THE RELATIVE EFFECTIVENESS OF SPINAL MANIPULATIVE THERAPY COMBINED WITH TRANSCUTANEOUS FLURBIPROFEN VERSUS SPINAL MANIPULATIVE THERAPY COMBINED WITH EITHER MENTHOL OR NON-MEDICATED PLACEBO PATCHES IN THE MANAGEMENT OF SACROILIAC SYNDROME.

BY

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I, Lineshnee Moodley do hereby declare that this dissertation represents my own work in both conception and execution.

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DEDICATION :

It is with immense pleasure that I dedicate this dissertation to :

Lord Shiva - through Him, all things are possible.

My parents - Thank you for your unconditional love and support. Your patience, encouragement and strength has allowed me to fulfil my dream of becoming a doctor of chiropractic. You both are the 'wind beneath my wings'.

My sister, Seshnee – You once gave me a card saying, 'Believe in yourself and your dream, though impossible things may seem'. That has been my mantra for the past few years. Thank you for all your encouragement. Soon your dreams too, will unfold.

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List of Abbreviations:

N.S.A.I.D.S - Non-steroidal Anti-inflammatory drugs

NRS - Numerical Pain Rating Scale

CN I - Cranial Nerve one

LAT - Local Action Transcutaneous

Rx - treatment

List of Appendices :

Definitions :

Adjustment :
The chiropractic adjustment is a specific form of direct articular manipulation using either long or short lever techniques with specific contacts and is characterized by a dynamic thrust of controlled velocity, amplitude and direction (Gatterman 1990: 405)

Biomechanics :
The application of mechanical laws to living structures. The study and knowledge of biological function obtained from an application of mechanical principles (Gatterman 1990:406)

Chiropractic:
Chiropractic is a discipline of the scientific healing arts concerned with the pathogenesis, diagnostic, therapeutics and prophylaxis of functional disturbances, pathomechanical states, pain syndromes, and neurophysiological effects related to the statics and dynamics of the locomotor system, especially of the spine and pelvis (Gatterman 1990:406).

Fixation:
The immobilisation of a vertebra in a position of movement when the spine is at rest, or in a position of rest when the spine is in movement (Gatterman 1990:408).

Manipulation:

A passive manual manoeuvre in which specially directed manual forces are applied to the vertebral and extra-vertebral articulations of the body, with the object of restoring mobility to the restricted areas (Gatterman 1990:410)

Mechanical Low Back Pain :

This is defined as pain resulting from the inherent susceptibility of the spine to static loads due to muscle, gravity forces and to kinematic deviation from the normal function (Gatterman 1990:129)

Motion Palpation :

Palpatory diagnosis of passive and active segmental joint ranges of motion (Gatterman 1990:412)

Sacroiliac syndrome:

Pain over the sacroiliac joint in the region of the posterior superior iliac spine, which may be accompanied by referred pain over the buttock, greater trochanter, groin, posterior thigh, knee, and occasionally to the postero-lateral calf, ankle and foot (Kirkaldy – Willis 1992:123).

Subluxation:

Aberrant relationship between two adjacent articular structures, which may have functional or pathological sequelae, causing an alteration in the biomechanical and/or neurophysiological reflexes, their proximal structures, and/or body systems that may be directly or indirectly affected by them (Gatterman 1990:415).

ABSTRACT:

McGregor et al (1998) stated that approximately 50 – 80 % of the population in Western society will experience low back pain at some point. According to Cibulka and Koldehoff (1999), the sacroiliac joint is a common cause of low back pain that is overlooked.

This study aimed to provide insight into the relative effectiveness of three different approaches in the management of sacroiliac syndrome. Giles and Muller (1999) concluded that spinal manipulative therapy was an effective form of treatment for spinal pain syndromes whilst Burgos et al (2001) states that the use of transcutaneous non-steroidal anti-inflammatories in the management of musculoskeletal conditions is a common therapeutic strategy.

This investigation aimed to determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen (TransAct® patches) versus spinal manipulative therapy combined with either menthol or non-medicated placebo patches in the management of sacroiliac syndrome, in terms of objective and subjective measures.

It was hypothesized that spinal manipulative therapy used in combination with transcutaneous flurbiprofen (TransAct® patches) would be the more effective treatment than spinal manipulative therapy combined with either menthol or non-medicated placebo patches.

The study design chosen was a randomized, controlled trial consisting of 3 groups of twenty patients each. Twenty patients were assigned to either group A (spinal manipulative therapy and transcutaneous flurbiprofen (TransAct® patches), group B (spinal manipulative therapy and non-medicated placebo patches containing menthol scent) or group C (spinal manipulative therapy and non-medicated placebo patches). All patients were between the ages of 21 – 65. Each patient received 4 chiropractic treatments and also underwent a one week follow-up consultation, within a two week period.

The statistical data was collected before the initial, fourth and final visit. The patients were assessed by means of obtaining subjective information consisting of the Numerical Pain Rating Scale – 101 and the Oswestry Disability Low Back Index questionnaires.

Objective data was obtained using the orthopaedic rating scale and the algometer readings.

The data was analyzed at a 5% level of significance, ie. $\propto = 0.05$. Non-parametric tests were used due to the sample size of twenty. The Kruskal-Wallis H test was used for the inter-group analysis, whilst the Friedman's test was used for intra-group analysis.

The intra-group analysis revealed that all treatment groups improved significantly between the initial and final consultations.

The inter-group analysis revealed no difference among the three groups at the final consultation. There was no statistically significant difference among the three treatment protocols.

In conclusion, all three treatment protocols were equally effective in the management of sacroiliac syndrome. Therefore, this study has been unable to establish the effectiveness of TransAct ® patches combined with spinal manipulative therapy in the treatment of sacroiliac syndrome.

Chapter One:

1.1 Introduction:

Mechanical low back pain is one of the most common clinical disorders that more people are seeking help for (Painting et al. 1998). The prevalence of low back pain increases with age and the magnitude depends on the population surveyed (Ecker; 2000). In the Western society, 60 – 80% of the general population will experience low back pain during adult life, with between 12-35 % suffering from it at any one time (Foster, 1998).

In a South African based study, research has shown that the lifetime incidence of low back pain in a Black community was 57,6% (Van der Meulen, 1997). In a similar study, it was found that the lifetime incidence of low back pain in Indians was 78,2% an in Coloureds 76,8% (Docrat, 1999). This suggests that approximately 70% of the adult population in these communities experience low back pain at some point in their lives, in Southern Africa.

Schwarzer (1995) reports that the sacroiliac joint is a significant source of pain in patients with chronic low back pain and further research on the sacroiliac joint is recommended while others doubt the role of the sacroiliac joint as a low back pain generator (Dreyfuss et al 1994).

The management of mechanical low back pain is vast, but the literature reveals that manipulation is a common form of intervention that is widely used (Di Fabio 1992; Giles and Muller; 1999). Kirkaldy-Willis and Burton (1992: 249), go on to say that manipulation of the sacroiliac joint often relieves the pain and restores the movement of the sacro-iliac joint. In Southern Africa, recommendations were made to the Ministry of Health and Social Welfare of Lesotho to educate the community on the importance of chiropractic services to reduce the incidence and prevalence of low back pain in rural patients (Worku, 2000). The consistency of the results provided in the

literature review promote the evidence that spinal manipulative therapy results in a greater improvement in mechanical low back pain.

Research conducted on topically administered non steroidal anti-inflammatory drugs has shown that these drugs have a high efficacy (Sugawara, 1990). One such topically applied anti-inflammatory agent comes in the form of a locally acting patch containing flurbiprofen (TransAct®). European clinical trials conducted by Ritchie et al,(1995) confirms the clinical effectiveness of transcutaneous flurbiprofen as a treatment for soft tissue musculoskeletal conditions.

This study, therefore compares three types of treatment for sacroiliac syndrome, combining spinal manipulative therapy and transcutaneous flurbiprofen versus spinal manipulative therapy with either menthol or non-medicated placebo patches; in order to determine which treatment protocol will enable a more effective treatment of sacroiliac syndrome.

The combined effects of spinal manipulative therapy with other forms of treatment have been shown to have beneficial physiological effects (Ross, 1997).If the addition of transcutaneous non-steroidal anti-inflammatories helps to reduce the signs and symptoms of sacroiliac syndrome, this intervention used in conjunction with spinal manipulative therapy could improve the patient's quality of life in a shorter time span.

1.2 The statement of the problem :

The aim of this investigation was to evaluate the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with either menthol or non-medicated placebo patches in the management of sacroiliac syndrome in terms of objective and subjective clinical findings.

1.2.1 Objective One

A) To determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with patches containing a menthol aroma in the management of sacroiliac syndrome in terms of subjective clinical findings and,

B) To determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with non-medicated placebo patches in the management of sacroiliac syndrome in terms of subjective clinical findings.

1.2.2 Objective Two

To determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with patches containing a menthol aroma in the management of sacroiliac syndrome in terms of objective clinical findings.

1.2.3 Objective Three

To determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with non-medicated placebo patches in the management of sacroiliac syndrome in terms of objective clinical findings.

Chapter Two:

Review of related literature

Introduction

The review of related literature will describe the incidence and prevalence of sacroiliac syndrome. The anatomy and biomechanics of the sacroiliac joint, as well as the clinical features and diagnosis of sacroiliac syndrome will be discussed. Finally, the role of manipulation and non-steroidal anti-inflammatory drugs in the management of sacroiliac syndrome will be explained.

2.1 Incidence and prevalence of sacroiliac syndrome:

It has been established that low back pain is the most common problem brought to chiropractors (Gemmel and Jacobson, 1990). McGregor et al, (1998), states that low back pain is now the largest single cause of disability in the Western society, predicting 50 to 80% of the population will experience low back pain at some point in their lives.

The sacroiliac joint is a common cause of low back pain but is overlooked (Cibulka and Koldehoff, 1999). Daum (1995) supports this claim stating that the sacroiliac joint is underappreciated in generating pain in the low back, pelvis and proximal lower extremities. Based on individual clinical experience, the author stated that as many as 40% of patients who presented with back complaints included sacroiliac joint disease.

Gemmel and Jacobson (1990) are uncertain of the exact incidence of sacroiliac joint dysfunction in the general population but the following studies conducted by these authors give an indication of sacroiliac joint dysfunction in certain groups of patients. These authors found an overall incidence of 33.5% for sacroiliac joint dysfunction in a recent study of elementary and high school students. In another study involving the

correction of sacroiliac joint dysfunction in patients that presented to a chiropractic centre over 1 day, found an incidence of 57% of sacroiliac joint dysfunction (Gemmel and Jacobson, 1990). Therefore, there is a high incidence of sacroiliac joint dysfunction in certain groups of patients.

Schwarzer et al (1995) concluded that the sacroiliac joint is accepted as a major cause of pain in patients with chronic low back pain, predicting a prevalence of sacroiliac syndrome in the range of 13 to 30%. The researchers made use of a sacroiliac joint block in an attempt to provide an objective means of diagnosis. The sacroiliac joint block was achieved by injecting 1% lignocaine into the sacroiliac joint. A contrast medium of 1ml was then injected into the joint, followed by 1 ml of 2% lignocaine. Zygopophysial joint blocks were initially performed in the lumbar spine as an internal control against placebo responses from the patients. When pain relief was accompanied by a negative control block, following the sacroiliac joint injection, it was accepted that the injected structure was the source of pain.

In a study conducted by Toussaint et al (1999) on construction workers it was concluded that a prevalence of 29% was found for sacroiliac dysfunction I and a prevalence of 6.3% was found for sacroiliac dysfunction II. Sacroiliac dysfunction I was determined if one of the following tests were positive: the standing flexion test, the spine test or the iliac springing test. Sacroiliac dysfunction II was determined if a combination of the standing flexion test, the spine test and iliac springing test were positive and/or a positive iliac compression test. This study, however, did not demonstrate any statistical association between low back pain and sacroiliac dysfunction.

Premature degenerative changes of the sacroiliac cartilage surfaces could also be a factor in the pathogenesis of mechanical low back pain (Cassidy, 1992). The sacroiliac joint has been and still is the topic of much deliberation however, chiropractors, osteopaths, and physical therapists place a great deal more importance on it as a source of low back pain (Cassidy, 1992).

2.2 The anatomy of the sacroiliac joint:

The sacroiliac joint is in a unique position. It is either the end of the spine or the beginning of the lower extremity.

The sacroiliac joint is a synovial joint formed between the auricular surface of the ilium and the ala of the sacrum. The auricular or 'c-shaped' surface of the sacrum is covered with hyaline cartilage while the cartilage on the corresponding surface of the ilium is usually a form of fibrocartilage (Palastanga et al. 2000: 390). A fibrous capsule surrounds the joint attaching to the articular margins on both bones. Synovial membrane lines the non-articular surfaces of the joint.

The sacroiliac joint is a weight bearing joint and is stabilized by a series of strong ligaments (Cassidy and Mierau, 1992:211). Only the anterior third of the connection between the sacrum and ilium is truly a synovial joint; the rest is composed of ligamentous connections (Harrison et al, 1997).

Moore (1992: 251) describes the sacroiliac ligaments as follows: - the interosseous sacroiliac ligament is a massive, strong ligament uniting iliac and sacral tuberosities. The fibres are supported by the thick and firm posterior sacroiliac ligaments. The posterior sacroiliac ligaments are composed of fibres joining the first and second tubercles of the lateral crest of the sacrum and the ilium, as well as fibres uniting the third and fourth transverse tubercles of the sacrum to the posterior iliac spines. The anterior sacroiliac ligament is a thin wide sheet of transverse fibres located on the anterior and inferior aspects of the sacroiliac joints. The iliolumbar, sacrotuberous and sacrospinous ligaments make up the accessory ligaments of the sacroiliac joint.

Over the decades the iliac cartilage degenerates more than the sacral cartilage, and later in life there is often a fibrous or sometimes a bony ankylosis of the joint (Kirkaldy-Willis, 1992:73). It is common to observe early signs of iliac osteoarthrosis by the third decade of life in males and ten to twenty years later in females. Large crevice formations and

surface erosions can also be present and tend to occur more frequently in middle-aged males (Cassidy, 1992).

The arterial supply to the joint is by the branches of iliolumbar artery anteriorly and the superior gluteal artery posteriorly. Branches from the lateral sacral arteries also supply the joint. Venous drainage occurs via correspondingly named veins, which drain into the internal iliac vein. Lymphatic drainage follows the arteries to the internal iliac group of nodes. (Palastanga et al 2000: 394).

According to Daum (1995), the sacroiliac joint has an extensive sensory innervation. Palastanga et al (2000: 394), confirms that the nerve supply to the joint is by twigs directly from the sacral plexus and dorsal rami of the first and second sacral nerves, as well as branches from the superior gluteal and obturator nerve, as they pass the joint.

2.3 Biomechanics of the sacroiliac joint:

Based on anatomical knowledge, movement of the sacroiliac joint is restricted to a small range of motion, which decreases with increasing age (Cassidy , 1992). Although some of the largest and most powerful muscles surround the joint, none are known to directly influence its movement.

