

**THE RELATIVE EFFECTIVENESS OF MANIPULATION USED
IN CONJUNCTION WITH A NON-STABILISING SACROILIAC
ORTHOTIC VERSUS MANIPULATION USED IN
CONJUNCTION WITH A STABILISING SACROILIAC
ORTHOTIC IN THE TREATMENT OF SACROILIAC
SYNDROME.**

BY

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compliance with the requirements for the Master's Degree in Technology:
Chiropractic*

I, Angela Hope Sawyer do declare that this dissertation is representative of my own
work.

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Date

DEDICATION

This work is dedicated to my mom for her continued support, love and companionship
and my loving dad.

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ABSTRACT

There has previously been a significant number of clinical trials supporting the efficacy of manipulation for the treatment of low back pain. In addition, the use of manipulation for the treatment of sacroiliac syndrome is well recognised. However, the management protocols involving the use of orthotics, used alone, or in combination with manipulation were found to be controversial. Orthotics seem to be frequently used in the clinical setting and yet there is a paucity of controlled clinical research advocating their application.

The aim of this study was to determine the relative effectiveness of chiropractic manipulation used in combination with a non-stabilising sacroiliac orthotic (strapping) versus chiropractic manipulation used in combination with a stabilising sacroiliac orthotic in the treatment of sacroiliac syndrome. It was hypothesised that both treatment protocols would be effective in the management of sacroiliac syndrome, and that manipulation used in combination with a stabilising sacroiliac orthotic over a two week period would be more effective than manipulation used in combination with a non-stabilising sacroiliac orthotic, in terms of subjective and objective clinical findings.

The study design chosen was a comparative, randomised, controlled clinical trial. Sixty consecutive patients diagnosed with sacroiliac syndrome were randomly assigned either to the group receiving manipulation used in combination with a non-stabilising sacroiliac orthotic or the group receiving manipulation used in combination with a stabilising sacroiliac orthotic. The age range of patients extended from eighteen to forty-nine, and included thirty-one males and thirty-three females. Statistically patients

in each group presented initially with a similar clinical picture, in terms of pain levels and disability.

Each group of thirty patients received a maximum of six treatments over a period of two weeks. The patients were assessed by means of obtaining subjective information consisting of the Numerical Pain Rating Scale 101, and the Oswestry Low Back Disability Questionnaire. In addition, a compliance questionnaire was administered in the group utilising the stabilising sacroiliac orthotic. Objective data was gathered from results of orthopaedic tests of the sacroiliac joints and pressure algometer measurements. The subjective and objective data were collected before the initial treatment, after the third consultation and after the final consultation.

The data was transferred to spread sheets and underwent statistical analysis. Paired t-tests and Wilcoxon Signed Rank tests were used to determine whether there was any significant change within each group between the first, third and final consultations (intra-group analysis). Unpaired t-tests and Mann Whitney U-tests were conducted in order to determine whether there was any statistically significant difference between the two groups at each data collecting consultation (inter-group analysis).

Intra-group analysis of the results indicated that both treatment groups improved significantly ($p < 0.025$) between the first and final consultations, for all measurements.

Inter-group comparison of the results indicated that there was no difference between the two treatment groups by the final consultation. Consequently, it was concluded that no statistically significant difference existed in the efficacy of the two treatment protocols in terms of subjective and objective clinical findings.

It is recommended that this study be repeated with a larger, more homogenous sample population. It is evident that without further research to establish the efficacy and cost-effectiveness of low back orthotics, their application remains an ethical dilemma, to be regarded by practitioners with caution in each separate case.

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DEFINITIONS

ADJUSTMENT

A specific form of direct articular manipulation utilizing a short lever and characterised by a dynamic, forceful, high velocity thrust of controlled amplitude, after appropriate stabilisation of other joints has occurred and the joint is tractioned (Bryner 1987:8).

FIXATION

A state whereby a vertebra or pelvic bone has become temporarily immobilised in a position which it may normally occupy during any phase of physiological spinal movement (Bryner 1987:19).

MANIPULATION

Paris (1983) proposes that manipulation is the skilled, passive movement of a joint (or spinal) segment either within or beyond its active range of motion.

This definition is broad and includes both mobilisation techniques and the more specific chiropractic adjustment.

MOTION PALPATION

Diagnosis of passive and active segmental joint ranges of motion (Bryner 1987:29).

