective results for group 2. The null hypothesis was rejected for all NRS 101 results indicating an improvement and accepted for all Oswestry Low Back Disability Questionnaire results indicating no improvement between consultation 3 and consultation 4.

Table 24: Wilcoxon Signed Ranks test assessing lumbar facet syndrome for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all objective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Orth Scale	0.002	0.001	0.030
Algometer	0.003	0.001	0.008

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4, and consultation 3 and consultation 4 for all objective results for group 1.

4.5.3.2. Sacroiliac syndrome

Table 25: Wilcoxon Signed Ranks test assessing sacroiliac syndrome for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.050	0.003	0.011
Oswestry	0.002	0.001	0.007

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4, and consultation 3 and consultation 4 for all subjective results for group 1.

Table 26: Wilcoxon Signed Ranks test assessing sacroiliac syndrome for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all objective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Orth Scale	0.001	0.001	0.014
Algometer	0.002	0.001	0.023

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4, and consultation 3 and consultation 4 for all subjective results for group 1.

Table 27: Wilcoxon Signed Ranks test assessing sacroiliac syndrome for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.126	0.001	0.012
Oswestry	0.016	0.001	0.014

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 4, and consultation 3 and consultation 4 for all subjective results for group 2. The null hypothesis was accepted for all NRS 101 indicating no improvement, and rejected for all Oswestry Low Back Disability Questionnaire results indicating an improvement between consultation 1 and consultation 3.

Table 28: Wilcoxon Signed Ranks test assessing sacroiliac syndrome for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all objective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Orth Scale	0.000	0.000	0.026
Algometer	0.017	0.001	0.088

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4, and consultation 3 and consultation 4 for all subjective results.

4.5.3.3 Acute mechanical low back pain

Table 29: Wilcoxon Signed Ranks test assessing acute low back pain for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.006	0.003	0.035
Oswestry	0.003	0.003	0.056

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4, and consultation 3 and consultation 4 for all subjective results for group 1.

Table 30: Wilcoxon Signed Ranks test assessing acute low back pain for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all algometer results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Algometer	0.005	0.005	0.085

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4, and consultation 3 and consultation 4 for all objective results for group 2.

Table 31: Wilcoxon Signed Ranks test assessing acute low back pain for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.154	0.007	0.030
Oswestry	0.028	0.008	0.030

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 4, and consultation 3 and consultation 4 for all subjective results for group 2. The null hypothesis was accepted for all NRS 101 indicating no improvement, and rejected for all Oswestry Low Back Disability Questionnaire results indicating an improvement between consultation 1 and consultation 3.

Table 32: Wilcoxon Signed Ranks test assessing acute low back pain for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all algometer results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Algometer	0.017	0.012	0.121

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, and consultation 1 and consultation 4 for all algometer results for group 2. The null hypothesis was accepted for all algometer results indicating no improvement between consultation 3 and consultation 4.

4.5.3.4 Chronic mechanical low back pain

Table 33: Wilcoxon Signed Ranks test assessing chronic low back pain for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.003	0.002	0.221
Oswestry	0.000	0.001	0.070

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4. The null hypothesis was accepted for the NRS-101 indicating no improvement between consultation 3 and consultation 4, and rejected for all Revised Oswestry Low back Pain Questionnaire results indicating an improvement between consultation 3 and consultation 4.

Table 34: Wilcoxon Signed Ranks test assessing chronic low back pain for Group 1 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all algometer results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Algometer	0.001	0.000	0.004

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4 and consultation 3 and consultation 4 for all objective results for group 1.

Table 35: Wilcoxon Signed Ranks test assessing chronic low back pain for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all subjective results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
NRS	0.010	0.001	0.011
Oswestry	0.003	0.000	0.103

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4. The null hypothesis was accepted for the Oswestry Low Back Pain Disability Questionnaire indicating no improvement between consultation 3 and consultation 4, and rejected for the NRS-101 indicating an improvement between consultation 3 and consultation 4.

Table 36: Wilcoxon Signed Ranks test assessing chronic low back pain for Group 2 comparing consultation 1 and 3, consultation 1 and 4, consultation 3 and 4 for all algometer results.

	Consultation 1 & consultation 3	Consultation 1 & consultation 4	Consultation 3 & consultation 4
Algometer	0.002	0.000	0.009

The null hypothesis was rejected according to the defined decision rule indicating an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4 and consultation 3 and consultation 4 for all algometer results for group 2.