Hendler et al. (1995), stated that the sacroiliac joint allows for a small amount of anterior-posterior rotary movement around a transverse axis, which occurs during flexion and extension of the trunk. The sacral promontory moves forward approximately 5-6 mm when the body weight is taken on the sacrum.

Harrison et al (1997), concluded that sacroiliac motion is a simultaneous combination of rotation and translation and does not occur about a single axis. They agreed with the previous authors that motions were small not exceeding 2- 3 degrees or 1-2 mm.

In vivo and vitro, kinematic studies have shown a variable degree of mobility in the sacroiliac joint, using different methods of measurements. Cassidy and Mierau (1992: 215) found the following:

1. The range of motion is small and decreases with age.
2. The range of motion is greater in women and increased in pregnancy.
3. The motions are coupled and dependent on some degree of joint separation.
4. The predominant motion is x –axis rotation coupled with some degree of z-axis translation.

The first and the fourth findings are in keeping with the previous authors.

Cassidy and Mierau (1992:211), further stated that even though the sacroiliac joint is crossed by some of the largest, most powerful muscles in the body. Palastanga et al (2000:396) confirms that the arrangement of the joint surfaces and ligaments allows little movement in the form of gliding and rotary movements between the two bones.

2.4 The sacroiliac syndrome:

Kirkaldy-Willis et al (1992: 126) stated that sacroiliac syndrome is well-defined common dysfunction. Vleeming et al (1990 b) concluded that with abnormal loading it was possible that a sacroiliac joint may be forced into a new position where ridge and depression are no longer complementary. This abnormal joint position was regarded as a blocked joint, otherwise known as a subluxation.

Sacroiliac subluxation may take the form of simple joint locking or this may be accompanied by compensating hypermobility in adjacent joints, especially in pregnant and menstruating females (Panzer and Gatterman, 1995:454). According to Kirkaldy-Willis et al (1992: 123), the sacroiliac syndrome presents with pain over the sacroiliac

joint in the region of the posterior superior iliac spine. This can also be accompanied by referred pain to the buttock, groin and leg.

The symptoms of sacroiliac dysfunction are exacerbated by daily activities that tend to load the pelvis asymmetrically (Daum, 1995). The author goes on to explain that sacroiliac dysfunction eliminates the inferior translation of the iliac spine on the affected side. Dreyfuss et al (1994) noted that the factors that cause a dysfunctional sacroiliac joint remain elusive.

Gemmel and Jacobson (1990) are of the opinion that the sacroiliac joint plays any role in the pathogenesis of mechanical low back pain. Contrary to this belief, Schwarzer (1995) concludes that the sacroiliac joint is a significant source of pain in patients with chronic low back pain and definitely warrants further study.

A study conducted by Broadhurst and Bond (1998), support the view that pain in the very low back area can come from the sacroiliac joint. Xiaodong and Yonggang (1994) noted that in patients where the sacroiliac joint became subluxated, movements were limited and the patient presented with a limp, not allowing the affected joint to weight bear. The authors went on to say that the posterior superior iliac spine on the affected side was higher than the opposite side if a forward subluxation was present, and conversely if there was a backward subluxation, the spine on the affected side was lower and protruded slightly posteriorly than the contralateral side

2.5 Diagnosis of Sacroiliac Syndrome:

The diagnosis of sacroiliac syndrome is based almost entirely on the history and clinical examination (Cassidy and Mierau, 1992). According to the same authors there is usually tenderness over the posterior superior iliac spine and posterior sacroiliac ligament.

Pain referral from the sacroiliac joint may radiate to the buttocks, posterior thigh, groin and occasionally to the lateral calf and ankle. The lack of nerve root tension signs and the absence of motor reflex or sensory deficits helps to distinguish sacroiliac syndrome (Bernard and Kirkaldy-Willis : 1992:204). Slipman et al (2000) concluded that variable patterns of pain referral are due to the complex innervation of the joint, irritation of adjacent structures and varying locations of injury within the sacroiliac joint itself.

Panzer and Gatterman (1995) describe the pain of sacroiliac syndrome as being typically located over the ipsilateral buttock, dull in character and worse on stiffening. Daum (1995) explains that events like a fall onto the buttocks, or a slip while pushing a heavy object, can produce hyperextension of the hip, resulting in a rotary injury of the sacroiliac joint.

According to Panzer and Gatterman (1995: 456), the manipulable sacroiliac subluxation is best detected through motion palpation. Most chiropractic sacroiliac joint function tests used the Gillet-Liekens method of motion palpation and a positive test implies sacroiliac joint hypermobility rather than pain (Gemmel and Jacobson, 1990).

The Gillet test is described by Haldemann (1992:220). The examiner places one thumb over the second sacral tubercle and the other thumb on the posterior superior iliac spine (PSIS) on the side of the joint being tested. Normally, when the subject who is standing flexes the hip and knee, the PSIS drops at the end of hip flexion because it will rotate posteriorly. If the joint is fixed, the PSIS remains level to the second sacral spinous process indicating reduced or absent sacroiliac mobility.

Cibulka et al (1999) determined that a cluster of sacroiliac joint tests are clinically useful in identifying sacroiliac joint dysfunction in patients with low back pain. Pain provocation tests, which stress the sacroiliac joint, were used to establish whether the pain is of sacroiliac origin.

Three out of the four clinical orthopaedic tests used were Gaenslen's, Patrick Faber and Yeomann's test (Erichson's test) (Cassidy and Mierau 1992:217). The posterior shear or 'thigh thrust' test was added as the fourth orthopaedic test. The posterior shear test was found to have high levels of reliability between therapists, therefore it is considered to be more than adequate to diagnose sacroiliac syndrome (Laslett and Williams, 1994).

Broadhurst and Bond (1998) performed a double blinded clinical trial to evaluate the sensitivity and specificity of Patrick Faber (pg. 38), the posterior shear test (POSH) (pg. 38) and the resisted abduction test (REAB) (described below), following a sacroiliac joint block against a criterion of 70 – 100 % . The REAB test is performed with the patient supine and the ipsilateral leg fully extended and abducted to 30 degrees. The therapist pushes the leg medially, stabilizing the ankle and the patient pushes the leg laterally. This test stresses the cephalic aspect of the sacroiliac joint.

Tests	**Sensitivity**	**Specificity**
Patrick Faber	77%	100%
POSH	80%	100%
REAB	87%	100%

The authors concluded that these tests were reliable enough to be used in a clinical setting.

2.6 Differential diagnosis

Bernard and Kirkaldy-Willis (1992) stated that the most reliable diagnostic indicator for sacroiliac syndrome is the joints' response to manipulation or injection. Other causes of sacroiliac pain are also possible.

Daum (1995), is of the opinion that even though ankylosing spondylitis is the most common inflammatory condition that affects the sacroiliac joint, most of the inflammatory arthritides can occur in the joint. He further explains that a febrile course in a patient with sacroiliac signs may be indicative of septic arthritis. The sacroiliac joint is not untouched by metabolic conditions such as gout.

Hendler et al (1995) state that primary neoplasms such as osteosarcoma, fibrosarcoma and chondrosarcoma may affect the joint. Metastatic lesions may also invade the joint and surrounding structures. The examiner must be aware of the possibility of infections, neoplasms and inflammatory arthropathies (Cassidy and Mierau , 1992).

In suspected cases of the above mentioned diseases, investigations should include radiographic examination of the lumbar spine and pelvis, a full blood count, erythrocyte sedimentation rate (ESR), anti-nuclear factor, HLA B27 antigen, rheumatoid factor and urinalysis to rule out conditions.

Conditions that may mimic sacroiliac joint syndrome include lumbar facet syndrome, myofascial pain syndrome, thoraco-lumbar and lower thoracic facet syndromes due to the similar nature of their pain referral patterns.

2.7 Management of sacroiliac syndrome

2.7.1 Manipulation

The consistency of the results below promotes the efficacy of spinal manipulative therapy in the treatment of mechanical low back pain (Twomey and Taylor, 1995; Mohseni-Bandpei et al, 1998; Di Fabio, 1992). Mohseni-Bandpei et al, 1998 conducted a review of 25 randomised controlled clinical trials between the period 1985 – 1997. The authors concluded that the manipulation was found more effective than other interventions (placebo therapy, medical interventions and exercise) in the treatment of low back pain, both in short and long term effects.

Twomey and Taylor (1995) concluded from literature that manipulation is a common treatment often used to increase range of motion and decrease pain associated with low back dysfunction. The authors also stated that spinal manipulative therapy would become the treatment of choice for many patients.

Based upon a review of manipulation literature, it was found that manipulation was valid and effective in the treatment of low back pain (Di Fabio, 1992). Further research has shown that a pilot clinical trial comparing acupuncture, non-steroidal anti-inflammatory drug and spinal manipulative therapy has indicated spinal manipulative therapy as the only intervention that achieved statistically significant improvement with regards to mechanical low back pain (a reduction of 30.7% on the Oswestry scale and a reduction of 50% on the Visual analogue scale) (Giles and Muller, 1999).

Assendelft et al, 1992 supports the claim that chiropractic treatment is an accepted and effective form of treatment. Therefore, spinal manipulative therapy has been recognised and accepted as an effective therapy for low back pain.

In spite of the evidence supporting the validity of spinal manipulative therapy, a small clinical trial conducted by Bronfort (1989) did not draw any conclusions as to the

effectiveness of medical treatment as compared to chiropractic spinal manipulative therapy. The author intimated a small sample size for this conclusion.

2.7.2 Manipulation of the sacroiliac joint

Gatterman (1995: 12) describes manipulation to be a manual procedure that involves a directed thrust to move a joint past the physiological range of motion, without exceeding the anatomic limit. Manipulation is a rotational type of manoeuvre, that was concluded to be the firstline treatment in increasing range of motion and decreasing pain in patients with central or paravertebral pain (Ross, 1997).

Panzer and Gatterman (1995:464) state that the treatment of choice for sacroiliac subluxation is specific manipulative therapy directed at the sacroiliac articulation. Cassidy and Mierau (1992:221) and Kirkaldy-Willis and Burton (1992:249) are also of the opinion that patients with sacroiliac syndrome respond well to success of manipulation.

Hendler et al (1995) reports that sacroiliac subluxations are dramatically relieved by manipulation. Xiaodong and Yonggang (1994) support the claim that manipulation is an easy and convenient method for treating subluxations of sacroiliac joint. 90% of the 100 patients that these 2 authors treated were pain free after 1 treatment.

Cooperstein et al (2001) considered the side posture manipulation for low back pain as the most common procedure used. Cassidy and Mierau (1992:221) also found the side posture method as being the most effective treatment for sacroiliac syndrome.

The literature indicates that manipulation of the sacroiliac joint is an effective form of treatment for sacroiliac syndrome.

2.7.3 Contra-indications and side effects of manipulation

Vertebral malignancy, tuberculosis, osteomyelitis, infectious arthritis, acute vertebral fracture, extreme osteoporosis and extensive disc prolapse are some of the contra-indications (Triano et al, 1992:352).

Cassidy et al (1992:291), reports the following additional contra-indications:

A) Relative

- osteopenia
- spondylo-arthropathies
- patient on anti-coagulant medication
- bleeding disorders
- psychological overlay

B) Absolute

- destructive lesions of the spine, ribs and pelvis
- healing fracture or dislocation
- gross instability
- cauda equina syndrome
- large abdominal aneurysm
- visceral referred pain

Leboeuf-Yde et al (1997) conducted a prospective study to investigate the characteristics of unpleasant side effects of spinal manipulative therapy. Results of this study showed that reactions were benign and transient. Local discomfort was the most common reaction. Less common reactions included headaches, fatigue or pain outside the are of treatment. Nausea, dizziness or 'other complaints' were rarely reported.

2.8 Non-steroidal anti-inflammatory medication:

2.8.1 Introduction :

Non-steroidal anti-inflammatories (N.S.A.I.D.S) are the most frequently prescribed medications for low back pain patients throughout the world (van Tulder et al 2000). Cherkin et al (1995) stated that the treatments of the strongest efficacy when treating low back pain were N.S.A.I.D.S., muscle relaxants and spinal manipulative therapy.

A systematic review of randomized controlled trials conducted by van Tulder et al (1997), revealed that N.S.A.I.D.S. were effective in managing acute low back pain. Van Tulder et al (2000) further explains that the rationale behind using N.S.A.I.D.S for the treatment of low back pain is the analgesic and anti-inflammatory action. Burgos et al (2001) supports the claim that the use of N.S.A.I.D.S in the management of musculoskeletal conditions is a common therapeutic strategy. The authors go on to explain that the main adverse effect of these drugs is their potential gastrointestinal toxicity. The recent introduction of the transcutaneous route of N.S.A.I.D. administration provides a safer alternative as compared to the harsh conventional route (Poul et al ,1993).

Sugawara (1990) states that the topically administered N.S.A.I.D.S are superior to oral drugs or suppositories because their effect is localized and prolonged to the affected site.

The N.S.A.I.D.S used in this study was flurbiprofen under the trade name of TransAct®.

2.8.2 Identification of TransAct® patches.:

Local action transcutaneous flurbiprofen is a topical formulation. It provides a defined dose of 40mg of flurbiprofen to the skin in a medicated adhesive patch that is of size 10

cm x 14cm (Ritchie et al, 1995). TransAct® patches are prepared by forming an ointment in which flurbiprofen is dissolved in peppermint oil and evenly distributed in an oil and water emulsion in an acrylic, moisturised base (Costa, 2000).

Flurbiprofen has a low molecular weight making it particularly suited to pass through the epidermis to achieve efficient skin and tissue penetration (Costa, 2000). Flurbiprofen also has the right balance of hydrophillic and lipophyllic properties to maintain high levels locally in the target tissue (Costa, 2000). Its hydrophillic quality allows penetration through the epidermis and its lipophyllic quality allow penetration through the stratum corneum (Costa, 2000).

Flurbiprofen is also very soluble in peppermint oil, which also acts as a penetration enhancer allowing fast and effective absorption. Peppermint oil also contributes to the cooling effect. (TransAct® package insert 2000 :Appendix I)

2.8.3 Flurbiprofen :

Flurbiprofen, 2-(2-fluoro-4-biphenyl) is a potent non-steroidal anti-inflammatory (N.S.A.I.D.) agent (Risdall et al, 1978). It is a proprionic acid derived N.S.A.I.D. that has been widely available since 1977 (Ritchie et al , 1995).

2.8.3.1 Pharmacological Properties:

Flurbiprofen's mode of anti-inflammatory action is via the inhibition of prostaglandin biosynthesis which prevents sensitisation of tissues to histamine, kinins and 5-hydroxytryptamine which are pain mediators. Flurbiprofen is also a potent inhibitor of platelet aggregation (Buchanan and Kassam , 1986).