NUTATION

Motion about the sacrum about the coronal axis in which the sacral base moves anteriorly and inferiorly and the tip of the coccyx moves posteriorly and superiorly (Bryner 1987:29).

ORTHOTIC

For the purpose of consistency, in this research study, the term, 'orthotic' will be used to describe any orthopaedic appliance used to provide extra support to an area of the body. In this case the term is specifically used with reference to the lower back, and includes corsets, braces, belts, strapping and any other form of support provided by an appliance.

STABILISING SACROILIAC ORTHOTIC

Levine (1984) describes a corset as a type of orthotic which functions by increasing intra-abdominal pressure, and a brace as an orthotic which functions by reducing mobility. This description of a brace applies to the stabilising sacroiliac orthotic used in this research study as it functions to reduce the mobility of the pelvis. This type of orthotic has been described in the literature by various names, including, trochanteric belt, sacroiliac belt, lumbar-sacral brace and sacroiliac brace.

NON-STABILISING SACROILIAC ORTHOTIC

Strapping or taping refers to the application of adhesive backed tape that adheres to the skin of a particular joint or limb, to provide support and compression (Davis 1995). Rigid elastoplast strapping was applied posteriorly between the right and left posterior superior iliac spine, between the iliac crests superiorly, and just below the posterior iliac spines inferiorly. The strapping provided no stabilising effect on the pelvis, but its effects included support of the local musculature and enhanced proprioceptive response (McNair and Heine 1999).

1. INTRODUCTION

"The sacroiliac joint is a significant source of pain in patients with chronic low back pain and warrants further investigation" (Schwarzer *et al.* 1995). This statement was based on a controlled clinical trial conducted by the authors, and supports the present investigation, evaluating two different methods of treating sacroiliac joint syndrome.

It is generally understood that low back pain is a commonly occurring condition in the population (Burton and Cassidy 1992:1). The sacroiliac joint however, seems to have a less well defined role in terms of its significance as a cause of low back pain, as can be seen in the review of related literature, conducted for the present study.

Bernard (1997:79) recognised that pain of sacroiliac joint origin was proposed to be a frequently occurring condition in the low back pain population, but he emphasised that the evidence supporting this hypothesis was empirical and derived from the successful treatment of patients who clinically fit the description of sacroiliac syndrome.

The following authors were also found to accept the sacroiliac joint as a significant source of low back pain: Bernard and Cassidy (1991), Kirkaldy-Willis (1992), Xiaodong and Yonggang (1994), Dontigny (1999). However, others continue to doubt its role as a pain mediator (Nachemson 1992).

The management of low back pain and more specifically sacroiliac joint syndrome is varied within different health fields, but it was found in the literature that manipulation was a widely used method of treating vertebral column pain (Twomey and Taylor 1995), and was also recognised as a popular treatment approach in sacroiliac joint syndrome (Cassidy and Mierau 1992; Kirkaldy-Willis and Burton 1992).

The acceptance of manipulation as an effective conservative treatment for low back pain was most likely due to the relatively high number of controlled, clinical trials which were available in the literature (Cassidy et al. 1992:292).

Manipulation was well accepted as an effective therapy for low back pain, when used as a single treatment modality (Cassidy and Mierau 1992; Manga et al. 1993; Kirkaldy-Willis and Burton 1992; Morton 1999), and yet there was sufficient evidence provided by Coxhead et al. (1981) to indicate that the response to treatment would positively correlate to an increased number of applied therapies. The study (which included manipulation as one of the modalities) showed, that when more than one treatment modality was administered, regardless of the specific modality, the patients condition improved more significantly than with a single treatment modality. This would suggest that a combination of manipulation with an additional therapy would be more beneficial to the patient's recovery than manipulation alone. For this reason, it was considered appropriate to evaluate the

possibility of finding an additional modality, which would compliment the use of the chiropractic adjustment for the treatment of sacroiliac syndrome.

While certain authors have emphasised the lack of documented evidence to support the use of orthotics in low back pain (Le Blanc et al. 1987; Flor and Turk 1984), Doran and Newell (1975) had previously demonstrated the benefits of their use. They found the low back orthotic to be less expensive than manipulation and physical therapy, safer than drugs and as effective as the other therapies. For these reasons the sacroiliac orthotic was chosen by the researcher of the present study to be used following manipulation of the sacroiliac joint. This approach was more recently suggested by Paris (1997:325) and Xiaodong and Yonggang(1994). The latter, questionably reported a 100% success rate using this procedure.