CHAPTER FIVE: DISCUSSION OF THE RESULTS

This chapter will discuss all the results of the subjective and objective results as recorded from the Numerical Pain Rating Scale-101 (NRS-101), the Revised Low Back Pain Disability Questionnaire, Algometer readings and the Orthopaedic Rating Scale, all of which have been presented in chapter four. The general trends of mechanical low back pain will be analysed, and specific trends of lumbar facet syndrome, sacroiliac syndrome, acute mechanical low back pain and chronic mechanical low back pain will also be analysed individually.

5.1 Mechanical low back pain

5.1.1 Inter-consultation comparison

The subjective statistical results (Table 1) indicate no difference between group 1 and group 2. NRS 101 results in consultation 3 indicated a difference and no difference for all ROLBPDQ results, between group 1 and group 2.

The objective statistical results (Table 2) indicated no difference between group 1 and group 2.

Graphical comparison of the mean values (Figure 5 – 7) shows no significant difference between the two treatment groups for all NRS-101, Oswestry and algometer results suggesting that both groups showed an equal improvement for the duration of the treatment.

5.1.2 Intra-group analysis

The subjective statistical data for group 1 (Table 3) from the analysis of the NRS-101 revealed that there was an improvement between consultation 1 and consultation 3, and consultation 1 and consultation 4, however no improvement

occurred between consultation 3 and consultation 4. The results from the ROLBPDQ analysis revealed that there was an improvement between all consultations.

The subjective statistical data for group 2 (Table 5) indicated an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4 and consultation 3 and consultation 4.

Non-parametric testing of NRS-101 and ROLBPDQ results (Tables 7 - 10) revealed that there was an improvement between all consultations and that a greater improvement occurred between the 1st and the 4th consultations for both groups.

The objective statistical data for group 1 (Table 4) revealed that there was an improvement between all consultations for all algometer results.

The objective statistical data for group 2 (Table 6) revealed that there was an improvement between all consultations for all algometer results.

Non-parametric testing of the algometer results (Tables 11 - 12) revealed that there was an improvement between all consultations and that a greater improvement occurred between the 1st and the 4th consultations.

Mean differences of all the Oswestry results (Figure 8) suggest that a greater improvement occurred between the 1st and 3rd treatments for group 1, however a greater improvement occurs between the 3rd and 4th treatments for group 2. A slightly greater overall improvement occurs for group 2 between the 1st and 4th treatments.

Mean differences of all the NRS-101results (Figure 9) suggest that a greater improvement occurs between the 1st and 3rd treatments for group 1, however a

greater improvement occurs between the 3rd and 4th treatments for group 2. A slightly greater overall improvement occurs for group 1 between the 1st and 4th treatments.

Mean differences of all algometer (Figure10) results suggest that a slightly greater improvement occurs in group 1 for all treatments.

5.2 Lumbar facet syndrome

5.2.1 Inter-group comparison

The subjective statistical results (Table 13) indicate that there was no difference for 1st consultations and 4th consultations between group 1 and group 2. A difference existed between group 1 and group 2 in the 3rd consultations for all NRS 101 results, and no difference existed in the 3rd consultations for ROLBPDQ results between group 1 and group 2.

The objective statistical results (Table 14) indicated that no difference existed between the 1st consultations, the 3rd consultations and 4th consultations for all objective results between group 1 and group 2.

5.2.2 Intra-group analysis

The subjective statistical results for group 1(Table 21) indicated that there was an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4. There was no improvement between consultation 3 and consultation 4.

The subjective statistical results for group 2 (Table 23) indicated an improvement between consultation 1 and consultation 3, and consultation 1 and consultation 4 for all subjective results for group 2. There was an improvement for all NRS 101

results and no improvement for all ROLBPDQ results between consultation 3 and consultation 4.

The objective statistical results for group 1(Table 22), and group 2 (Table 24) indicated that there was an improvement between all consultations for both groups.

5.3 Sacroiliac syndrome

5.3.1 Inter-group comparison

The subjective statistical results for group 1 (Table 15) indicated that no difference existed for the 1st consultations, the 3rd consultations and 4th consultations for all subjective results between group 1 and group 2.

The objective statistical results (Table 16) indicated that no difference existed between the 1st consultations, the 3rd consultations and 4th consultations for all objective results between group 1 and group 2.