It is one of the most potent members of the phenylalkonoic acid series. As a non-selective inhibitor, it supresses both prostaglandin E2 and F2, via inhibition of endoperoxygenase (Kantor 1986). Application of TransAct® patch results in diffusion of the flurbiprofen molecule through the skin and subcutaneous fat to the deeper tissues. Although the bioavailabilty from the formulation is low (approximately 2%), concentrations of flurbiprofen in the deeper tissues around joints are similar to those seen after conventional oral dosing (Sugawara 1990).

A study conducted by Taburet et al (1995) showed that the relative bioavailability of flurbiprofen absorbed from the 40mg patch is 4% of that of a 50mg tablet. Transcutaneous absorption of flurbiprofen into the systemic circulation was relatively slow, and the plasma concentrations peaked 6-20 hours after application of the first patch, but this shortened with successive application to 3-4 hours.

Elimination of flurbiprofen from peripheral circulation is biphasic with a terminal half life for drug disappearance of approximately 5.5 hours. Long term administration of flurbiprofen neither induces or inhibits it's own metabolism. Hydroxyflurbiprofen is the primary metabolite.

Excretion of flurbiprofen is via the kidney. More than 95% of each daily dose was excreted within 24 hours. (Kaiser et al 1986)

2.8.3.2 Indications and therapeutic uses:

Flurbiprofen is indicated for symptomatic relief of localized pain and inflammation associated with

- soft tissue rheumatism

- trauma , and
- osteoarthritis (TransAct® package insert 2000 : Appendix I)

The clinical efficacy of the transcutaneous flurbiprofen formulation in the treatment of soft tissue rheumatism has been proven in a double-blind placebo controlled study carried out by Poul et al (1993). 104 patients aged 18-75 years were randomised to receive a non-woven polyester backed patch containing 40mg of flurbiprofen 12-hourly over 14 days or a non-medicated control. It was concluded that flurbiprofen was an effective form of treatment for soft tissue lesions. It was statistically significant that the patients being treated with the placebo patch required additional rescue medication that was double the amount of the flurbiprofen group.

Burgos et al (2001) conducted a randomised, double-blind, double-dummy parallel group study on 129 patients. The first group received flurbiprofen patches twice daily and the second group received piketoprofen cream over a period of two weeks. He concluded that transcutaneous flurbiprofen is an effective well-tolerated form of treatment that is easy to use, reliable and convenient.

2.8.3.3 Toxicity of Flurbiprofen

The potential gastro-intestinal toxicity of N.S.A.I.D.S limits their use. Musculoskeletal conditions are relatively superficial and research has been focused on developing topical applications to avoid systemic distribution of these drugs (Burgos et al, 2001).

Koes et al (1997), evaluated 26 randomized clinical trials evaluating N.S.A.I.D.S for low back pain. Complications of N.S.A.I.D.S that were reported in most of these trials included abdominal pain, diarrhoea, oedema, rash, dizziness, dry mouth, headaches, tiredness etc. A study conducted by Buchanan and Kassam (1986), revealed that the

adverse reactions associated with oral flurbiprofen are mild and dose-related and are gastro-intestinal in nature.

In another study evaluating the efficacy and the tolerability of a topical N.S.A.I.D. patch and oral diclofenac sodium in the treatment of soft tissue rheumatism, Martens (1997) concluded that transcutaneous flurbiprofen was found to be superior to oral diclofenac sodium in terms of efficacy and tolerability. The only adverse effects of the topical patch were mild skin irritation at the site of application.

Other side effects that can occur as a result of transcutaneous flurbiprofen application are: Itching, redness and tingling at the site of application, epigastric pain, nausea, diarrhoea, oedema, gastro-intestinal ulceration and hypersensitivity reactions. (TransAct® package insert 2000: Appendix I)

2.8.3.4 Safety and Efficacy of flurbiprofen

Koes et al (1997) concluded that N.S.A.I.D.S are effective for symptomatic short term relief in patients with 'uncomplicated' back pain.

Kantor (1986) stated that maximum therapeutic doses show flurbiprofen 10 – 12 times more effective than ibuprofen. The daily dose of flurbiprofen in the majority of the clinical trials did not exceed 200mg. This was 200mg less than the generally accepted level of 400mg of flurbiprofen, therefore the efficacy and safety of flurbiprofen is well documented.

In a study conducted by Martens (1997) comparing the efficacy and tolerability of a topical N.S.A.I.D. patch and oral dicofenac sodium in the treatment of soft tissue rheumatism, 49 out of 53 patients in the transcutaneous flurbiprofen group had improved by the 14th day as compared with the 36 out of 49 in the diclofenac sodium group. The difference was in favour of flurbiprofen.

Poul et al (1993) performed a placebo controlled study to assess the efficacy and tolerability of transcutaneous flurbiprofen. He concluded that the high clinical efficacy of transcutaneous flurbiprofen is due to the low plasma levels of flurbiprofen (13.4 – 338.7 ng/ml) {median = 57.9} which, in turn are related to low levels of adverse effects. He goes on to say that transcutaneous flurbiprofen may reduce the need for local steroid injection.

2.9 Summary

There are documented trials involving a comparison between N.S.A.I.D.S and spinal manipulative therapy for the treatment of mechanical low back pain (Login ,2001; Giles and Muller, 1999 and Bronfort, 1989). The study conducted by Login (2001) showed both N.S.A.I.D.S and spinal manipulative therapy to be effective in relieving the signs and symptoms of mechanical low back pain, but there was no conclusive proof which treatment was more effective than the other. The trials conducted by Giles and Muller (1999) and Bronfort (1989) support the use of spinal manipulative therapy in the management of mechanical low back pain, above the use of prescription medication. Further comparison of the trials revealed that the risk of side effects was higher with N.S.A.I.D.S than with spinal manipulative therapy.

In summary, the sacroiliac joint syndrome has been accepted as a significant source of low back pain . (Schwarzer et al, 1995; Dreyfuss et al ,1994; Cibulka et al, 1999)

The consistency of results reveals that spinal manipulative therapy has been proven to be the treatment of choice (Giles and Muller ,1999; Hendler et al, 1995 ; Xiaodong and Yonggang, 1994).

Van Tulder et al (2000) suggests the need for more randomized controlled trials to evaluate the effectiveness of N.S.A.I.D.S in treating patients with acute low back pain.

He goes on further to state that the most effective dose of N.S.A.I.D.S with the lowest risk of side effects still needs to be investigated. The effectiveness of transcutaneous flurbiprofen in the treatment of soft tissue musculoskeletal conditions has been proven (Burgos et al 2001; Ritchie et al 1995).

Salter (1999) suggested that an effective co-intervention with manipulation needs to be established with regards to the treatment of sacroiliac syndrome. Manipulation alone has been proven to be both effective and cost effective, whilst local acting transcutaneous flurbiprofen constitutes a therapeutic development. Therefore, the combination of spinal manipulative therapy together with transcutaneous flurbiprofen could result in improving the quality of existing treatment.

Chapter Three:

Materials and Methods

3.1 Introduction

This chapter gives a detailed description of the design, the primary and secondary data, the subjects and the interventions utilized. An overview of each questionnaire is discussed. Statistical evaluation is also discussed.

3.2 The Data

The data consisted of the primary and secondary data.

3.2.1 Primary data

- The case history (appendix A), physical examination (appendix B), lower back regional examination (appendix C).
- The patient's perception of their disability obtained from the Oswestry Low Back Disability Index (appendix F).
- The patient's pain perception as derived from the Numerical Pain Rating Scale 101 (appendix G)
- The Orthopaedic Rating Scale consists of four sacroiliac provocation tests (appendix E).
- The patient's pressure threshold in terms of pain (Wagner algometer) (appendix E)

3.2.2 Secondary data

Relevant data were obtained from journal articles, books and the Internet (Medline and Pubmed).

3.3 The Subjects

The study drew on subjects from Durban and surrounding areas by means of pamphlets that were distributed locally, as well as by advertisements placed on notice boards in the Technikon Natal Chiropractic Day Clinic, Technikon Natal Campus and daily newspaper. The study was limited to patients suffering from chronic sacroiliac syndrome. No stratification of the patients took place and they were accepted without criteria regarding gender occupation, race, severity or chronicity of the condition. Upon reply, patients were telephonically interviewed to assess their eligibility for the study, with questions pertaining to their history and the progression of their complaint and to explain the nature of the study to the prospective candidates.

Patients were immediately excluded from the study if they did not fit the age criteria of 21 – 65 years, if they were pregnant, had a history of asthma or gastro-intestinal problems (TransAct® package insert – 2000) (appendix I). All the accepted patients underwent a case history, physical examination, and low back regional examination and sacroiliac provocation tests according to the protocol at the Technikon Natal Chiropractic Day Clinic.

3.4 Method

An initial screening was conducted in order to make a diagnosis of sacroiliac syndrome. An orthopaedic rating scale made up of the following tests namely, the posterior shear test (Laslett and Williams, 1994) ; Gaenslen's test (Haldeman 1992:292) ; Patrick Faber test (Magee 1992:343) and Yeomann's test (Haldeman 1992: 292) was used to determine the

presence of sacroiliac syndrome. Each test was given a score of two with the exception of the posterior shear test that was given a score of four due to its apparent sensitivity (Laslett and Williams, 1994). Only patients with a rating of 6 out of 10 were accepted into the study.

The patients selected for the study received a letter of information (appendix K) at the initial consult. This served to explain the research procedure to each patient. Patients were also required to complete an informed consent form (appendix H), before the initial consult. All three groups underwent 4 chiropractic treatments and a one-week follow- up, over a two week period.

Subjective measurements included the Numerical Pain Rating Scale (Jenson et al, 1986) (appendix G) and the Oswestry Low back Disability Index questionnaire (Fairbank, 1980) (appendix F). These measurements were completed by each patient prior to the first and 4th treatments and the one week follow-up visit.

Objective measures were be obtained with the use of the aforementioned orthopaedic rating scale and algometer readings (Fischer, 1987). These measurements were be recorded by the researcher prior to the first and 4th treatments and the one week follow-up visit.

Patients who became asymptomatic in terms of subjective clinical findings before the final treatment, received no further treatment. The patients were still required to return for all remaining consultations for observational purposes. If a patient's condition became subjectively worse as a result of treatment, the condition was re-evaluated before continuing treatment, and if necessary the patient was excluded from the study.

No patients were coerced into participation. Patients in all three groups received an established form of treatment in terms of manipulation. All patients were informed that they were free to withdraw at any stage and without reason. All patient information was confidential.

3.5 Exclusion and inclusion criteria

3.5.1. Inclusion Criteria:

1. Patients between the ages of 21 and 65 were accepted into the study. (TransAct ® package insert – 2000) (appendix I)

2. Patients had to score 6 or more out of 10 on the orthopaedic rating scale to be included in the study.

3. Each subject had to be diagnosed with sacroiliac syndrome.

4. Associated conditions to the sacroiliac syndrome (e.g. lumbar facet syndrome/ myofascial component) did not exclude patients from the study, although these conditions were not treated.

3.5.2. Exclusion Criteria:

1. Patients younger that 21 or older than 65 were excluded from the study. (TransAct® package insert – 2000) (appendix I).

2. Patients with a history of asthma were excluded. (TransAct® package insert – 2000)(appendix I).

3. No pregnant applicants were incorporated into this study. (TransAct® package insert – 2000)(appendix I).

4. Subjects with a history of peptic ulceration, gastrointestinal haemorrhage,ulcerative colitis, cardiac decompensation and hypertension (TransAct® Package insert – 2000) (appendix I).

5. Subjects who have previously shown a hypersensitivity to flurbiprofen. (TransAct®Package insert – 2000) (appendix I).

6. Patients who presented with signs of nerve root tension were not accepted into this study.

7. Patients who presented with a lumbar facet syndrome as the primary causative factor of the low back pain were not accepted into the study.

8. Patients with suspected contra-indications to spinal manipulation were not considered for this study.

9. Patients who used analgesics and / or other anti-inflammatory drugs, or received any additional treatment during the two week period were excluded from the study.

10. Patients who were currently on medication were permitted into the trial if the patient was prepared to halt medication for the duration of the trial and undergo a 4 day washout period with no medication before joining the trial.

3.6 The Sample Group

The sample for the study consisted of 60 patients, selected according to the criteria defined above. Patients were randomly allocated into 1 of 3 groups without the use of stratification, depending on whether they chose a piece of paper out of an envelope, with the number A, B or C on it till each group had twenty patients. Twenty patients were assigned to group A (spinal manipulative therapy and transcutaneous flurbiprofen), twenty patients were assigned to group B (spinal manipulative therapy and non-medicated patches containing menthol aroma) and the remaining twenty patients were assigned to group three (spinal manipulative therapy and non-medicated placebo patches).

3.7 Measurements

3.7.1 Objective Data:

Objective measurements were recorded from the results obtained from the algometer readings and the orthopaedic tests.

3.7.1.1 Algometer

The algometer used in this trial was the FDK 20 Force Dial; a product of Wagner Instruments. Fischer (1986) confirmed the validity of the algometer measurements in evaluating manipulative intervention to identify patient improvement.

The measurement was taken by applying a force to the most tender area over the affected sacroiliac join. The force readings were measured in kilograms per square centimetre. The higher the reading the less the tenderness felt by the patient; this then indicating a higher tolerance to pain.

The algometer was fitted with a one centimetre rubber disc, as this was considered a more suitable way to assess tenderness in tendons, ligaments and joint capsules (Fischer;1986). The pressure was gradually increased at a rate of 1kg per second (Fischer;1986). The patient was asked to say 'now' at the point when the pressure sensation became a point of pain or discomfort. The reading was recorded at that point. The dial was set to zero before recording each reading, by pressing the rest button.

3.7.1.2. Orthopaedic Rating Scale - (appendix E)

Four orthopaedic provocation tests were used to confirm the diagnosis of sacroiliac syndrome. A cluster of sacroiliac joint tests can be useful in identifying sacroiliac joint dysfunction in patients with low back pain (Cibulka; 1999).

1. Posterior shear or 'thigh thrust' test:

   Patient supine. The ipsilateral hip and knee are flexed. Excessive adduction of hip is avoided because flexion and adduction combined is normally uncomfortable. The examiner exerts a posterior shearing stress to the ipsilateral sacroiliac joint through the femur while feeling for excessive joint motion with the opposite hand under the right sacroiliac joint. If pain was elicited over the region of the ipsilateral sacroiliac joint, a positive test was constituted (Laslett and Williams; 1994). Being the most sensitive test according to Laslett and Williams (1994) for sacroiliac syndrome, it is given a score of 4, when positive.

2. Patrick Faber test:

   Patient supine. The ipsilateral leg at the ankle was placed in front of the contralateral thigh above the knee. The examiner then establishes the contralateral iliac crest; with his right hand, while the examiner's left hand presses down on the knee of the ipsilateral leg. A positive test was recorded if this position elicited pain over the region of the ipsilateral sacroiliac joint. Haldeman (1992:295). This test was given a score of 2.