The purpose of this study was to compare the effectiveness of manipulation used in conjunction with a non-stabilising sacroiliac orthotic and manipulation used in conjunction with a stabilising sacroiliac orthotic. It was hypothesised by the author that there would be significantly more improvement displayed by the group treated with manipulation used in conjunction with the stabilising sacroiliac orthotic.

The first objective of the study was to assess the two treatment methods in terms of subjective clinical findings.

The second objective was to assess the two treatment methods in terms of objective clinical findings.

The results of this study may help to establish the efficacy of combining manipulation, a well-recognised chiropractic therapy, with an orthotic, which has not been subjected to the same level of controlled, clinical assessment.

2. REVIEW OF RELATED LITERATURE

2.1 INTRODUCTION

The review of related literature will describe, the epidemiology and prevalence of sacroiliac syndrome in relation to low back pain. The sacroiliac joint anatomy and biomechanics will be discussed, as well as the clinical features and diagnosis of the sacroiliac joint syndrome. Finally, the role that manipulation and orthotics have played in the management of this condition will be described.

2.2 EPIDEMIOLOGY OF LOW BACK PAIN AND THE PREVALENCE OF SACROILIAC SYNDROME

It is well known that the lifetime prevalence of low back pain is between 60% and 90% (Burton and Cassidy 1992:2).

In an epidemiological study on non-elderly Americans, Shekelle et al. (1995) analysed, insurance claim forms from a community-based, randomised control trial on the use of health services, over a 3-5 year period. Twenty-two percent of 3105 patients had at least one episode of back pain over the prescribed period. This prevalence of back pain was dramatically increased when the source population was involved in manual labour, as indicated in the more recent study by Toussaint et al.

(1999) who found that over the previous 12 month period, 49.3% of 480 construction workers had experienced pain in the lumbar spine.

The concept of the sacroiliac joint as a primary source of low back pain is gaining recognition but lacks universal acceptance (Bernard 1997:79). In the review of the literature conducted for this study, it was found that the prevalence of the sacroiliac joint as a primary source of back pain remains controversial among authors, and the various opinions are discussed below.

A number of authors view sacroiliac syndrome as a significant portion of the low back pain population, with clinical and empirical estimates between 23 % and 90% of this group (Bernard and Kirkaldy-Willis 1992; Urli and Till 1995; Dontigny 1999).

Bernard and Cassidy (1991:2114) believe that sacroiliac syndrome is a common but frequently overlooked source of low back pain. In a retrospective study conducted over a 12-year period, at a low back pain clinic in Saskatoon, the medical records of 1293 low back pain patients were reviewed. It was revealed that the sacroiliac joint was the primary source of pain in 23% of the patient population (336 patients). Sacroiliac syndrome was listed as the highest occurring diagnosis, with posterior facet syndrome in 22% and herniated disc in 14% of patients, being respectively the second and third highest listings (Bernard and Kirkaldy-Willis 1992:210).

In a small sample (N=30) of the nursing population in South Africa, 33.3% of nurses with low back pain were diagnosed with sacroiliac syndrome (using the Kirkaldy-Willis model of classification), 6.6% with myofascial syndrome and 60% with a combination of both syndromes (Urli and Till 1995).

Daum (1995), recognised through clinical practice, the sacroiliac joint as an under-appreciated pain generator, and extended this opinion to the specific diagnosis of sacroiliac dysfunction. In a review of their office records, Daum and his colleagues found that 40% of low back pain patients included sacroiliac disease. He stated that the diagnosis of sacroiliac joint disease included infectious, metabolic, inflammatory, neoplastic and degenerative origins but that the most common source of low back pain was sacroiliac dysfunction. In the review, Daum did not give any prevalence values, which were specific for sacroiliac dysfunction and no comparisons could therefore be made with the other prevalence values mentioned.

A publication by Dontigny (1999), concluded that sacroiliac joint dysfunction was the most likely mechanism of idiopathic low back pain, and that manual correction of the dysfunction, would result in at least a 90% success rate in the treatment of patients with low back pain. The author seemed to base this value on individual clinical experience and on the reports of several low back pain studies which shared similarly high prevalence values, but gave no indication of how these values were reached.

Opposition to these claims, suggests that the prevalence of the sacroiliac joint as a pain generator, was as low as 3.5 - 6.5% of the low back pain population (Laslett

1997:294). Authors such as (Nachemson 1992) questioned whether pain of sacroiliac origin could be considered within the differential diagnosis at all. The author's skepticism seemed to be due to the lack of validated reliability of clinical tests for sacroiliac joint dysfunction, and the relatively small amount of movement observed in the normal sacroiliac joint.