5.3.2 Intra-group analysis

The subjective statistical results for group 1 (Table 25) indicated that there was an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4, and consultation 3 and consultation 4 for group 1.

The subjective statistical results for group 2 (Table 27) indicated that there was an improvement between consultation 1 and consultation 4, and consultation 3 and consultation 4. There was no improvement for all NRS-101 results, and there was an improvement for all ROLBPDQ results between consultation 1 and consultation 3 for group 2.

The objective statistical results for group 1 (Table 26), and group 2 (Table 28) indicated that there was an improvement between all consultations for both groups.

5.4 Acute mechanical low back pain

5.4.1 Inter-group comparison

The subjective statistical results (Table 17) indicated that no difference between the 3rd consultations and the 4th consultations. A difference existed between group 1 and group 2 in the 1st consultations for all NRS 101 results, and no difference existed in the 1st consultations for ROLBPDQ results.

The objective statistical results (Table 18) indicated that no difference existed between the 1st consultations, the 3rd consultations and 4th consultations for all objective results between group 1 and group 2.

5.4.2 Intra-group analysis

The subjective statistical results for group 1(Table 29) indicated that there was an improvement between all consultations in group 1.

The subjective statistical results for group 2 (Table 31) indicated that there was an improvement between consultation 1 and consultation 4, and consultation 3 and consultation 4. There was no improvement for all NRS 101, and there was an improvement for all ROLBPDQ results between consultation 1 and consultation 3 in group 2.

The objective statistical results for group 1 (Table 30) indicated that there was an improvement between all consultations for all algometer readings in group 1.

The objective statistical results for group 2 (Table 32) indicated that there was an improvement between consultation 1 and consultation 3, and consultation 1 and consultation 4. There was no improvement between consultation 3 and consultation 4 for all algometer results in group 2.

5.5 Chronic mechanical low back pain

5.5.1 Inter-group comparison

The subjective statistical results (Table 19) indicated that no difference existed between the 1st consultations, 3rd consultations and 4th consultations for all subjective results between group 1 and group 2.

The objective statistical results (Table 20) indicated that no difference existed between the 1st consultations, 3rd consultations and 4th consultations for all algometer results between group 1 and group 2.

5.5.2 Intra-group analysis

The subjective statistical results for group 1 (Table 33) indicated that there was an improvement between consultation 1 and consultation 3, and consultation 1 and consultation 4. There was no improvement for all the NRS-101results and there was an improvement for all ROLBPDQ results between consultation 3 and consultation 4 for group 1.

The subjective statistical results for group 2 (Table 35) indicated that there was an improvement between consultation 1 and consultation 3, consultation 1 and consultation 4. There was no improvement for all ROLBPDQ results and there was an improvement for all the NRS-101results between consultation 3 and consultation 4 for group 2.

The objective statistical results for group 1 (Table 34), and group 2 (Table 36) indicated that there was an improvement between all consultations for both groups

5.6. Problems with the subjective data

Most subjects expressed difficulty in describing the intensity of their pain in answering the Numerical Pain Rating Scale-101. Furthermore, some subjects found that certain criteria in the Revised Oswestry Low Back Pain Disability Questionnaire did not pertain to their existing condition and had difficulty answering the questionnaire.

5.7 Problems with the objective data

The validity and sensitivity of the orthopaedic tests used in the Orthopaedic Rating Scale have been established, however the validity and sensitivity of the rating scale is yet to be investigated.

Variations in the placement of the algometer due to human error may have influenced pain threshold levels.

5.8 Subject exclusion

Number of subjects			Reason for exclusion
Group 1	Group 2	Interview	
		1	Biomechanical abnormality
		2	Disc herniation
2	5		Poor compliance
		1	Radiographic examination required
		4	Diagnostic criteria incomplete
1	1		Side-effects to medication
		1	Exceeded relevant age limit
2			Contra-indications to NSAID's

A total number of 20 applicants were excluded from the trial.

5.9 Demographics

The gender distribution in the groups showed variations with 19 male and 11 female in group A, and 11 male and 19 female in group B. This variation was coincidental and may not have had any dramatic effect on the outcome of the trial.

Chronicity for the groups was relatively equal with 11 acute and 19 chronic in group A, and 9 acute and 21 chronic in group B. Comparisons between the groups was possible using non-parametric statistical analysis and conclusions were drawn from these findings.