3. Gaenslen's test :

   Patient supine. Examiner flexes the patient's ipsilateral knee and hip while pressing downward over the contralateral thigh to hyperextend the contralateral hip. A positive test was recorded if pain was elicited over the region of the contralateral sacroiliac joint (Haldeman 1992:292). This test would score 2.

4. Yeomann's test (Erichson's test):

   Patient prone. Examiner places one hand under the ipsilateral thigh above the knee on the affected side, to extend the ipsilateral hip. The examiner's other hand presses downward over the crest of the ipsilateral ilium. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint (Haldeman 1992:292). This test also received a score of 2.

A negative result was recorded as zero points if the patient expressed 'no pain' or pain in the lumbar spine, hip joint or any other site that the sacroiliac joint. Only patients with a rating of 6 out of 10 and higher will be included in the study.

3.7.2. Subjective Data

Subjective measurements were recorded in the form of 2 questionnaires, namely the Numerical Pain Rating Scale 101 and the Oswestry Low Back Disability Index.

3.7.2.1 Numerical Pain Rating Scale 101 (NRS –101) (appendix G)

The NRS – 101 is a questionnaire used to measure the intensity of pain a patient is experiencing (Jenson et al; 1986). The patient was requested to indicate by means of a percentage their intensity of pain on a scale of 0 to 100, where 0 represented 'no pain', and 100 represented 'pain as bad as it could be'. Pain intensity was recorded at its most intense and at its least. The average between these two figures was then taken as the intensity of pain they were experiencing prior to the treatment sessions.

Bolton and Wilkinson (1998) conducted a study to compare the responsiveness of three pain scales and found the NRS to be the most responsive of the measures. (Effect size of

NRS = 0,86 as compared to effect size = 0,77 for the Visual Analogue scale and 0,76 for the Verbal Rating Scale.)

3.7.2.2 Oswestry Back Disability Index (appendix F)

This questionnaire is designed to give the researcher an indication of how back pain affects the subject's ability to perform daily functional activities.

There are 10 questions, with 6 possible answers to each question. The questionnaire allows a maximum score of 5 and a minimum score of 0 in each section. The questionnaire score is scored out of 50 and represented as a percentage disability (Fairbank, 1980).

Beurskens et al (1995) concluded that the Oswestry Low Back Pain Disability index was a valuable outcome measure for the assessment of low back pain, after a review of the quality of 4 diagnostic specific questionnaires. However, the inclusion of both performance and capacity based questions, made it unclear for the patient to answer whether they can perform the action.

The interpretation of the results by Fairbank et al (1980) as follows:

0 - 20 %	Minimal disability
20 - 40 %	Moderate disability
40 - 60 %	Severe disability
60 - 80 %	Crippled
80 - 100%	Bed bound

3.8 Interventions

Each patient accepted into the study underwent a total of 5 consultations over a two week period. The first 4 consults in the first week, followed by a 1 week follow-up in the 2nd week.

3.8.1 Motion Palpation :

Motion palpation was only used to establish the manipulable lesion and not as an outcome measurement. Motion palpation of the sacroiliac joint was conducted using the Gillet method, as described by Cassidy and Mierau (1992:220).

To evaluate the superior joint motion, one thumb was placed on the patient's sacral base and the other thumb on the posterior superior iliac spine of the side being tested. The patient was asked to raise the flexed knee of the side being tested up towards the chest, as if taking a huge step. The separation of the thumbs is noted. Ordinarily, the sacral base will move downward and backward. The test is then repeated, by raising the contralateral knee. If the superior sacroiliac joint is fixated, the thumbs will not separate because the pelvis will move as a unit.

To evaluate inferior joint motion; a thumb was placed on the ischial protuberance. The patient was asked to flex the knee of the side being tested. The ischium should move anteriorly – superiorly and slightly lateral on the sacrum. If the inferior joint is locked, there will be no separation of the thumbs as the ischium and the sacral apex will move as a unit (Schafer and Faye 1990: 259-265).

3.8.2 Manipulation :

There are many different techniques available to manipulate the sacroiliac joint, but the side posture technique was found to be the most effective method (Cassidy and Mierau: 1992:221).

Research conducted by Salter (1999) in South Africa, upholds other authors who advocate manipulation of the sacroiliac joint in the treatment of sacroiliac joint (Kirkaldy – Willis and Burton 1992:249; Panzer and Gatterman 1995: 464; Cooperstein et al 2001:24: 407 – 424). The standard side posture method of manipulation was used on the fixated area of the right or left sacroiliac joint, depending on the motion palpation finding. A record was kept of the motion palpation findings and the applicable adjustments delivered to each patient on each visit.

3.8.3 Medication :

The NSAID used in this study was flurbiprofen LAT with the trade name of TransAct®. TransAct® was chosen because of the following reasons:

3.8.3.1 TransAct® Patches

- Burgos et al (2001) concluded that transcutaneous flurbiprofen is an effective well tolerated topically applied NSAID formulation in the treatment of extra articular rheumatism.

- Topical treatment with flurbiprofen with flurbiprofen LAT was found to be superior to orally administered N.S.A.I.D.S in terms of efficacy and tolerability (Martens, 1997).

- The use of the flurbiprofen LAT as a localised treatment for musculoskeletal soft tissue lesions will elicit a lower incidence of systemic adverse effects that normally occur with oral N.S.A.I.D.S (Taburet et al, 1996).

- The sacroiliac joints lie close to the surface of the body, therefore making it more accessible for TransAct ® application.

- TransAct ® is a schedule one drug and is available at pharmacies.

3.8.3.2 Placebo patches with menthol scent

The placebo patches were identical to the TransAct® patches but they were non-medicated and contained a menthol scent. One bottle of 11ml of essential peppermint oil was diluted with 100ml of alcohol and sprayed onto the placebo patches. A piece of wax paper within each patch prevented the menthol mixture from being absorbed into the skin. Ritchie et al. (1995), stated that the odour of the menthol contained in the TransAct® patches strongly influenced the physical effect of the patches.

Chemoreceptors are required to perceive any sense of olfaction. Approximately 100 million chemoreceptors or olfactory cells are located in the olfactory membrane, which is located in the superior part of the nasal cavity near its association with the cribriform plate of the ethmoid bone. The dendritic end of each olfactory cell terminates in an olfactory vesicle that contains cilia called olfactory hairs. Olfactory glands constantly secrete mucus that keeps the olfactory membrane moist, therefore allowing it to dissolve many odoriferous substances. The mucus is constantly replaced allowing for the sensation of new odours (Solomon et al 1990:557).

Odourant molecules first need to be drawn past the extensive absorptive surface present in the nasal cavity. Molecules then diffuse through the mucus to gain final access to the receptors.

It has been suggested that these access barriers can affect different odourants differently (Hornung and Mozell 1981: 33).

When the odoriferous substance in the upper nasal cavity is exposed to the olfactory hairs, it combines with specific protein receptors on the membrane of the olfactory hair. Depolarization occurs and a generator potential develops that then initiates nerve action potentials along the axon of the olfactory cells. There are as many as 50 specific protein receptors on the olfactory hairs. Olfactory axons merge to form the olfactory nerves (CN I), which terminates in the olfactory bulbs located at the inferior surface of the frontal lobes of the cerebrum. The axons of the olfactory bulb neurons constitute the olfactory tract that courses to the primary olfactory area of the cerebral cortex. Here the impulses are integrated and interpreted as the sense of smell (Solomon et al 1990:558).

This explains how the scent of menthol is perceived. These patches were designed to investigate if the menthol scent influenced the rate of improvement of the sacroiliac syndrome

3.8.3.3 Non-medicated placebo patches:

These patches looked identical to the TransAct® patches but did not contain any active ingredient. Ritchie et al (1995) concluded from the many placebo controlled trials that confirmed the clinical effectiveness of flurbiprofen, the patient's responses to placebo were marked. The authors go on further to explain that the physical effect of applying a topical formulation might influence the placebo response rate.

These patches were used to investigate the effectiveness of the sacroiliac adjustment. Undoubtedly, the role of placebo plays an extraneous variable in a study of this nature.

Each patient in each of the groups received 14 patches. All three patches looked identical although the constituents were different. The patients were not aware of which patch they

were receiving. Each patch had a life of 12 hours. After 12 hours, the patch had to be replaced by a new one. The patients were instructed to coincide bath routines with patch changes. This dosage of patches will last the patient for one week. Patients were required to be compliant with this regime unless they became asymptomatic in which case they remained on the study for observation or if they showed any signs of side effects or intolerance in which case they were excluded from the study.

3.9 Treatment of the Sub problems:

The purpose of this study was to investigate the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen compared with spinal manipulative therapy combined with either menthol or non-medicated placebo patches in the management of sacroiliac syndrome.

3.9.1 The First Sub problem

The first objective was to

A) determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with patches containing menthol aroma in the management of sacroiliac syndrome, in terms of subjective clinical findings and

B) determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with non-medicated placebo patches in the management of sacroiliac syndrome, in terms of subjective clinical findings.

3.9.2 The Second Sub problem

To determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with patches containing menthol aroma in the management of sacroiliac syndrome, in terms of objective clinical findings.

3.9.3 The Third Sub problem

To determine the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with non-medicated placebo patches in the management of sacroiliac syndrome, in terms of objective clinical findings.

3.10 Statistical Analysis

3.10.1 Treatment of the Data

3.10.1.1 Subjective data

The subjective data were treated as follows:

- Questionnaires that the patients completed were screened to ensure that they had been completed correctly.
- Raw data from the two questionnaires were converted into percentages and recorded separately for each group.
- The data were analysed using a 5% significance level.

3.10.1.2 Objective data

The objective data were treated as follows:

- The algometer readings were recorded separately for each group.
- The results of the orthopaedic tests were recorded separately for each group.
- The data were analysed using a 5% significance level.

3.10.2 Statistical analysis of the data

The Technikon Natal research statistician was consulted concerning the manner in which the research study was analysed. Due to the small sample size, ie. twenty patients per group, non-parametric tests were used. Data were transferred into a spreadsheet in the SPSS software package for statistical analysis.

The Kruskal-Wallis H test was used for the inter-group analysis. The Friedman's T test was used for the intra-group analysis of the subjective and objective data. Reference will be made later to the p-value. The p-value is a probability, with a value ranging from zero to one (Instat 2001). If the p value is small, it is unlikely that random sampling causes the difference between samples, it is therefore concluded that the samples have different means.

3.10.2.1 The Kruskal-Wallis H test:

The Kruskal -Wallis H test is a non-parametric test that compares three or more independent groups (Daniel 1978:200). If the p-value is small, one can conclude that at least one of the treatments differs from the rest, it is therefore necessary to look at post tests to determine which groups differ from other groups (Instat 2001). In this study, the post test used was a multiple comparison procedure called the Dunn procedure for use with Kruskal-Wallis H test (Daniel 1978: 213). The Kruskal-Wallis test was used to determine if there was any significant difference according to NRS 101, the Oswestry Disability low back index, the orthopaedic rating scale and the algometer readings among the three groups A,B and C.

Hypothesis testing:

The null hypothesis H_0 stated that there was no difference among the three groups with regards to the variable of interest. The alternative hypothesis H_1 stated that there was a difference between the three groups with regards to the variable of interest.

- H_o : $M_A = M_B = M_C$ (There is no difference in the treatment effects among the three groups).
- H_1 : (At least one treatment is different from the rest.)
- $\propto = 0.05$ = level of significance of the test.

Decision rule:

For a two -tailed test:

- Reject H_o at $\propto$ level of significance of $p < \propto$.
- Accept H_o at $\propto$ level of significance if $p \geq \propto$.

The Dunn Procedure for the Kruskal-Wallis H test:

If the null hypothesis is rejected for the Kruskal-Wallis H test, then this multiple comparison procedure will be applied to determine which of the treatments is significantly different (Daniel 1978:213).

3.10.2.2 The Friedman's T Test for K-related samples:

The Friedman's T test is a non-parametric test that compares three or more related groups (Instat 2001). If the p-value is small one can conclude that at least one of the treatments differs from the rest, it is therefore necessary to look at post tests to determine which groups differ from other groups (Instat 2001). In this study the post test used was a multiple comparison procedure called the Dunn Procedure for use with the Friedman's T test (Daniel 1978: 224). The Friedman's test was used between the three groups to determine if there was any significant difference according to NRS 101, the Oswestry Disability low back index, the orthopaedic rating scale and the algometer readings between the 1st and 4th treatment and the one week follow-up visit.

Hypothesis testing:

The null hypothesis H_o stated that there was no difference between consultations with regards to the variable of interest. The alternative hypothesis H_1 stated that there was a difference (improvement) between consultations with regards to the variable of interest.

- H_o : The three treatments yield identical results
- H_1 : At least one treatment tends to yield larger values than at least one other method.
- $\propto = 0.05$ = level of significance of the test.

The Decision Rule :

For a one -tailed test:

- Reject H_o at $\propto$ level of significance of $p/2 < \propto$
- Accept H_o at $\propto$ level of significance if $p/2 \geq \propto$.

The Dunn Procedure for the Friedman's T test:

If the null hypothesis is rejected for the Friedman's T test, then this multiple comparison procedure will be applied to determine which of the treatments is significantly different (Daniel 1978:231).

3.11 Means of Collection of Data :

All the data required were collected from the participating patients at the Technikon Natal Chiropractic Day Clinic. The researcher carried out the data collection. The patients in both groups were required to complete the pain questionnaires before the initial, 4^{th} and 5^{th} consultations. The algometer readings were also obtained before the initial, 4^{th} and 5^{th} consultations. The information was stored in each patient's file after the consultations.

3.12 Summary:

Sixty patients suffering from mechanical low back pain, specifically sacroiliac syndrome, were selected into the study. Twenty patients were randomly allocated into the three treatment groups.

Those in group A received manipulation and TransAct® patches. Treatment group B received manipulation and placebo patches with menthol aroma and groups C received manipulation and non-medicated placebo patches. Each patient was assessed in terms of objective and subjective clinical findings and all the necessary data was obtained for statistical analysis.

Chapter Four:

The Results:

4.1 Introduction:

The first part of this chapter contains the demographic data of all the patients included in the study. Twenty patients were in each of the three groups. The second part of this chapter contains the statistical analysis of the subjective and objective data obtained from the patients over the treatment period.

The patients in group A received spinal manipulative therapy and TransAct® patches. The patients in group B received spinal manipulative therapy and placebo patches patches with a menthol aroma. . The patients in group C received spinal manipulative therapy and non-medicated placebo patches.

4.2 Criteria governing the Admissibility of the Data:

Information obtained from the case history, low back regional examination, Numerical Pain Rating Scale 101,Oswestry Low Back Disability Index, the orthopaedic rating scale and the algometer were used as data for the study. All the pain questionnaires were explained to the patient, who then completed the questionnaires. The researcher took all the algometer readings.