An understandable reason for the opposition to this diagnosis, may also be due to the lack of a well defined, objective clinical picture. Radiographic changes due to sacroiliac syndrome, were not usually detected (Kirkaldy-Willis *et al.* 1992; Laslett and Williams 1994). The presence of sacroiliac dysfunction is commonly used to aid the diagnosis of sacroiliac syndrome, but locking of the joint has never been demonstrated on x-ray (Lewit and Rosina 1999). Furthermore, while sacroiliac dysfunction is commonly used to aid the diagnosis of sacroiliac syndrome, findings of Gemmel and Jacobson (1990) indicate that there was no significant correlation between low back pain and sacroiliac joint dysfunction ($p < 0.05$), in a group of 83 fit college students. These findings were mirrored recently by Toussaint *et al.* (1999) who found no significant correlation with a confidence interval between 0.51 and 2.1, when examining 480 male construction workers. The authors could offer no explanation for the existence of asymptomatic sacroiliac joint dysfunction.

The two studies discussed above cannot be considered conclusive, due to contrary findings in an earlier study by Mierau *et al.* (1984), which suggested that a statistically significant association ($p < 0.01$) existed between a recurring or prolonged

history of low back pain and sacroiliac joint dysfunction, in school children. A second, more recent study, examined the association between inominate torsion and four clinical tests of sacroiliac dysfunction. None of the tests, showed any value in identifying inominate torsion. However, one test, the Gillet test, showed a good correlation with low back pain, and the author suggests that it is possible, that the test is a measure of sacroiliac hypomobility, rather than inominate torsion. (Levangie 1999).

Due to the controversy surrounding the prevalence of pain of sacroiliac joint origin, it was considered necessary to take into account evidence based on a more objective assessment and diagnosis, as opposed to the non-validated use, of various clinical examinations.

The following two studies met that requirement:

Schwarzer et al. (1995) and Fortin et al. (1994b) both accepted the sacroiliac joint as a major source of low back pain, predicting a prevalence of sacroiliac syndrome in between 13 and 30% of patients with low back pain, as a result of their findings.

These studies both recognised, the present lack of validity of clinical assessment of the joint in diagnosing pain of sacroiliac joint origin and how this lack of satisfactory measurement criterion, would further negate its existence. In an attempt to provide an objective means of diagnosis the researchers made use of a sacroiliac joint block and injection/ arthrography technique respectively. In this way, pain was provoked and relieved, and in both instances zygapophysial joint blocks were performed initially in the lumbar spine as an internal control against placebo responses from the

patients. When pain relief following sacroiliac joint injection, was accompanied by a negative control block, it was accepted, as evidence that the injected structure was the source of pain.

Schwarzer et al. (1995) suggested that the prevalence estimates should be considered minimum values because the low back pain population investigated only included patients with pain below L5-S1. The authors stated that the trial was biased against finding the condition because they had ruled out possible sacroiliac syndrome patients from patients presenting with pain above this level. However, it would seem possible that including the patients presenting with low back pain above L5 would in fact increase the proportion of patients who were unlikely to have pain of sacroiliac joint origin, thereby decreasing the prevalence ratio of sacroiliac joint pain in the low back population.

The researcher of the present study does however agree that the estimated prevalence in the study by Schwarzer et al. (1995) should be considered a minimum value. Each patient evaluated in this study had been considered to be in severe enough pain by the referring clinician, to warrant invasive investigation. It would seem likely that patients in the mild to moderate category of pain, who were not considered for the study, would certainly carry a significant portion of possible sacroiliac joint patients.

Fortin et al. (1994b) emphasised that due to the similar presentation of sacroiliac joint syndrome and intervertebral disc syndrome, the failure to consider the former diagnosis could result in a large percentage of patients receiving unnecessary and expensive diagnostic tests and misguided treatment. Consequently, the frequency of the diagnosis of "sacroiliac syndrome" has recently increased among physical therapists (Mooney 1991:1556).

2.3 ANATOMY OF THE SACROILIAC JOINT

The paired sacroiliac joints lie within the pelvic ring and are surrounded by a joint capsule. Anteriorly, a thickening of this capsule forms the anterior sacroiliac ligament. Posteriorly, the capsule is rudimentary or absent and the posterior border of the joint is formed by the strong, thick interosseous ligament and the posterior sacroiliac ligament which provide the main stabilising force of the weight-bearing joint (Bernard and Cassidy 1991:2110-1).