Age distribution favoured the 41-65 age group with 28 subjects (12 group A, 16 group B), with 25 subjects from 26-40 (14 group A, 11 group B) and 7 subjects from 18-25 (4 group A, 3 group B). There was a relatively even age distribution between the groups.

Sacroiliac and lumbar facet syndromes were relatively evenly dispersed, but due to random sampling, there were slight variations but would not have had a significant impact on the results.

CHAPTER SIX

6.1 Recommendations

A study of this nature involving either sacroiliac syndrome or lumbar facet syndrome only would be interesting with larger sample groups for each syndrome, so as to ascertain if any varying effects to anti-inflammatory medication exists between the two.

Although this was a single blinded study, a double-blinded study whereby one researcher administers the medication while another researcher applies spinal manipulation may be more scientifically acceptable.

A one-month follow up may be of interest to determine long-term benefits, although this may not allow for patient compliance by avoiding other treatments.

A study comparing different doses of anti-inflammatory medication and applying spinal manipulation to both groups might have interesting results, however ethical considerations may be a complication.

Financial constraints and impending deadlines made statistical analysis difficult and probably less accurate. Studies of this nature need to be analysed by persons more qualified in statistical methods and interpretation.

6.2 Conclusions

This study attempted to determine a more effective treatment protocol when comparing spinal manipulation with either NSAID therapy or placebo therapy, in the management of mechanical low back pain. The statistical analysis revealed significant improvement in both groups after the course of both treatments for all subjective and objective clinical findings. These results indicate that there was no dramatic difference between the two groups for the duration of the treatment. These findings suggest that NSAID therapy combined with spinal manipulation was no better than placebo therapy combined with spinal manipulation, and therefore spinal manipulative therapy alone may be a more effective approach in the treatment of mechanical low back pain.

However, it may be argued that by combining chiropractic treatment with the lowest effective dosage of NSAID medication, the potential for side effects may be reduced (Gabriel, 1997:39) particularly with patients who require NSAID medication and who would otherwise be at higher risk of the adverse effects. Furthermore, by lowering doses of NSAIDs or alternatively only administering NSAID's when necessary, a more effective approach to the management of mechanical low back pain may be suggested through more thorough professional interaction between complementary practitioners and conventional practitioners (Brussee et al. 2001:12).

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Appendix A

DICLOFENAC PACKAGE INSERT

SCHEDULING STATUS: S3

PROPRIETARY NAME:
(and dosage form)

ADCO-DICLOFENAC 25 mg Tablets
ADCO-DICLOFENAC 50 mg Tablets

COMPOSITION:
Each enteric-coated tablet contains 25 mg or 50 mg diclofenac sodium.

PHARMACOLOGICAL CLASSIFICATION:
A 3.1 Antirheumatics (Anti-inflammatory Agents)

PHARMACOLOGICAL ACTION:
Diclofenac sodium is a non-steroidal compound, a phenylacetic acid derivative, with analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium inhibits the biosynthesis and release of prostaglandins which are known to be implicated in the pathogenesis of inflammation, pain and fever. ADCO-DICLOFENAC tablets are enteric-coated, so that absorption occurs in the gastrointestinal tract to give peak plasma concentrations approximately two hours after ingestion. There is at least 99% binding to plasma-proteins and excretion of metabolites is mainly in the urine.

INDICATIONS:
Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, ankylosing spondylitis, osteo-arthrosis, painful post-operative and post-traumatic inflammation and swelling and dysmenorrhoea.

CONTRA-INDICATIONS:
Diclofenac sodium is contra-indicated in patients with known hypersensitivity to diclofenac and in patients who respond to aspirin and aspirin-type drugs with sensitivity reactions like asthma, acute rhinitis and urticaria. Diclofenac sodium is absolutely contra-indicated in patients with peptic ulceration or a history of such ulceration, and should be used with caution in patients with renal or hepatic insufficiency.

WARNINGS:
Serious interactions have been reported after the use of high dose methotrexate with diclofenac.