The null hypothesis H_0 stated that there was no difference between consultations with regards to the variable of interest. The alternative hypothesis H_1 stated that there was a difference between consultations with regards to the variable of interest. The level of significance ($\propto$) was set at 0.05.

4.3 **The Sample Size**:

The sample size of the study was limited to 60 patients with 20 patients in each of the three groups. 92 patients responded to the advertisements for treatment of mechanical low back pain. The patients were screened telephonically according to the study criteria. 75 of the original 92 patients were then assessed at the Technikon Natal Chiropractic Day Clinic of whom 66 patients satisfied the selection criteria and were accepted into the study. 6 patients were excluded from the study during the course of the study due to non-compliance.

4.3.1 Patients that were excluded during initial screening process :

Table 4.1 - Reasons for Research patients not meeting selection Criteria during the telephonic screening or the initial screening appointment:

Exclusion Criteria	No. of patients	Percentage
Age < 21	1	4 %
Age > 65	2	8 %
Facet Syndrome	4	15 %
Myofasciitis	4	15 %
Patients who did not meet orthopaedic test criteria for sacroiliac syndrome	5	19 %
Pregnant females	4	15.4%
History of adverse reactions to NSAIDS	1	4%
Patients with a history of asthma.	5	19 %

4.3.2 Reasons for patients not completing the research:

Table 4.2 - Reasons for the patients not completing the treatment period:

Reasons	No. of patients	Percentage
1. Lack of Transport	2	33 %
2. National cricket tour	1	17 %
3. Non-compliance	3	50 %

4.4 Demographic Data :

Demographical data included gender and age and racial distribution, occupation of patient as well as the side of the sacroiliac syndrome.

4.4.1 Gender distribution within the sample group of sixty

Table 4.3 - Gender

	Group A	Group B	Group C
Females (51,7 %)	6	12	13
Males (48 %)	14	8	7

The male to female ratio is 1: 1.1

4.4.2 Age Distribution within the sample group of sixty

Table 4.4 - Age Prevalence

Age	Group A	Group B	Group C	%
21 – 31	5	9	11	41.6
32 –42	8	2	2	20
42 – 53	6	6	4	26.7
54 – 65	1	3	3	11.7

The mean age of Group A = 39.05

The mean age of Group B = 38.9

The mean age of Group C = 36.3

The mean age of all three groups = 38.1

4.4.3. Racial Distribution within the sample size of sixty

Table 4.5 - Racial Distribution.

	Group A	Group B	Group C
White	9	5	4
Black	-	2	3
Indian	9	11	12
Mixed Race	2	2	1

4.4.4 Occupations of patients

Table 4.6 - Occupation:

Group A	No	%	Group B	No	%	Group C	No	%
Pensioner	1	5	Student	4	20	Student	9	45
Fitter	2	10	Businessmen	2	10	Housewife	2	10
Supervisor	2	10	Housewife	3	15	Clerk	2	10
Land Surveyor	1	10	Aroma-therapist	1	5	Fire-fighter	1	5
Car Guard	1	5	Psychologist	1	5	Domestic worker	2	10
Fire fighter	1	5	Manager	3	15	Lecturer	1	5
Housewife	1	5	Lecturer	1	5	Pensioner	1	5
Social worker	1	5	Marketing assistant	1	5	Manageress	1	5
Student	1	5	Clerk	2	10	Personal assistant	1	5
Cashier	1	5	Electrical assistant	1	5			
Unemployed	1	5	Cleaner	1	5			
Broker	1	5						
Secretary	1	5						
Manager	1	5						
Sales Co-ordinator	1	5						
Health and safety officer	1	5						
Technician	1	5						
Photographer	1	5						

4.4.5. Side of Sacroiliac Syndrome

Table 4.7 - Side of the Sacroiliac Syndrome:

Side	Group A	Group B	Group C
Right	15	12	10
Left	5	8	10

4.4.6 NSAID data:

Table 4.8 - NSAID data :
No. of patients reporting adverse effects:

Symptoms	No. of patients	Discontinued Treatment
Diarrhoea	2	No

4.5 Analysis of Data :

Non parametric testing was done in order to analyse the data. The Kruskal-Wallis H- test was used for inter-group analysis. The Friedman's T test was used for intra-group analysis of the objective and subjective data. If the null hypothesis H_0 was rejected for either of the tests, then the corresponding multiple comparison procedure will have to be applied to determine which of the treatment is significantly different (Daniel, 1978).

4.5.1 The Inter-group analysis using the Kruskal-Wallis H-test:

Table 4.9 - Comparison of Groups A, B and C using the Kruskal-Wallis H-test to analyse the results obtained from the Numerical Pain Rating Scale- 101 at treatment 1 and the one week follow-up visit.

Numerical Pain Rating Scale – 101							
	Group A		Group B		Group C		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	P value
NRS 1	52.55	20.05	54.33	19.54	42.93	21.17	0.096
NRS 5	30.35	26.38	24.63	23.26	33.27	26.05	0.505

The null hypothesis was accepted for the Numerical Pain Rating Scale –101, indicating that at the $\alpha = 0.05$ level of significance there was no statistically significant difference among the three groups for NRS 1 (initial consult) and NRS 5 (follow-up).

Table 4.10 - Comparison of Groups A,B and C using the Kruskal-Wallis H-test to analyse the results obtained from the Oswestry Low Back Disability Index Questionnaire at treatment 1 and the one week follow-up.

Oswestry Low Back Disability Index							
	Group A		Group B		Group C		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	P value
Oswes 1	40.50	17.47	39.70	12.00	29.50	15.24	0.043
Oswes 5	21.60	23.67	17.40	14.77	13.80	11.96	0.669

The null hypothesis was rejected for the Oswestry Low Back Disability Index, indicating that at the $\alpha = 0.05$ level of significance there was a statistically significant difference among the three groups at the Oswes 1 (initial consult). The null hypothesis was accepted for the Oswestry Low Back Disability Index, indicating that at the $\alpha = 0.05$ level of significance there was no statistically significant difference between the three groups at the Oswes 5 (follow-up).

Table 4.11 - Comparison of Groups A,B and C using the Kruskal-Wallis H-test to analyse the results obtained from the Orthopaedic Rating Scale at treatment 1 and the one week follow-up.

Orthopaedic Rating Scale							
	Group A		Group B		Group C		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	p value
ORS 1	7.7	1.22	8.2	0.62	7.6	0.94	0.151
ORS 5	2.8	1.77	2.45	1.4	2.65	1.6	0.876

The null hypothesis was accepted for the Orthopaedic Rating Scale indicating that at the $\alpha = 0.05$ level of significance there was no statistically significant difference among the three groups at the ORS 1 (initial consult) and ORS 5 (follow-up).

Table 4.12 - Comparison of Groups A, B and C using the Kruskal-Wallis H-test to analyse the results obtained from the algometer readings for pain pressure threshold at treatment 1 and the one week follow-up.

Algometer Readings for Pain Pressure Threshold							
	Group A		Group B		Group C		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	p value
Algo 1	2.79	0.73	2.59	0.68	2.64	0.63	0.616
Algo 5	3.66	0.79	3.60	1.04	3.43	0.74	0.689

The null hypothesis was accepted for the algometer readings for pain pressure threshold, indicating that at the $\alpha = 0.05$ level of significance there was no statistically significant difference among the three groups at Algo 1 (initial consult) and Algo 5 (follow-up).

4.5.1.1 The Dunn Procedure for use with the Kruskal-Wallis H-test:

If the null hypothesis is rejected for the Kruskal-Wallis H-test, then this multiple comparison procedure will have to be applied to determine which of the medians were significantly different.

The null hypothesis was rejected for the Oswestry Disability Low Back Index percentages obtained from the three groups. It was then necessary to apply then Dunn Procedure (described below) to the readings to determine which of the treatments were significant.

Let R_I and R_j be the ranks of the i^{th} and j^{th} samples respectively.

Let α be the experiment wise error rate. Usually the values of α are 0.15, 0.20 and 0.25 depending on the value of k (as k increases, α increases).

Decision Rule:

$$|Ri - Rj| > z\sqrt{\frac{N(N+1)}{12}\left(\frac{1}{ni} + \frac{1}{nj}\right)}$$

In the above formula:

k = The number of samples

N = number of observations in all samples combined

z = the value in the inverse normal distribution correspond

$(1 - [\alpha / k\,(k\text{-}1)])$

In this case $k = 3$, $\alpha = 0.15$, $z = 1.96$. Therefore, according to the equation:

$$|Ri - Rj| > z\sqrt{\frac{N(N+1)}{12}\left(\frac{1}{ni} + \frac{1}{nj}\right)}$$

$$|Ri - Rj| > 1.96\sqrt{\frac{60(60+1)}{12}(\frac{1}{20}+\frac{1}{20})}$$

$$|Ri - Rj| > 1.96\sqrt{\frac{61}{2}}$$

$$|Ri - Rj| > 10.82$$

4.5.1.1.1 The Dunn Procedure for Oswestry Low Back Disability Index for treatment one between all three groups.

The rank totals are :

Rank 1 - The treatment total for group A = (RA) = 34.25
Rank 2 - The treatment total for group B = (RB) = 34.72
Rank 3 - The treatment total for group C = (RC) = 22.52

R1 – R2 =	34.25 – 34.72 =	0.47
R2 – R3 =	34.72 – 22.52 =	12.20
R1 – R3 =	34.25 – 22.52 =	11.73

Between group A and group B, 0.47 < 10.82. The result is insignificant. Therefore there is a difference between group A and group B.

Between group B and group C, 12.20 > 10.82. The result is declared significant. Therefore, there is a difference between group B and C.

Between group C and group A, 11.73 > 10.82. The result is declared significant. Therefore groups C and A are different.

Conclusion: At the initial consultation, all three groups had different levels of pain.

4.5.2 The Intra-group analysis using the Friedman's T test:

Table 4.13 - Comparison of groups A, B and C using the Friedman's T Test to analyse results obtained within the groups from the NRS 101 at treatment 1, 4 and the one week follow-up.

Numerical pain rating Scale - 101									
	Group A			Group B			Group C		
	Rx* 1	Rx 4	fuv*	Rx 1	Rx 4	fuv	Rx 1	Rx 4	fuv
Mean	52.55	35.25	30.35	54.33	36.13	24.63	42.93	32.75	33.27
S.D	20.05	26.97	26.38	19.54	24.20	23.26	21.17	16.88	26.05
P value	0.001			0.000 (< .001)			0.002		

Rx* = Treatment

fuv* = one week follow-up visit

For all groups, the Null hypothesis was rejected for the NRS 101, indicating that at the ($\propto$) = 0.05 level of significance, that there was a statistically significant improvement between consultations.

Table 4.14 - Comparison of groups A, B and C using the Friedman's T Test to analyse results obtained within the groups from the Oswestry Low Back Disability Index at treatment 1, 4 and the one week follow-up.

Oswestry Low Back Disability Index									
	Group A			Group B			Group C		
	Rx 1	Rx 4	Fuv	Rx 1	Rx 4	fuv	Rx 1	Rx 4	Fuv
Mean	40.5	25.00	21.60	39.7	24.3	17.40	29.5	18.30	13.80
S.D	17.47	24.34	23.67	12.00	16.19	14.77	15.24	11.72	11.96
P value	0.000 (< .001)			0.000 (< .001)			0.000 (< .001)		

For all groups, the Null hypothesis was rejected for the Oswestry Low Back Disability Index , indicating that at the $\propto = 0.05$ level of significance, that there was a statistically significant improvement between consultations.

Table 4.15 - Comparison of groups A, B and C using the Friedman's T Test to analyse results obtained within the groups from the Orthopaedic Rating Scale at treatment 1, 4 and the one week follow-up.

Orthopaedic Rating Scale									
	Group A			Group B			Group C		
	Rx* 1	Rx 4	Fuv	Rx 1	Rx 4	fuv	Rx 1	Rx 4	Fuv
Mean	7.7	4.95	2.8	8.2	4.7	2.45	7.6	4.8	2.65
S.D	1.22	1.15	1.77	0.62	1.22	1.4	0.94	1.24	1.6
P value	0.000 (< .001)			0.000 (< .001)			0.000 (< .001)		

For all groups, the Null hypothesis was rejected for the Orthopaedic Rating Scale , indicating that at the $\propto = 0.05$ level of significance, that there was a statistically significant improvement between consultations.

Table 4.16 - Comparison of groups A, B and C using the Friedman's T Test to analyse results obtained within the groups from the algometer at treatment 1, 4 and the one week follow-up.

Algometer Readings									
	Group A			Group B			Group C		
	Rx* 1	Rx 4	Fuv	Rx 1	Rx 4	fuv	Rx 1	Rx 4	Fuv
Mean	2.79	3.39	3.66	2.59	3.25	3.60	2.64	3.15	3.43
S.D	0.73	0.58	0.79	0.68	1.06	1.04	0.63	0.66	0.74
P value	0.000 (< .001)			0.000 (< .001)			0.000 (< .001)		

For all groups, the Null hypothesis was rejected for the Orthopaedic Rating Scale , indicating that at the $\propto = 0.05$ level of significance, that there was a statistically significant improvement between consultations.

4.5.2.1 The Dunn Procedure For use with the Friedman's T Test :

If the null hypothesis was rejected for the Friedman's T test, then this multiple comparison procedure will have to be applied to determine which of the treatments are significantly different (Daniel 1978).

The null hypothesis was rejected for all the objective and subjective findings in all 3 groups. It was then necessary to apply Dunn procedure (described below) to determine the treatments that were significantly different.

Let R_j and $R_{j'}$ be the j^{th} *and* $j^{'th}$ treatment rank totals.

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

Decision Rule :

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

In the above formula :

b = the number of blocks

k = the number of treatments

z = value in the inverse normal distribution corresponding to

$\{1- [\ \alpha/k\ (k-1)]\}$

In order to complete the treatment rank totals, the values in each block were ranked from highest to lowest and then the sum of the ranks for each treatment was computed.

In this case k =3 , α =0.10 , z =2.12

Therefore according to the equation,

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

$$|Rj - Rj'| \geq 2.12\sqrt{\frac{20.3(3+1)}{6}}$$

$$|Rj - Rj'| \geq 13.41$$

4.5.2.1.1 A) The Dunn procedure for NRS – 101 Group A

The rank totals are:

Rank 1 (R1)= 52

Rank 4 (R4)= 38.4

Rank 5 (I week follow-up visit) = (R5) = 29.6

R1 – R4 =	52 – 38.4 =	17.6
R4 – R5 =	38.4 – 29.6 =	8.8
R1 – R5 =	52 – 29.6 =	22.4

Between treatment 1 and 4, $17.6 \geq 13.4$. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 8.8 is not ≥ 13.4. The result is declared insignificant. There is no difference between treatment 4 and 5.