Daum (1995) described the function of the sacroiliac joint ligaments in comparison to the cables of a suspension bridge maintaining stability in a joint that offers little intrinsic articular stability, despite the significant forces it sustains.

The sacroiliac joint is a true diarthrodial articulation consisting of a fibrocartilagenous iliac surface and a thicker hyaline sacral surface (Warwick and William 1973:444). The joint surface is auricular or 'C' shaped, with the convexity facing anteriorly and slightly inferiorly and qualifies as a true synovial joint due to the following four facts:

1. The presence of a joint cavity, containing synovial fluid.
2. Adjacent bones having liagmentous connections.
3. An outer fibrous joint capsule with an inner synovial lining.
4. Cartilagenous surfaces allowing motion. (Bernard and Cassidy 1991:2109).

Unlike other synovial joints in humans, there are distinct microscopic differences between the sacral and iliac sides of the joint. Prior to puberty, the iliac side is rough in texture and bluish in colour, with the friable appearance of fibrocartilage, while the sacral surface appears smooth, glistening and creamy-white in colour, typical of hyaline cartilage. These differences are evident throughout life (Bernard 1997:75). In the second decade of life, a concavity develops on the entire length of the iliac surface that corresponds to the concavity on the sacral side, with degenerative changes presenting as early as the third decade, on the iliac side (Bernard and Cassidy 1991:2110).).

The contours of the joint surfaces continue to change with age and by the third decade there is an increase in the number and size of the elevations and depressions, which interlock to limit mobility (Gatterman 1990:112). These changes, which occur later in females are manifested by increased joint irregularities, crevice formation and fibrillation, and are only evident on the sacral side around the fourth or fifth decades. By the sixth and seventh decades marked degenerative change is present in the form of large osteophytes, deep erosions, thickened, stiff capsules and fibrous interconnections linking the joint surfaces. In sacroiliac joint dissections by Bowen and Cassidy (1981) it was noted that despite the restricted mobility due to the degenerative changes, all specimens maintained some degree of mobility, and even as late as the eighth decade, true bony ankylosis was rare.

In human dissections both the iliac and sacral surfaces displayed roughening of the cartilage and Vleeming *et al.* (1990a) described a coarse texture with the consistent presence of ridges and depressions. The author considered the roughening a

physiological adaptation and not pathological change. It was hypothesised by the author of the present study, that this roughening of the cartilage, occurring as a normal adaptation to the loads on the joint, could contribute to the sacroiliac joint locking in an altered biomechanical position, referred to by chiropractors as joint dysfunction.

Innervation of the sacroiliac joint is extensive and will be discussed in section 2.4 as a result of the implications of nerve irritation on pain referral and the consequent clinical picture.

2.4 BIOMECHANICS: MOBILITY OF THE SACROILIAC JOINT AND SACROILIAC DYSFUNCTION (EVIDENCE OF THE SUBLUXATION).

2.4.1 SACROILIAC JOINT MOBILITY

The sacroiliac joint has two functions: to provide elasticity to the pelvic rim and to serve as a buffer between the lumbosacral and hip joints (Kikaldy-Willis et al. 1992).

Gatterman (1995:453) commented that until recently, the sacroiliac joints were not commonly considered to be mobile enough, to cause significant dysfunction from restricted motion. However, as early as 1974, Frigerio had demonstrated that although sacroiliac motion is very slight (3-5°), it has been shown to occur in both anatomic specimens and living subjects. Frigerio (1974) suggested, that this shift in

the understanding of sacroiliac joint motion resolved a long-standing controversy in manipulative orthopaedics.

More recently, further studies have supported the mobility findings by Frigerio (1974) in both symptomatic and asymptomatic patients, as well as cadavers.

Sturesson (1997:175) used the sophisticated roentgen stereophotogrammetric analysis to demonstrate mobility in the sacroiliac joints of twenty-five patients with sacroiliac joint disorders. There were no differences found between the symptomatic and asymptomatic joints, with average rotations between 2.5° and translation of 0.7mm. Wang and Dumas (1998), examined the mechanical behaviour of the sacroiliac joints in female cadavers. Lateral rotation and nutation rotation were found to be the predominant motion, limited to 1.2° , while translation was recorded up to 0.9 mm.