DOSAGE AND DIRECTIONS FOR USE:

Usual Adult Dose:
25 mg to 50 mg taken three times daily. The tablet must be taken whole during or after meals. Initially this dose may be increased to 150 mg daily and may be reduced to 75 mg to 100 mg daily in milder cases or for long-term and maintenance therapy. Diclofenac sodium is not recommended for use in children as safety and efficacy have not been established.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Gastric or intestinal ulceration with associated bleeding has been reported – ADCO-DICLOFENAC therapy should be discontinued immediately in such cases. Skin rashes and gastro-intestinal disturbances may occur. Headache, dizziness, oedema, nervousness, pruritus, tinnitus, insomnia, blurred vision and other ocular reactions, peripheral oedema, malaise, jaundice, elevated transaminase levels, drowsiness and hypersensitivity reactions (e.g. bronchospasm) have occurred. Blood counts and monitoring of hepatic and renal function are advised during prolonged therapy with ADCO-DICLOFENAC as blood dyscrasias have been reported. The safe use of ADCO-DICLOFENAC in pregnancy has not been demonstrated. Blood concentrations of lithium are increased when ADCO-DICLOFENAC is administered concommitantly. ADCO-DICLOFENAC should be given with care to patients with bleeding disorders, cardiovascular disease, and in those who are receiving coumarin anticoagulants. Patients who are sensitive to aspirin generally should not be given ADCO-DICLOFENAC.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See "Side-effects and special precautions". Treatment is symptomatic and supportive.

IDENTIFICATION:
25 mg tablet: Yellow, round enteric-coated tablets.
50 mg tablet: Tan coloured, round, enteric-coated tablets.

PRESENTATION:
ADCO-DICLOFENAC 25 mg Tablets are presented in bottles and securitainers of 30 and 500 tablets.
ADCO-DICLOFENAC 50 mg Tablets are presented in bottles and securitainers of 21 and 500 tablets.

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

REGISTRATION NUMBER:
ADCO-DICLOFENAC 25 mg: D/3.1/181
ADCO-DICLOFENAC 50 mg: D/3.1/182

NAME AND ADDRESS OF THE APPLICANT:
Adcock Ingram Limited
Adcock Ingram Park
17 Harrison Avenue
Bryanston Ext. 77
Private Bag X69
Bryanston, 2021

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
February 1990

290390 09/97

Dexter Dan

Appendix B

NUMERICAL PAIN RATING SCALE

Numerical Rating Scale – 101 Questionnaire

Date:_____ File no: _____ Visit no:____

Patient name:_____

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

_____

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

_____

Appendix C

REVISED OSWESTRY LOW BACK DISABILITY QUESTIONNAIRE

Low back pain and Disability Questionnaire (Revised Oswestry)

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 relate to you, but please just mark the box which closely describes your problem right now.

Section 1 – Pain Intensity

- ☐ The pain comes and goes and is very mild.
- ☐ The pain is mild and does not vary much.
- ☐ The pain comes and goes and is moderate.
- ☐ The pain is moderate and does not vary much.
- ☐ The pain comes and goes and is very severe.
- ☐ The pain is severe and does not vary much.

Section 2 – Personal Care

- ☐ I would not have to change my way of washing or dressing in order to avoid pain.
- ☐ I do not normally change my way of washing or dressing even though it causes some pain.
- ☐ Washing and dressing increase the pain but I manage not to change my way of doing it.
- ☐ Washing and dressing increase the pain and I find it necessary to change my way of doing it.
- ☐ Because of the pain I am unable to do some washing and dressing without help.
- ☐ Because of the pain I am unable to do any washing and dressing without help.

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.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I manage if they are conveniently positioned (e.g. 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 only lift very light weights at the most.

Section 4 – Walking

- ☐ I have no pain on walking.
- ☐ I have some pain on walking but it does not increase with distance.
- ☐ I cannot walk more than one mile without increasing pain.
- ☐ I cannot walk more than ½ mile without increasing pain.
- ☐ I cannot walk more than ¼ mile without increasing pain.
- ☐ I cannot walk at all without increasing pain.

Section 5 – Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me from sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than ½ hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ I avoid sitting because it increases pain straight away.

Section 6 – Standing

- ☐ I can stand as long as I want without pain.
- ☐ I have some pain on standing but it does not increase with time.
- ☐ I cannot stand for longer than one hour without increasing pain.
- ☐ I cannot stand for longer than ½ hour without increasing pain.
- ☐ I cannot stand for longer than 10 minutes without increasing pain.
- ☐ I avoid standing because it increases the pain straight away.

Section 7 – Sleeping

- ☐ I get no pain in bed.
- ☐ I get pain in bed but it does not prevent me from sleeping well.
- ☐ Because of pain my normal night's sleep is reduced by less than ¼.
- ☐ Because of pain my normal night's sleep is reduced by less than ½.
- ☐ Because of pain my normal night's sleep is reduced by less than ¾.
- ☐ Pain prevents me from sleeping at all.