Between treatment 1 and 5, $22.4 \geq 13.4$. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

B) The Dunn Procedure for NRS –101 Group B

The Rank totals are
Rank 1 (R1)=56.5
Rank 4 (R4)= 36
Rank 5 (one week follow- up visit)= (R5)= 27. 6

R1 – R4 =	56.5 – 36 =	20.5
R4 – R5 =	36 – 27.6 =	8.4
R1 – R5 =	56.5 – 27.6 =	28.9

Between treatment 1 and 4, 20.5 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 8.4 is not ≥ 13.4. The result is declared insignificant. There is no difference between treatment 4 and 5.

Between treatment 1 and 5, 28.9 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

C) The Dunn Procedure for NRS – 101 Group C:

The rank totals are:
Rank 1 (R1)=52
Rank 4 (R4)=37
Rank 5 (1 week follow-up visit)= (R5)=31

R1 – R4 =	52 – 37 =	15
R4 – R5 =	37 – 31 =	6
R1 – R5 =	52 – 31 =	21

Between treatment 1 and 4, 15 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 6 is not ≥ 13.4. The result is declared insignificant. There is no difference between treatment 4 and 5.

Between treatment 1 and 5, 21 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

4.5.2.1.2 A) The Dunn Procedure for the Oswestry Disability Low Back Index - Group A:

The Rank Totals are:
Rank 1 (R1) = 57
Rank 4 (R4) = 36
Rank 5 (1 week follow-up visit) =(R5) = 27

R1 – R4 =	57 – 36 =	27
R4 – R5 =	36 – 27 =	9
R1 – R5 =	57 – 27 =	30

Between treatment 1 and 4, 27 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 9 is not ≥ 13.4. The result is declared insignificant. There is no difference between treatment 4 and 5.

Between treatment 1 and 5, 30 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

B) The Dunn procedure for the Oswestry Disability Low Back Index - Group B:

The rank totals are:
Rank 1 (R1) =58
Rank 4 (R4) = 38
Rank 5 (I week follow-up) (R5) = 24

R1 – R4 =	58 – 38 =	20
R4 – R5 =	38 – 24 =	14
R1 – R5 =	58 – 24 =	34

Between treatment 1 and 4, 20 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 14 ≥ 13.4. The result is declared significant. There is a difference between treatment 4 and 5.

Between treatment 1 and 5, 34 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

C) The Dunn procedure for the Oswestry Disability Low Back Index - Group C:

The Rank totals are:
Rank 1 (R1) = 57.6
Rank 4 (R4) = 39
Rank 5 (1 week follow-up) =(R5)= 23.4

R1 – R4 =	57.6 – 39 =	18.6
R4 – R5 =	39 – 23.4 =	15
R1 – R5 =	57.6 – 23.4 =	34.2

Between treatment 1 and 4, 18.6 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 15 ≥ 13.4. The result is declared significant. There is a difference between treatment 4 and 5.

Between treatment 1 and 5, 34.2 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

4.5.2.1.3 A) The Dunn Procedure for the Orthopaedic Rating Scale – Group A:

The Rank Totals are:
Rank 1 (R1)= 60
Rank 4 (R4)= 37.6
Rank 5 (1 week follow-up) (R5)= 22.6

R1 – R4 =	60 –37.6 =	22.4
R4 – R5 =	37.6 – 22.6 =	15
R1 – R5 =	60 – 22.6 =	37.4

Between treatment 1 and 4, 22.4 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 15 ≥ 13.4. The result is declared significant. There is a difference between treatment 4 and 5.

Between treatment 1 and 5, 37.4 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

B) The Dunn Procedure for the Orthopaedic Rating Scale – Group B:

The Rank Totals are:
Rank 1 (R1)= 60
Rank 4 (R4)= 37.6
Rank 5 (1 week follow-up visit)= (R5)= 22.6

R1 – R4 =	60 –37.6 =	22.4
R4 – R5 =	37.6 – 22.6 =	15
R1 – R5 =	60 – 22.6 =	37.4

Between treatment 1 and 4, 22.4 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 15 ≥ 13.4. The result is declared significant. There is a difference between treatment 4 and 5.

Between treatment 1 and 5, 37.4 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

C) The Dunn Procedure for the Orthopaedic Rating Scale – Group C:

The Rank totals are:
Rank 1 (R1) =60
Rank 4 (R4) = 38
Rank 5 (1 week follow-up) (R5) = 22

R1 – R4 =	60 –38 =	22
R4 – R5 =	38 – 22 =	16
R1 – R5 =	60 – 22 =	38

Between treatment 1 and 4, 22 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 16 ≥ 13.4. The result is declared significant. There is a difference between treatment 4 and 5.

Between treatment 1 and 5, 38 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

4.5.2.1.4. The Dunn Procedure for the algometer readings– Group A:

The Rank totals are:
Rank 1 (R1) = 25.4
Rank 4 (R4) = 41.6
Rank 5 (1 week follow-up visit) (R5) = 53

R1 – R4 =	25.4 – 41.6 =	16.2
R4 – R5 =	41.6 – 53 =	11.4
R1 – R5 =	25.4 – 53 =	27.6

Between treatment 1 and 4, 16.2 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 11.4 is not ≥ 13.4. The result is declared insignificant. There is no difference between treatment 4 and 5.

Between treatment 1 and 5, 27.6 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

B) The Dunn Procedure for the algometer readings– Group B:

The Rank totals are:
Rank I (R1) = 21.6
Rank 4 (R4) = 40.6
Rank 5 (1 week follow-up visit) (R5) = 58

R1 – R4 =	21.6 – 40.6 =	19
R4 – R5 =	40.6 – 58 =	17.4
R1 – R5 =	21.6 – 58 =	36.4

Between treatment 1 and 4, 19 ≥ 13.4. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 17.4 is ≥ 13.4. The result is declared significant. There is a difference between treatment 4 and 5.

Between treatment 1 and 5, 36.4 ≥ 13.4. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

C) The Dunn Procedure for the algometer readings– Group C:

The Rank totals are:
Rank 1 (R1) = 22
Rank 2 (R2) = 42.6
Rank 3 (R3) = 55.6

R1 – R4 =	22 – 42.6 =	20.6
R4 – R5 =	42.6 – 55.6 =	13
R1 – R5 =	22 – 55.6 =	33.6

Between treatment 1 and 4, $20.6 \geq 13.4$. Therefore, the result is declared significant. There is a difference between treatment 1 and 4.

Between treatment 4 and 5, 13 is not ≥ 13.4. The result is declared insignificant. There is no difference between treatment 4 and 5.

Between treatment 1 and 5, $33.6 \geq 13.4$. The result is declared significant.
There is a difference between treatment 1 and 5.

There has been consistent improvement in the patients' condition.

4.5.3 Median Value Changes:

These values were obtained from the summary of the statistics. The values used were recorded at the first, fourth and final consultations for groups A, B and C. These values are used to indicate differences between the three groups. Figures 4.1 to 4.4 reflect these changes.

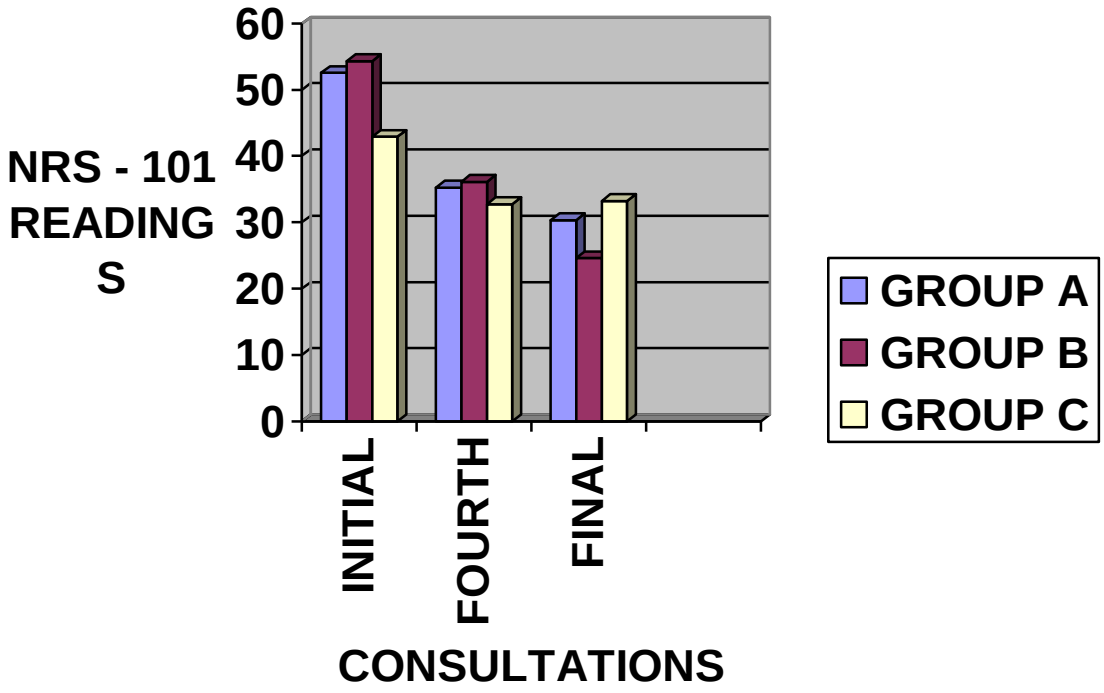

Figure 4.1 Mean Values of the Numerical Pain Rating Scale- 101 at the initial, fourth and final consultations comparing the group A,B and C.

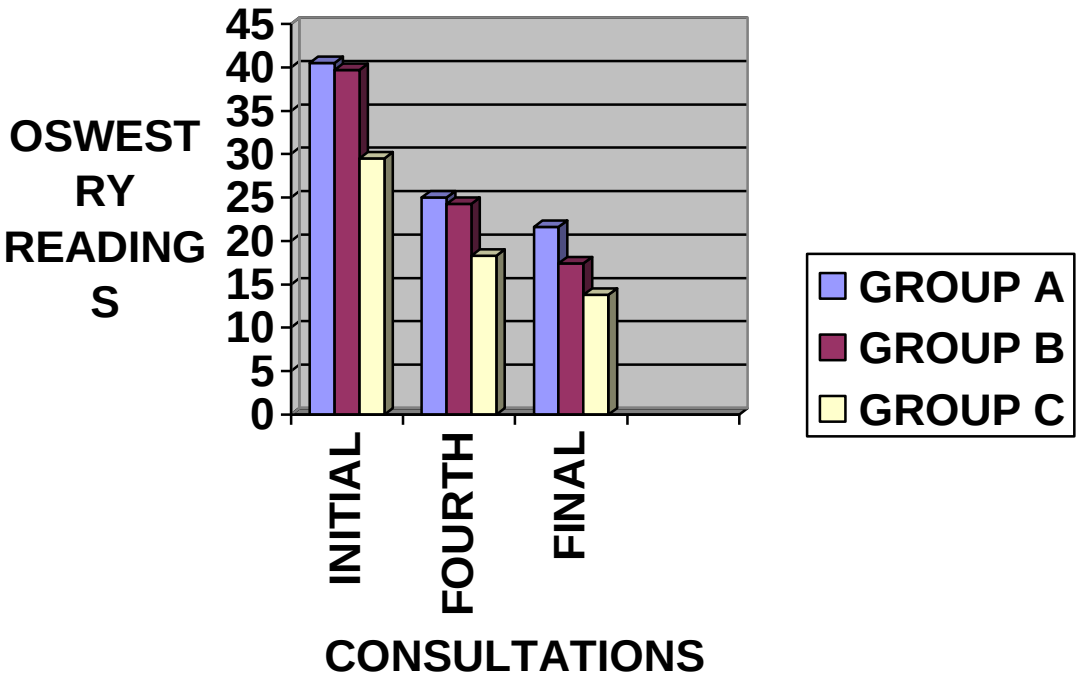

Figure 4.2 Mean values of the Oswestry Low Back Pain Disability Index at the initial, fourth and final consultations comparing Group A, B and C.

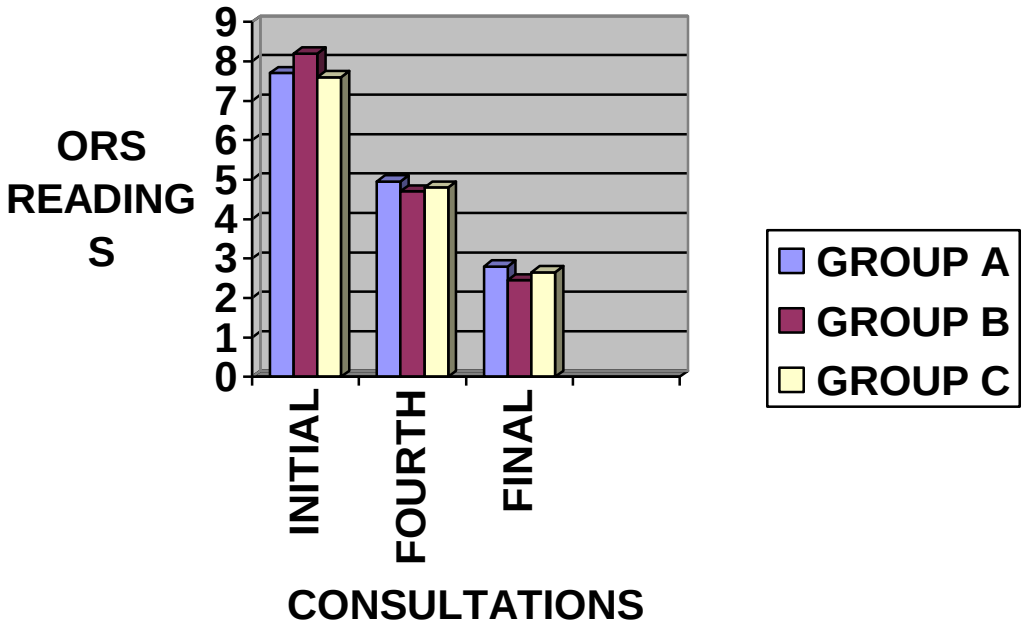

Figure 4.3 Mean values of the Orthopaedic Rating Scale at the initial, fourth and final consultations comparing Group A,B and C.

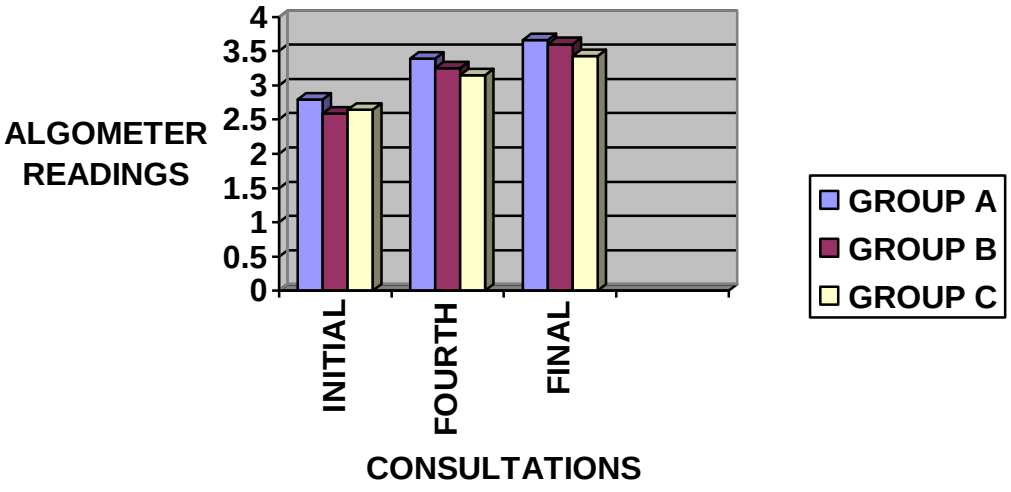

Figure 4.4 Mean values of the algometer readings at the initial, fourth and final consultations comparing Group A,B and C.