The demonstration of sacroiliac joint motion, in the above studies gave support to the chiropractic theory that with the significant evidence of sacroiliac joint motion and subsequent joint subluxation, this joint is treatable by the chiropractic adjustment.

Cyriax and Cyriax (1983:76), agreed that movement occurred at the sacroiliac joint, limited to 0.25mm, but seemed to question the joints involvement in back pain and emphasised that the sacroiliac joint was rarely at fault in cases of low back pain.

However, a decade later (1993:80), they stated that minor subluxations of the joint could be a source of pain and that these cases would respond well to manipulation.

2.4.2 EFFECTS OF AGE AND SEX ON SACROILIAC JOINT MOBILITY

There was very little evidence to suggest that mobility of the sacroiliac joint, would be reduced with age. Within the age range employed in the present trial (18-49), there was no indication that motion may be reduced due to increasing age. However, there was sufficient evidence in the reviewed literature to suggest that mobility within the female sacroiliac joints was likely to be greater than the male sacroiliac joints. The effects of both age and sex on the mobility of the sacroiliac joints will be discussed below, as reviewed in the appropriate literature.

Kirkaldy-Willis et al. (1992:123) state that after the sixth decade fibrosis within the joint can result in fibrous ankylosis, and rarely bony ankylosis. In contrast, Vleeming et al. (1992) believe that ankylosis of the sacroiliac joint is not the normal situation and in a study of embalmed elderly humans, most sacroiliac joints were mobile, allowing rotation of up to 4°. This was in agreement with Jacob and Kissling (1995), who found that in a group of healthy volunteers between 20 and 50 years old there was no decrease in mobility with age.

In a biomechanical study of the sacroiliac joints, Vleeming et al. (1990b), concluded that under abnormal loading conditions of sacroiliac joints with ridges and depressions it is theoretically possible that a sacroiliac joint is forced into a new position where ridge and depression are no longer complementary. The author regarded this abnormal joint position as a blocked joint, with an abnormal axis of

motion. Gatterman (1995:454) referred to this as a manipulable subluxation and postulated that the resultant restriction of movement or aberrant motion that occurs from a shift in the normal axis of rotation then produces a sacroiliac subluxation syndrome.

In a former anatomical study, (Vleeming et al. 1990a) noted that the female sacroiliac joint was both smaller and flatter than the male. This anatomical difference combined with the hormonal weakening of ligaments and pubic symphysis in pregnant and menstruating females, may lead to a relative hypermobility of the sacroiliac joints (Cassidy and Mierau 1992).

In the mobility study by Stureson (1997:175) the ratio of female to male patients diagnosed with sacroiliac joint dysfunction was 28:6 and the researchers found an average 30-40% more mobility in the sacroiliac joints of the female patients. These anatomical and biomechanical differences between the sexes may explain the high ratio of sacroiliac joint pain in female to male patients selected from a source population of one hundred patients with low back pain. The source population, with low back pain, had a ratio of 7:3 male to female patients. Each patient was subjected to a sacroiliac joint block, using 1% lignocaine. Patients who had pain relief following a positive response to a sacroiliac joint injection, formed a new group in which the male to female ratio was lowered to 1:1, indicating that females in this study had a higher proportion of pain of sacroiliac origin than males (Schwarzer et al. 1995).

Other studies have shown a similar predominance of females to males with sacroiliac joint dysfunction, including a study by Gemmel and Jacobson (1990) in 83 college students, and a study on the usefulness of sacroiliac joint tests in 219 patients by Cibulka and Koldehoff (1999).

Both studies had a relatively higher ratio of females with sacroiliac dysfunction when compared to the ratio of male to female patients with low back pain. Paris (1997) suggested that joint dysfunction was a result of hypermobility of the joint allowing the joint to become 'locked' in a position at the end range of motion, and in correlation with the studies above, he believed that this was commonly found in young females.

2.4.3 CLINICAL ASSESSMENT OF SACROILIAC JOINT BIOMECHANICS

This locking of the sacroiliac joint has never been demonstrated on x-ray (Lewit and Rosina 1999). However, it was these researchers who developed a new motion palpation technique, which failed to demonstrate a change in motion of the bony landmarks on x-ray, but did demonstrate a noticeable change in thumb position of the examiner, when markers were placed under the thumbs. The explanation of this phenomenon, was that the perceived motion of the sacroiliac joints, was actually a change in tissue tension over the joint, which was absent if the sacroiliac joint was restricted.