Section 8 – Social life

- ☐ My social life is normal and gives me no pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. dancing, etc
- ☐ Pain has restricted my social life and I do not go out very often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have hardly any social life because of the pain.

Section 9 – Traveling

- ☐ I get no pain whilst traveling.
- ☐ I get some pain whilst traveling but none of my usual forms of travel make it any worse.
- ☐ I get extra pain whilst traveling but it does not compel me to seek alternative form of travel.
- ☐ I get extra pain whilst traveling which compels me to seek alternative forms of travel.
- ☐ Pain restricts all forms of travel.
- ☐ Pain prevents all forms of travel except that done lying down.

Section 10 – Changing degrees of pain

- ☐ My pain is rapidly getting better.
- ☐ My pain fluctuates but overall is definitely getting better.
- ☐ My pain seems to be getting better but improvement is slow at present.
- ☐ My pain is neither getting better nor worse.
- ☐ My pain is gradually worsening.
- ☐ My pain is rapidly worsening.

Adapted from Hsieh et al 1992

Appendix D

ALGOMETER READINGS

MOTION PALPATION AND ALGOMETER READINGS

Patient Name: _____ Date: _____

File No: _____

MOTION PALPATION

	Initial	Third	Fourth
Level			
Side			
Direction			

ALGOMETER

	Initial		Third		Fourth	
	Left	Right	Left	Right	Left	Right
Readings						

Appendix E

ORTHOPAEDIC RATING SCALE

ORTHOPAEDIC RATING SCALE

Patient's Name:_____ Date:_____

File No.:_____

Lumbar facet syndrome	Initial	Third	Fourth
Kemp's Test (4):			
Prone Hyperextension (2):			
Muscle Spasm (2):			
Facet Challenge (2):			
Total (out of 10):			

Sacroiliac syndrome	Initial	Third	Fourth
Posterior shear (4):			
Patrick Faber (2):			
Gaenslen's (2):			
Yeoman's (2):			
Total (out of 10):			

Appendix F

CASE HISTORY

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient:_____ Date:_____

File #:_____ X-Ray#:_____

Age:_____ Sex:_____ Occupation:_____

Intern:_____ Signature:_____

FOR CLINICIAN'S USE ONLY

Initial visit clinician:_____ Signature:_____

Case History:

Examination:
Previous: Current:

X-Ray Studies:
Previous: Current:

Clinical Path. Lab:
Previous: Current:

Case Status:

PTT: Conditional: Signed Off: Final Sign Out:

Recommendations:

Intern's Case History

1. Source of History:

2. Chief Complaint: (patient's own words)

3. Present Illness:

- Location
- Onset
- Duration
- Frequency
- Pain (Character)
- Progression
- Aggravating Factors
- Relieving Factors
- Associated S & S
- Previous Occurrences
- Past Treatment and Outcome

4. Other Complaints:

5. Past Medical History:

- General Health Status
- Childhood Illnesses
- Adult Illnesses
- Psychiatric Illnesses
- Accidents/Injuries
- Surgery
- Hospitalizations

6. Current health status and life-style:

- Allergies
- Immunizations
- Screening Tests
- Environmental Hazards (Home, School, Work)
- Safety Measures (seat belts, condoms)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
- Tobacco
- Social Drugs

7. Immediate Family Medical History:

- Age
- Health
- Cause of Death
- DM
- Heart Disease
- TB
- Stroke
- Kidney Disease
- CA
- Arthritis
- Anaemia
- Headaches
- Thyroid Disease
- Epilepsy
- Mental Illness
- Alcoholism
- Drug Addiction
- Other

8. Psychosocial history:

- Home Situation and daily life
- Important experiences
- Religious beliefs

9. Review of Systems

- General
- Skin
- Head
- Eyes
- Ears
- Nose/Sinuses
- Mouth/Throat
- Neck
- Breasts
- Respiratory
- Cardiac
- Gastro-intestinal
- Urinary
- Genital
- Vascular
- Musculoskeletal
- Neurological
- Haematologic
- Endocrine
- Psychiatric

Appendix G

PHYSICAL EXAMINATION

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient:_____ File #:_____ Date:_____

Clinician:_____ Signature:_____

Intern:_____ Signature:_____

1. VITALS

Pulse rate:
Respiratory rate:
Blood pressure: R L
Temperature:
Height:
Weight:

2. GENERAL EXAMINATION

General Impression:
Skin:
Jaundice:
Pallor:
Clubbing:
Cyanosis (Central/Peripheral):
Oedema:
Lymph nodes: - Head and neck:
- Axillary:
- Epitrochlear:
- Inguinal:

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

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

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

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

Pulses
- General Impression:
- Radio-femoral delay:
- Carotid:
- Radial:
- Dorsalis Pedis:
- Posterior tibial:
- Popliteal:
- Femoral:

Percussion: - borders of heart

Auscultation: - heart valves (mitral, aortic, tricuspid, pulmonary)

- Murmurs (timing, systolic/diastolic, site, radiation, grade).

4. RESPIRATORY EXAMINATION

1) Is this patient in **Respiratory Distress?**

Inspection
- Barrel chest:
- Pectus carinatum/cavinatum:
- Left precordial bulge:
- Symmetry of movement:
- Scars:

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

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

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

5. ABDOMINAL EXAMINATION

1) Is this patient in **Liver Failure?**

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegaly:

- Masses (intra- or extramural):
  - Aorta:

Percussion
- Rebound tenderness:
- Ascites:
- Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

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

- Pupillary light reflexes = Direct:
  = Consensual:
- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

V a. Sensory - Ophthalmic:
- Maxillary:
- Mandibular:

b. Motor - Masseter:
- Jaw lateral movement:

c. Reflexes - Corneal reflex:
- Jaw jerk:

VI Lateral movement of eyes:

VII a. Motor - Raise eyebrows:
- Frown:
- Close eyes against resistance:
- Show teeth:
- Blow out teeth:

b. Taste - Anterior two-thirds of tongue:

VIII General Hearing:

Rinnes = L: R:

Webers lateralisation:

Vestibular function - Nystagmus:
- Rombergs:
- Wallenbergs:

Otoscope examination:

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

XI Shoulder lift:
SCM strength:

XII Inspection of tongue (deviation):

Motor System:

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

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

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

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

Sensory System:

a. Dermatomes
- Light touch:
- Crude touch:
- Pain:
- Temperature:
- Two point discrimination:

b. Joint position sense
- Finger:
- Toe:

c. Vibration
- Big toe:
- Tibial tuberosity:
- ASIS:
- Interphalangeal Joint:
- Sternum:

Cerebellar function:

Obvious signs of cerebellar dysfunction:
= Intention tremor:
= Nystagmus:
= Truncal Ataxia:

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

8. SPINAL EXAMINATION: (See Regional examination)

Obvious Abnormalities:
Spinous percussion:
ROM:
Other:

9. BREAST EXAMINATION:

Summon female chaperon.

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

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

Appendix H

LOW BACK REGIONAL EXAMINATION

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

REGIONAL EXAMINATION – *LUMBAR SPINE AND PELVIS.*

PATIENT: _____

FILE #: _____ DATE: _____

INTERN/RESIDENT: _____

SUPERVISING CLINICIAN: _____

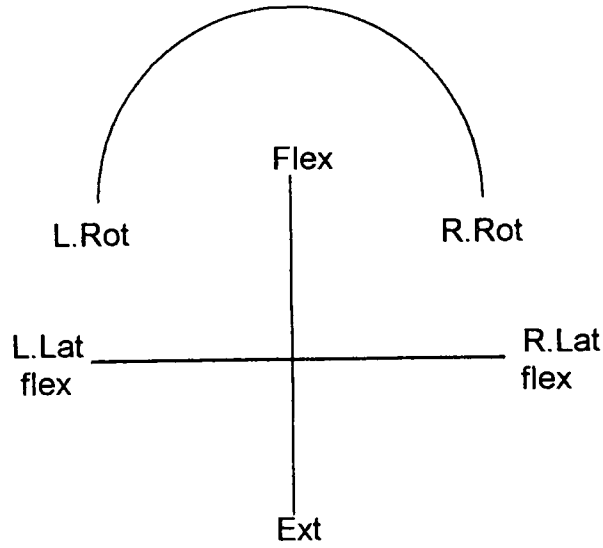
STANDING:

Posture
Minor's Sign
Skin
Scars
Discoloration
Muscle tone
Bony & Soft Tissue Contours

Spinous Percussion
Schober's Test (6cm)
Treadmill
Body Type
Attitude

RANGE OF MOTION

Forward Flexion = 40-60° (15cm from floor)
Extension = 20-35°
L/R Rotation = 3-18°
L/R Lateral Flexion = 15-20°