Chapter Five:

5. Discussion of the Results

This chapter deals with the discussion of the objective and subjective data that was recorded in chapter four. The measurements were obtained from the initial, fourth and final consultations.

SUBJECTIVE DATA - Numerical Pain Rating Scale – 101
- Oswestry Low Back Disability Index

OBJECTIVE DATA - Algometer readings
- Orthopaedic Rating Scale

The results are discussed in two sections as outlined below.

Inter-group results: The data from the first consultation from the three groups was assessed to determine if there was any difference between the three treatment groups in terms of signs and symptoms of the presenting conditions. A comparison of the results from the final treatment of the three groups will indicate which of the three treatments regime showed a higher efficacy in the treatment of sacroiliac syndrome.

Intra-group results: The evaluation of the data obtained before the fourth and final treatment represents the efficacy of the treatment regime.

5.1 Inter-group analysis

5.1.1 Subjective Measurements:

An inter-group analysis was conducted on the subjective measurements.

5.1.1.1 The Numerical Pain Rating Scale –101 (NRS)

The results of the inter-group analysis of the NRS readings can be found in Table 4.9. Statistical analysis at the first consultation did not reveal any differences in the level of pain intensity for Group A,B or C indicating that patients in all three groups entered the study with similar levels of pain (p=0.096). Analysis of data before the final consultation showed no statistical difference between the groups, indicating that the level of pain intensity remained constant among the three groups.

5.1.1.2. The Oswestry Low Back Disability Index:

The results of the inter-group analysis of the Oswestry Low Back Disability Index readings can be found in table 4.10. Statistical analysis at the first consultation revealed a statistically significant difference in disability due to low back pain indicating that patients in all three entered the study with different levels of disability due to low back pain (p=0.043). Analysis of the data before the final consultation (p=0.669) showed no statistical difference among the groups indicating that the level of pain intensity remained constant among the three groups.

5.1.1.3. Summary

In conclusion, it can be seen that the inter-group comparisons of the NRS-101 revealed that patients in all three groups entered the study with similar levels of pain intensity. Inter-group comparisons of the Oswestry Low Back Disability Index revealed that the patients in all three groups entered the study with different levels of disability (p = 0.043

< 0.05) due to the low back pain. The measurements recorded from the final consultation did not reveal any evidence as to which group had benefited more from the respective treatments.

It was hypothesised that there would be a difference between the treatment groups in terms of subjective clinical findings, demonstrating one protocol to be more effective for the treatment of sacroiliac syndrome than the other.

The null hypothesis (section 3.10.2.1) was accepted for the subjective data collected from consultations 1 and 5, as none of the three treatment protocols showed any statistical advantage over the other. Therefore at a 5% significance level, the three treatment protocols were all found to be as effective in improving the symptoms of sacroiliac syndrome.

5.1.2 Objective Measurements:

An inter-group analysis was conducted on the objective measurements.

5.1.2.1 The Orthopaedic Rating Scale (ORS)

The results of the inter-group analysis of the ORS can be found in table 4.11. Analysis of the data revealed that patients in all three groups scored similar results for positive sacroiliac joint tests at the onset of the treatment (p=0.151). There was no statistical difference between the three groups before the final consultation (p= 0.876). All three treatment protocols were equally effective in reducing the number of positive orthopaedic test, and thus reducing the signs and symptoms of sacroiliac syndrome.

5.1.2.2 The Algometer Readings:

The results of the inter-group analysis of the algometer readings can be found in table 4.12. Statistical analysis at the first consultation revealed that patients in all three groups

entered the study with a similar pain threshold (p= 0.616). Analysis of the data before the final consultation revealed no evidence of any statistical difference between the three groups. All three treatment protocols were, therefore equally effective in increasing pain pressure threshold.

5.1.2.3. Summary

In conclusion, it can be seen that the inter-group comparisons of the objective data suggests that patients in all three treatment groups experienced relatively similar levels of pain pressure threshold and positive sacroiliac joint orthopaedic tests at the commencement of the study. At the final consultation, there was no evidence that either group had benefited more than the other from the respective treatment.

It was hypothesised that there would be a statistically significant difference between the three groups in terms of objective clinical findings, demonstrating one treatment protocol to be more effective for the treatment of sacroiliac syndrome than the other. The null hypothesis (section 3.10.2.1) was accepted for all the subjective data collected from consultations as non of the treatment protocols showed any statistical advantage over the other. Therefore at a 5% significance level, the three treatment protocols were equally effective in the treatment of sacroiliac syndrome.

5.2 Intra- group analysis:

5.2.1 Subjective Measurements:

5.2.1.1. The Numerical Pain Rating Scale –101 (NRS):

The results of the intra-group analysis of the NRS readings can be found in table 4.13. Analysis of the comparison between the first, fourth and final consultation revealed the overall improvement in group A ($p = 0.001$), group B ($p = 0.000$) and group C ($p = 0.002$) with regards to the level of pain intensity.

The statistically significant differences in the means between treatment for all three groups were represented in the form of bar graphs in order to illustrate symptomatic improvements following each treatment (Figure 4.1)

5.2.1.2 The Oswestry Low Back Disability Index:

The results of the intra-group analysis can be found in table 4.14. Analysis of the comparison between the first, fourth and final consultation revealed the overall improvement in group A ($p = 0.000$), group B ($p = 0.000$) and group C ($p = 0.000$) with regards to the level of disability.

The statistically significant differences in the means between treatment for all three groups were represented in the form of bar graphs in order to illustrated symptomatic improvements following each treatment (Figure 4.2).

5.2.1.2. Summary

In conclusion, it was hypothesised that there would be a significant improvement among the treatments in each of the three groups in terms of subjective clinical findings. From the intra-group comparisons of the subjective data, it can be seen that patients in all three groups experienced a significant overall improvement in terms of pain threshold levels and disability due to low back pain. The null hypothesis (section 3.10.2.2) was rejected for both subjective data, indicating a statistically significant improvement for all three groups at a 5% significance level.

5.2.2 Objective Measurements:

An intra-group analysis was conducted on the objective measurement.

5.2.2.1 The Orthopaedic Rating Scale (ORS)

The results on the intra-group analysis can be found in table 4.15. Analysis of the comparison between the first, fourth and final consultation revealed the overall improvement in group A (p= 0.000), group B (p=0.000) and group C (0.000) with regards to the signs and symptoms of sacroiliac syndrome.

The statistically significant differences in the means between treatment for all three groups were represented in the form of bar graphs in order to illustrate symptomatic improvements following each treatment (Figure 4.3)

5.2.2.2. The Algometer

The intra-group analysis of the algometer readings can be found in table 4.16. Analysis of data revealed a statistically significant improvement between the first, fourth and final visits (Group A , p=0.000 ; Group B , p= 0.000 : Group C , p= 0.000).

The statistically significant difference in the means between treatment for all three groups were represented in the form of bar graphs in order to illustrate symptomatic improvements following each treatment (Figure 4.4).

5.2.2.3 Summary

In conclusion, it was hypothesised that there would be a significant difference among the treatments in each of the three groups in terms of objective clinical findings. The intra-group comparisons of the data suggest that patients in all three groups experienced a significant overall improvement in terms of a decrease in the number of positive orthopaedic tests. The null hypothesis (section 3.10.2.2) was therefore rejected for both objective data, indicating a statistically significant improvement for all three groups at a 95% confidence level.

5.3 Discussion of Demographic Data :

The gender distribution within the sample group of sixty (table 4.3) was fairly equal. There was a slightly higher proportion of females in group B and group C. The present research study is in contrast to prior studies. Schwarzer et al (1995) indicated that the females in his study had a higher proportion of pain of sacroiliac origin than the males. Studies conducted by Cibulka and Koldehoff (1999) and Gemmel and Jacobson (1990) revealed relatively higher ratio of females with sacroiliac joint dysfunction when compared to the ratio of male to female patients with low back pain.

The age distribution (table 4.4) revealed that most patients were within the 21-31 year age group. The 21-31 year age group had the most patients in group B and group C. The 32-42 year group had a high proportion of patients in group A.

The racial distribution within the sample of study (table 4.5) showed a high predominance of Indian patients (53%) with 9 in group A, 11 in group B and 12 in group C. White patients made up 30% of the sample size. 8% were Black patients and 8% were Mixed race patients. The research study showed a predominance of Indian patients with sacroiliac syndrome.

The occupation of patients (table 4.6) revealed that the highest proportion of patients with sacroiliac syndrome were students. The present study upholds authors, Gemmel and Jacobson (1990) who found that the overall incidence of sacroiliac joint dysfunction was 33.5% in a group of scholars. Home executives also had a high predominance of sacroiliac pain (10%) as compared to the other professions.

This study revealed a right- sided predominance of sacroiliac syndrome (table 4.7). The right side to left side ratio was 1.6: 1. Toussaint et al (1999) found a 60:40 right sided predominance of sacroiliac syndrome in a group of 480 construction workers. The results of this study are similar to that ratio. Schwarzer et al (1995) stated that sacroiliac syndrome is likely to be unilateral in 60% of the patients. All the patients in this study had a unilateral presentation of sacroiliac syndrome.

Two of the sixty patients complained of diarrhoea (table 4.8). The patients did not discontinue the treatment.

5.4 Limitations of the study

Perhaps the biggest limitation to this study was the elimination of a long- term follow-up consultation, which might have divulged valuable information with long term efficacy of these three treatments. An estimation as to the duration of pain relief whilst the patient is no longer receiving treatment, would have been invaluable in a study of this nature.

5.4.1 Limitations encountered with the subjective data:

The homogeneity of the study was limited due to a lack of patient stratification according to baseline characteristics such as age, gender, chronicity of the problem, occupation and extent of pain disability. An unavoidable limitation of a study of this nature is the possibility of patients attempting to enhance their treatment response positively in order to please the researcher – the "Hawthorne effect" (Mouton, 1996).

The Oswestry Index (Fairbanks et al,.1980) was not specifically designed to evaluate sacroiliac syndrome and this may have affected patient responses in term of improvement. It is also possible that some of the patients did not fully understand the questionnaires, therefore affecting their response either negatively or positively. The researcher noted that at least 5 of the patients spoke English as a second language and did had some difficulty in understanding the questions completely.

Emotional stress, psychological problems and physical activities were not taken into consideration. These factors may have had an influence on the outcome of the study, because they were out of the researcher's control.

Patients who were accepted into the study were instructed to refrain from any sudden changes in lifestyle such as onset of vigorous exercise or activity. However, it was not within the researcher's control to prevent the patient from continuing with this. This

could have had a negative impact on the study possibly negating the relief afforded by the treatment.

5.4.2 Limitations encountered with the objective data:

The possibility of the objective measurements recorded by the algometer being incorrect is largely due to varying reliability as a result of human error.

Patients were encouraged to comply with the instructions on patch application. The researcher verbally enquired about the use of the patches at each appointment. However, it possible that the patients could have given the researcher false information.

5.5 Comparison of the results.

The results of the present trial has been compared to a previous low back pain trial conducted by Login (2000) that investigated the effectiveness of non-steroidal anti-inflammatories (N.S.A.I.D.S) combined with spinal manipulative therapy.

Login (2001) conducted a randomised controlled clinical trial to evaluate the relative effectiveness of manipulation and diclofenac sodium (N.S.A.I.D.S) in the management of mechanical low back pain. It was important to note that Login (2001) reported that both forms of treatment were shown to be effective in relieving the signs and symptoms associated with mechanical low back pain, but there was no conclusive proof that either method was more effective than the other.

All intra-group comparisons in this research revealed significant improvement in terms of pain reduction and a decrease in disability.

All inter-group comparisons in the research revealed that there was no difference in the treatment among the three groups.

This research paper showed that all three treatment protocols were effective in reducing the signs and symptoms associated with sacroiliac syndrome. There was no conclusive proof as to which treatment protocol was more significant than the other. This study has been unable to establish the effectiveness of the combination of TransAct® patches and manipulation in the treatment of sacroiliac syndrome.

This research paper upholds authors who advocate manipulation of the sacroiliac joint in the treatment of sacroiliac syndrome (Haldeman, 1992:221; Salter, 1999; Ranwell, 2001).

Chapter Six :

6. Recommendations and conclusions

6.1 Recommendations:

The author is of the opinion that the following recommendations could improve the validity of future studies investigating the management of sacroiliac syndrome.

In the present study, the sample size was limited to sixty patients to allow for the use of parametric testing to enable the detection of subtle changes in the data. A larger sample size is recommended to minimize the chances of a Type II error and to produce more accurate results.

The use of a digital algometer will minimize the chance of human error and will ensure that the clinical findings are of a higher standard.

To ensure homogeneity within the three groups, it is recommended that stratification be included in future studies. Stratification should be employed with respect to age, gender, duration and severity of the complaint and occupational groups.

This study allowed for four treatments and a 1 week follow-up within a two week period. Without specification of when each treatment was to be administered. Each treatment between the groups, should have been scheduled as strictly as possible in order to ensure the consistency and validity of the treatment.

Of particular importance for future studies is the inclusion of a long term follow-up consultation of the patients after completion of the treatment. This would illicit information regarding the long term efficacy of the respective treatment.

It is recommended that the pain and disability questionnaires be multi-lingual due to the broadening patient base into all races. However, the linguistic implications of this are

realised. Assessment of the objective measurements by someone other than the researcher would eliminate possible researcher bias, and would therefore increase the validity of the study.

The possibility of side effects play an important part in the prescription of N.S.A.I.D.S. Two of the thirty patients that were prescribed the TransAct® patches complained of diarrhoea, but remained part of the study. It would be of interest to perform long term follow –up consultation after cessation of the treatment regimes to establish if there was any long term side effects.

6.2 Conclusions:

The aim of this investigation was to evaluate the relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with either menthol or non-medicated placebo patches in the management of sacroiliac syndrome, in terms of objective and subjective clinical findings.

At a 5% level of significance, it was found that all three treatment protocols were effective in treating sacroiliac syndrome. None of the three groups showed any statistically significant advantage over the other in overall treatment efficacy.