Schaefer and Faye (1990:95) described sacroiliac motion in terms of upper and lower articulations. The lower section allows a slight sliding motion anteriorly-inferiorly and posteriorly-superiorly, as well as a rotating action, while the upper section offers relief to the relatively weak antero-superior sacroiliac ligaments. The upper articulation is at the level of the first sacral segment and the lower one is level with the second and third sacral segments. Schaefer and Faye considered this important from a chiropractic perspective, because, when functioning optimally these two articulations would act reciprocally. However, if one joint becomes partially fixated, the contralateral side will only be able to pivot around the abnormal axis of the fixated joint, with obvious biomechanical alterations.

The sacroiliac joint may cause pain due to disease, inflammation, or movement dysfunction (Hesch 1997:535). Movement dysfunction was described as hypermobility or hypomobility. If the sacroiliac joint was hypomobile it would not be able to absorb shock optimally and the stresses of daily living would begin to overload surrounding structures. Hesch (1997:535), went on to describe the hypomobility as transient and responsive to treatment and often coexistent with contralateral hypermobility. He differentiated this 'apparent' hypomobility from true hypomobility, which is resistant to treatment and more likely to be associated with degenerative change.

Gatterman (1990:114) described the sacroiliac joint like a typical vertebral-motion-segment, which may take the form of simple joint locking or joint locking with compensatory hypermobility in adjacent articulations.

This compensatory hypermobility proposed by Hesch (1997:535) and Gatterman (1990:114) would result in the contralateral sacroiliac joint, being subject to increased motion demands and possibly more prone to overload and subsequent inflammation and pain. Gatterman (1990) in agreement with Kirkaldy-Willis et al. (1992) further suggested that pain over the hypermobile joint could be due to piriformis muscle spasm in an attempt to stabilize the joint.

This hypothesis proposes that sacroiliac joint dysfunction may activate muscle contraction and subsequent spasm in the musculature overlying the joint (piriformis). The theory of muscle activation seems to be substantiated by a recent study conducted on porcine specimens. However, the muscles involved did not include the piriformis muscle. The recent publication by Indahl et al. (1999) described the regulatory function of the sacroiliac joint on reflex muscle activation. Ten domestic pigs were used to demonstrate how stimulation of nerves in the ventral sacroiliac joint, activated contractions in gluteus medius and quadratus lumborum muscles, while stimulation of the dorsal sacroiliac joint capsule activated contractions in the multifidus muscle fibres nearest to the joint. The authors proposed that in light of their findings, the range of motion of the joint and its innervation seem well suited

for detecting various loading patterns during locomotion and subsequently affecting segmental level control in the lumbar spine and overall posture.

2.5 CLINICAL FEATURES OF SACROILIAC SYNDROME

2.5.1 CASE HISTORY

The clinical history of sacroiliac syndrome will not always include onset following traumatic injury, although Gatterman (1990) mentioned a number of minor traumatic injuries that involved torsional stress to the affected joint. The implicated mechanisms of injury included, falls, lifting injuries with rotational stress, twisting in bed and stepping off a curb, resulting in jamming of the joint, usually at an extreme range of motion, either in the sagittal or horizontal plane.

In a study concerned with sacroiliac joint prevalence by Schwarzer *et al.* (1995), the onset of pain was work-related in 42% of patients, 37% of patients had been involved in an MVA, and the remaining 21% were listed with other causes.

A predominance of sacroiliac joint syndrome in female patients, has been discussed earlier in this review, with reference to the development of ligamentous laxity, during and following pregnancy, as well as prior to the onset of menstruation, which would render the sacroiliac joint more vulnerable to mechanical strain (Cassidy and Mierau 1992). This hormonal induced laxity would predispose the joint to slippage and

fixation, to the degree that Gatterman (1990) recommended the use of a trochanteric belt (sacroiliac orthotic) to stabilise the joint during this period.

2.5.2 SIGNS AND SYMPTOMS

The clinical presentation of sacroiliac joint syndrome was found to be obscure (Fortin et al. 1994a) and as a result these authors used an injection/arthrography technique to map pain referral generated from within the sacroiliac joint. The results indicated a distribution of pain over the medial buttock, sometimes including the lateral buttock extending to the greater trochanter and superior lateral thigh.