SUPINE

Skin
Hair
Nails
Palpate Abdomen/groin
Pulses (abdomen)

Observe abdomen
Fasciculations
Abdominal Reflexes

Pulses (extremities)
SLR
Bowstring
Plantar Reflex
Circumference (thigh, calf)
Leg length:
- Actual
- Apparent

Sciatic Notch
Patrick FABERE
Gaenslen's Test
Gluteus Maximus Stretch
Hip Medial rotation
Psoas Test
Thomas' Test:
- Hip joint
- Rectus Femoris

LATERAL RECUMBENT

S-I compression
Ober's Test
Femoral Nerve stretch
Myotomes:
- QL
- Gluteus Medius

NON ORGANIC SIGNS

Pin Point Pain
Axial compression
Trunk Rotation
Burn's Bench Flip Test
Flip Test
Hoover's
Ankle Dorsiflexion Test

GAIT

Rhythm
On toes (standing)
On Heels (standing)
Half squat on one leg

PRONE

Gluteal skyline
Skin rolling
Iliac crest compression
Facet joint challenge
S-I tenderness
Erichson's Test
Pheasant's Test
Myotome:
- Glut. Max

Active MF Trigger Pts:
- QL
- Glut. Med

Glut Min
- Glut Max
- Piriformis
- Hamstrings
- TFL

NEUROLOGICAL EXAMINATION

DERMATOMES		
	L	R
T12		
L1		
L2		
L3		
L4		
L5		
S1		
S2		
S3		

MYOTOMES		
	L	R
Hip Flexion		
Hip int. rotation		
Hip ext. rotation		
Hip abduction		
Hip adduction		
Knee flexion		
Knee extension		
Dorsiflexion		
Plantarflexion		
Eversion		
Ext. hal. Long.		

REFLEXES		
	L	R
Patella		
Achilles		
Hamstring		

Tripod
Kemp's Test

MOTION PALPATION and JOINT PLAY:

LEFT: Upper Thoracics:
Lumbar Spine:
Sacroiliac Joint:

RIGHT: Upper Thoracics:
Lumbar Spine:
Sacroiliac Joint:

Basic Exam: Hip

Case History:

ROM: Active:
Passive:
RIM:

Orthopaedic/Neuro/
Vascular:

Observ/Palpation:

Basic Exam: Thoracic Spine

Case History:

ROM: Motion Palp::
Active:
Passive:

Orthopaedic/Neuro/
Vascular:

Observ/Palpation:

Appendix I

INDEMNITY FORM

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, Mr P O'Donoghue and Technikon Natal against prospective legal action.
2. Telephonic or other consultations are necessary part of the research. The patient acknowledges this and makes no claim against default in such cases.
3. Any consultation or special investigation deemed necessary by the research team will be followed by the patient concerned, failing which the patient is freely entitled to be excluded from the study. This clause does not revoke the constitutional rights of the patient in terms of freedom of will.
4. I am prepared to undertake emergency or other treatment at a government hospital should the need arise. Private or attached costs will not be borne by Technikon Natal, Mr P. O'Donoghue or any other member of the research team.

SIDE EFFECTS OF DICLOFENAC DRUGS

1. Gastric or intestinal bleeding.
2. Headache, dizziness, oedema (swelling of body) especially at ankles.
3. Nervousness, pruritus(itching), tinnitus(ringing in the ears)
4. Insomnia, blurred vision, malaise, jaundice, drowsiness.
5. Hypersensitivity reactions(eg bronchospasm)
6. Elevated transaminase levels.

** 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: _____ SIGN _____

PARENT: _____ SIGN _____

DATE: _____

Appendix J

INFORMED CONSENT FORM

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject)

Date:_____

Title of research project : The efficacy of combined Diclofenac therapy and spinal manipulation compared to combined placebo therapy and spinal manipulation in the treatment of mechanical low back pain.

Name of supervisor : Dr R.Mathews

Name of research student : Rowan White

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 reason for withdrawing, and		
c) without affecting your future heallth care.		
9. Do you agree to voluntarily participate in this study.	Yes	No

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

Please Print in the block letters:

Patient/Subject Name:_____ Signature:_____

Parent/Guardian Name:_____ Signature:_____

Witness Name:_____ Signature:_____

Research Student Name: **Rowan White** Signature:_____