At the inception of the study, it was hypothesised that the combination of TransAct® patches and manipulation would result in an effective treatment protocol for sacroiliac syndrome. However, results of the research conclude that the addition of the TransAct® patches were ineffective in reducing the signs and symptoms of sacroiliac syndrome. Placebo patches with menthol scent were introduced into the research to determine if the scent of menthol had an extraneous role in influencing the improvement of the condition. This research upholds Ritchie et al (1995), concluding that menthol scent strongly

influences the physical effect of the patches. Non-medicated patches were incorporated into the study to determine the role of placebo. The results of this research indicate that the patients' responses to placebo were marked, therefore indicating that the physical effect of applying a topical formulation does influence the placebo response rate. All three patches resulted in an improvement in the condition, without any one particular patch being more effective than the other. The TransAct® patches proved to be as effective as the placebo patches with menthol scent and the non-medicated placebo patches, even though only the TransAct® patches contained an active ingredient (ie. flurbiprofen).

The use of manipulation in the management of sacroiliac syndrome has already been proven to be effective and well tolerated. The use of N.S.A.I.D.S depends on the judgement of the spinal manipulative therapist and the severity of the condition. The risk of side effects obscure the potential benefits of N.S.A.I.D.S, therefore the use of spinal manipulative therapy in the treatment of sacroiliac syndrome could be a safer alternative.

In conclusion, this study has been unable to establish the effectiveness of TransAct® patches together with manipulation in the treatment of sacroiliac syndrome. Further research is necessary to determine the most effective treatment protocol for sacroiliac syndrome.

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APPENDIX A :

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
- Alcohol
- Social Drugs

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

APPENDIX B :

TECHNIKON NATAL

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

5. ABDOMINAL EXAMINATION

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

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

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

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

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

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

b. Motor
- Masseter:
- Jaw lateral movement:

c. Reflexes
- Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

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

b. Taste
- Anterior two-thirds of tongue:

VIII General Hearing:
Rinnes = L: R:
Webers lateralisation:
Vestibular function
- Nystagmus:
- Rombergs:
- Wallenbergs:

Otoscope examination:

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

XI
Shoulder lift:
S.C.M. strength:

XII Inspection of tongue (deviation):

Motor System:

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

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

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

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

Sensory System:

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

b. Joint position sense
- Finger:
- Toe:

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

Cerebellar function:

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

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

8. **SPINAL EXAMINATION:**(See Regional examination)

Obvious Abnormalities:
Spinous Percussion:
R.O.M:
Other:

9. **BREAST EXAMINATION:**

Summon female chaperon.

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

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

APPENDIX C:

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

REGIONAL EXAMINATION - *LUMBAR SPINE AND PELVIS.*

PATIENT: _____

FILE #: _____ DATE: _____

INTERN/RESIDENT: _____

SUPERVISING CLINICIAN: _____

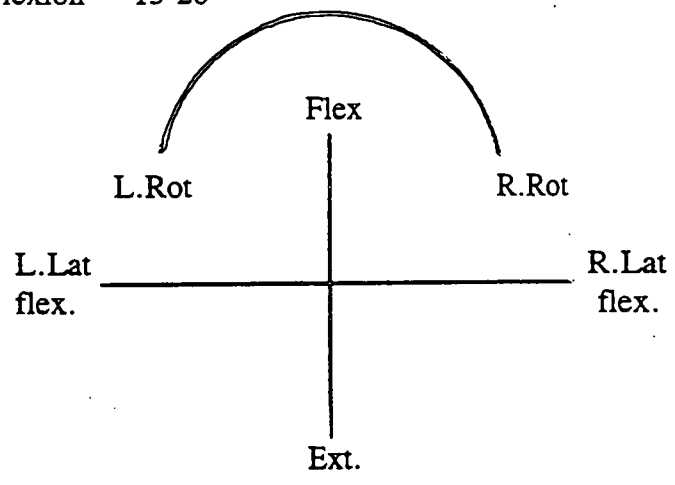
STANDING:

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 Test
Flip Test
Hoover's Test
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			MYOTOMES			REFLEXES		
	L	R		L	R		L	R
T12			Hip Flex			Pat.		
L1			Hip int rot			Achil		
L2			Hip ext rot			H/S		
L3			Hip abd					
L4			Hip add					
L5			Knee flex					
S1			Knee ext					
S2			Dorsiflex					
S3			Plantarflex					
			Eversion					
			Ext.hal.long					

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:
Orthpaedic/Neuro/
Vascular:

Observ/Palpation:

APPENDIX D:

1.	Age of the patient	
2.	Where is the pain located	
3.	Does the pain progress to other areas?	Y/N
4.	How long have you had this pain?	
5.	Do you experience any tingling ,numbness or pins and needles in your legs?	Y/N
6.	Are you allergic to any medication?	Y/N
7.	Do you have a history of asthma?	Y/N
8.	Are you pregnant or could you be pregnant?	Y/N

APPENDIX E :

Patients Name:_____ Date:_____

File no :_____

	Motion Palpation		
	Initial Visit	4th Visit	Final Visit
Side			
Direction			

	Algometer					
	Initial Visit		4th Visit		Final Visit	
	Left	Right	Left	Right	Left	Right
Readings						

Orthopaedic assessment Rating:

Sacro - iliac Rating			
	Initial Visit	4th Visit	Final Visit
Post Shear(test 4)			
Gaenslens (2)			
Patrick Faber (2)			
Erichsons (2)			
Total out of 10			

APPENDIX F:

Low back pain and Disability Questionaire (Revised Oswestry)

ient Name:_____ File no:_____Date_____

his questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage everyday life. Please wer 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 tion relate to you, but please just mark the box which most 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 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 - Travelling

- ☐ I get no pain whilst travelling.
- ☐ I get some pain whilst travelling but none of my usual forms of travel make it any worse.
- ☐ I get extra pain whilst travelling but it does not compel me to seek alternative form of travel.
- ☐ I get extra pain whilst travelling 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 degree 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.

Pain Severity Scale:

Rate your usual level of pain today by checking one box on the following scale

0	1	2	3	4	5	6	7	8	9	10

No pain **Excruciating pain**

Adapted from Hsieh et al 1992

APPENDIX G:

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 H:

INFORMED CONSENT FORM

(To be completed by patient / subject)

Date :

Title of research project : The relative effectiveness of spinal manipulative therapy combined with transcutaneous flurbiprofen versus spinal manipulative therapy combined with either menthol or non-medicated placebo patches in the management of sacro-iliac syndrome.

Name of supervisor : Dr H. White

Name of research student : Lineshnee Moodley

Please circle the appropriate answer

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

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

Please Print in block letters:

Patient /Subject Name:_____ Signature:_____

Parent/ Guardian:_____ Signature:_____

Witness Name:_____ Signature:_____

Research Student Name:_____ Signature:_____

APPENDIX I:

SCHEDULING STATUS
Schedule 1

PROPRIETARY NAME (AND DOSAGE FORM)
TransAct: An adhesive patch (TransAct patch - local action transcutaneous patch)

COMPOSITION
TransAct patch : Each TransAct patch contains 40 mg flurbiprofen.

PHARMACOLOGICAL CLASSIFICATION
A 3.1 Antirheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION
TransAct contains flurbiprofen, chemically described as 2 - (2- fluoro-4-biphenylyl) propionic acid, a non-steroidal anti-inflammatory agent which has anti-inflammatory, analgesic and antipyretic properties. Flurbiprofen is an inhibitor of prostaglandin synthetase enzymes.

Application of TransAct results in the diffusion of the flurbiprofen molecule through the skin and subcutaneous fat to the deeper tissues. Although the bioavailability from the formulation is low (approximately 2%), concentrations of flurbiprofen in the deeper tissues around the joints are similar to those seen after conventional oral dosing.

Concentrations of flurbiprofen in the blood are, however, much lower, with maximal plasma levels of 38,5 ng/ml observed at 13.8 hours after a single 14 hour application.

Plasma concentrations of flurbiprofen continue to rise on repeated application to reach steady state in about 1-2 weeks.

However, steady state plasma levels (about 100-200 ng/ml) remain very much lower than after oral therapy. After removal, plasma flurbiprofen levels decline more slowly than after oral administration due to continued distribution from the tissues, and fall to undetectable levels within 48 hours.

In blood, flurbiprofen is highly protein bound (> 99%).

Elimination of flurbiprofen is via the kidney, mostly in the form of metabolites. The metabolic profile following topical administration is similar to that after oral dosing; hydroxyflurbiprofen is the principle metabolite.

INDICATIONS
TransAct is indicated for the symptomatic relief of localised pain and inflammation associated with soft tissue rheumatism, trauma and osteoarthritis.

CONTRA-INDICATIONS
TransAct is contra-indicated in patients who have previously shown a hypersensitivity to flurbiprofen. TransAct should not be applied to the skin of patients who have experienced bronchospasm, anaphylactoid reactions, angioedema or other hypersensitivity type reactions related to the use of aspirin or of other non-steroidal anti-inflammatory agents.

It should not be applied to broken or fragile skin, or to sites affected by dermatoses or infection. Systemic absorption is increased if TransAct$_{LAT}$ is applied to damaged skin.

WARNINGS
Keep out of reach of children.

Safety and efficacy in children have not been established and therefore TransAct is not indicated for use in children under 12 years of age.

Insufficient safety data are available for continuous use for more than 4 weeks, therefore TransAct is not indicated for continuous use for more than 4 weeks.

TransAct should be used with caution in patients with a history of non-allergic asthma.

The safety of TransAct during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE
TransAct is for external use only.

The affected area should be cleaned and only one patch should be applied at a time to a single site. A fresh patch is applied every 12 hours.

The backing film is removed by rubbing a corner between the fingers and the adhesive side applied to the skin.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
The most common reactions are local and include itching, redness, numbness and tingling at the site of application. If local irritation develops, treatment with TransAct$_{LAT}$ should be discontinued.

Where TransAct is applied over a prolonged period of time, the possibility of systemic side-effects cannot be completely excluded.

Side-effects as experienced with systemically absorbed flurbiprofen include the following:

Epigastric pain, eructation, nausea and diarrhoea, headache or slight dizziness. If they persist or are troublesome, the preparation must be discontinued.

There have been reports of skin rash, peripheral oedema, gastro-intestinal ulceration or haemorrhage, hypersensitivity reactions (e.g. bronchospasm, anaphylactic/anaphylactoid systemic reactions), elevated transaminase levels, jaundice, hepatitis, renal failure and nephrotic syndrome.

Isolated cases of dyshaemopoiesis (leucopenia, thrombocytopenia, aplastic anaemia) and of erythema multiforme have been observed.

During prolonged treatment with TransAct, blood counts and monitoring of hepatic and renal function are indicated as precautionary measures.

PRECAUTIONS
Caution should be exercised when commencing treatment with TransAct in patients with a history of peptic ulceration, gastrointestinal haemorrhage, ulcerative colitis, cardiac decompensation and hypertension.

As it has been shown that flurbiprofen given systemically may prolong bleeding time, TransAct should be used with caution by patients with a potential for abnormal bleeding.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Overdosage is unlikely to occur because of the nature of the formulation. There is no specific antidote to flurbiprofen.

IDENTIFICATION
TransAct Patch: A 10 x 14 cm patch consisting of an un-woven polyester backing spread evenly with a white to pale yellow ointment and covered by a peel - off liner. The ointment has an odour of peppermint.

PRESENTATION
TransAct 10's: Carton containing 2 resealable laminated sachets. Each sachet contains 5 TransAct patches.

TransAct 5's: Carton containing 1 resealable laminated sachet. Each sachet contains 5 TransAct patches.

STORAGE INSTRUCTIONS
Store below 25 °C. Keep out of reach of children. Reseal sachet after use. The product must not be used longer than one month after opening the sachet.

REGISTRATION NUMBER
28/3.1/0268

NAME AND BUSINESS ADDRESS OF THE APPLICANT
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APPENDIX J:

INSTRUCTIONS ON PATCH APPLICATION

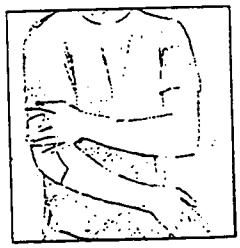
1. Wipe the skin over lying the sacroiliac joint clean.
2. Remove one patch form the sachet and ensure that the sachet is securely re-closed.
3. Remove the peel off liner and apply adhesive side to the skin.
4. When applying the patch, stretch the patch gently to prevent the surface from wrinkling.
5. It is recommended that bathing should be arranged to coincide with routine changing of the patch.
6. Do not wet patch. Remove before bathing.
7. Replace every 12 hours.
8. Use only one patch at a time.

1. Wipe the affected area clean.

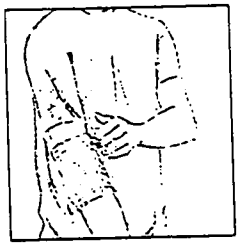
2. Remove one patch from the sachet and ensure that the sachet is securely resealed.

3. First rub the corner of the patch between the thumb and fingers to peel off the backing and apply the adhesive side to the skin.

4. When applying stretch the patch gently to prevent the surface of the patch wrinkling. When first applied this product may feel cool.



5. Where a joint is affected slightly bend the joint before applying.



6. You may find it helpful to use the bandage supplied to keep the patch in place on joints like a knee or elbow.

APPENDIX K:

Dear Participant

The aim of this study is to compare the relative effectiveness of spinal manipulative therapy combined with TransAct® with spinal manipulative therapy combined with either menthol or non-medicated placebo patches in the management of sacro-iliac syndrome.

Sixty people will be required to complete this study. These participants will be divided into three treatment groups of twenty patients each. Patients in all groups will receive treatment.

One group will receive spinal manipulative therapy and transcutaneous placebo patches. The second group will receive spinal manipulative therapy and locally acting transcutaneous patches (TransAct® patches) containing Flurbiprofen, a non-steroidal anti-inflammatory drug, which helps to control inflammation and pain. The last group will receive placebo patches with a menthol scent as well as spinal manipulative therapy. The TransAct patches may however produce side effects in some patients such as gastric irritation, gastric bleeding or skin irritation. All three groups of patients will receive 5 chiropractic treatment sessions over a period of 7 to 10 days. Patients will be supplied with either an active or a placebo patch that will be worn for 12 hours and then replaced with another patch. The patients will not know what patches they are receiving.

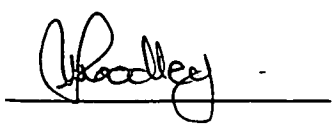
All patients in this study will undergo an initial consultation consisting of a case history, a physical examination pertinent to low back pain and a lower back regional examination to confirm the diagnosis of sacro-iliac syndrome.

Patients with broken or damaged skin over the low back, a history of adverse reactions to anti-inflammatory drugs, peptic ulcers or gastrointestinal bleeding will be excluded from this study. You are also kindly asked to inform the researcher, if you need to take any other medication during the research as this may alter the results of the research.

All treatments will be performed under the supervision of a qualified Chiropractor and will be free of charge.

Thank you

Yours faithfully



Lineshnee Moodley
(6th year junior intern)