Kirkaldy-Willis et al. (1992) included the presence of pain, over the joint in the region of the posterior superior iliac spine, that varies in the degree of severity with referral to the groin, over the greater trochanter, down the back of the thigh to the knee and occasionally, down the posterior calf to ankle, foot and toes. It was not clear from the text, whether this pain distribution was established by clinical experience or clinical trials. However, the similarities to the pain map used by Fortin et al. (1994a) add to the reliability of both the described patterns. Schwarzer et al. (1995) established that when comparing patients with pain of sacroiliac joint origin and those with low back pain which was not of sacroiliac joint origin (determined by a placebo-controlled injection study) the only distinguishing factor between patients with sacroiliac pain and those without, was groin pain. In addition, the authors established that the condition would be unilateral in about 60% of the patients.

Schaefer and Faye (1990:264) describe the innervation of the anterior aspect of the joint from the posterior branches of the L3-S2 nerve roots and the superior gluteal nerves (L5-S2). The authors believe that irritation to the joint anteriorly usually refers pain to the groin and anterior thigh. The posterior aspect of the joint is innervated by the posterior rami of the L5-S2 spinal nerves and inflammation of the posterior aspect of the joint refers pain to the buttocks, back, thigh and follows dermatomal distribution. If the sciatic nerve pierces the piriformis muscle (a common occurrence), rather than passing above or below the muscle as it exits the pelvis, sacroiliac distortion or inflammation may involve any of the sciatic fibres, due to the relationship of the piriformis muscle to the sacroiliac joint.

Cassidy and Mierau (1992) suggest that the varied referred pain patterns of this syndrome are a result of innervation of the joint, being from such a wide range of spinal nerve levels.

According to Bernard and Cassidy (1991:2115) the pain may be sharp, aching or dull and is aggravated by bending, sitting or riding in a motor vehicle, and alleviated by standing and walking. Bernard and Cassidy (1991:2115) go on to say that the pain is usually unilateral with a right-sided predominance. This lateralisation is thought by the author of the present study to be directly associated to the presence of right-sided dominance in the general population. Interestingly, Toussaint *et al.* (1999)

found a 60:40 right-sided predominance of sacroiliac dysfunction, which was not necessarily, related to the pain distribution, in a group of 480 construction workers.

There are no signs of nerve root tension or neurological deficit in sacroiliac syndrome, however, straight-leg raising may be reduced due to hamstring tightness and or the low back pain (Cassidy and Mierau 1992). Furthermore, the patient may complain of paraesthesias but there would always be preservation of temperature, pain, position and deep pressure sense. Any reported weakness in the lower limbs would be a subjective weakness due to pain and not a neurological deficit. Deep tendon reflexes are always preserved. (Cassidy and Mierau 1992).

2.6 DIAGNOSIS OF SACROILIAC SYNDROME

Patients presenting with the clinical picture discussed above should always be considered under the following classification of back pain (Macnab 1990:22-25):

1. Viscerogenic
2. Neurogenic
3. Vascular
4. Psychogenic
5. Spondylogenic

Bernard and Kirkaldy-Willis (1992:203) logically considered making a specific diagnosis a prerequisite for initiating an effective treatment programme. The authors considered referred pain and radicular pain syndromes in their differential diagnosis of mechanical low back pain. Posterior joint syndrome, sacroiliac joint syndrome, myofascial syndromes, Maigne's syndrome, spondylolisthesis and segmental instability, are referred pain syndromes, all of which cause low back pain predominantly, with variable radiation of referred pain into an extremity. Radicular pain syndromes discussed, included, the intervertebral disc syndrome, lateral and central spinal stenosis, and caused low back and leg pain. They were clinically distinguished from referred pain syndromes by the presence of nerve root tension signs and motor, reflex or sensory deficits.

Bernard and Kirkaldy-Willis (1992:211) indicated that the most reliable means to make a specific diagnosis of sacroiliac syndrome is a positive response to manipulation or injection of the joint. For the purpose of the present research programme, both of these methods were impractical in terms of making a specific diagnosis prior to acceptance into the study and the use of clinical examination was indicated.

According to Kirkaldy-Willis et al. (1992:123-126), the objective presentation of sacroiliac syndrome includes tenderness or pressure over the posterior superior iliac spine in the region of the sacroiliac joint or buttock. Movement of the joint is usually

restricted. The syndrome is often accompanied by, unilateral, lumbar, paraspinal muscle spasm and gluteal trigger points. (Cassidy and Mierau 1992).

Patients are subjected to pain provocation tests, which stress the sacroiliac joint in order to establish whether the pain is of sacroiliac origin. The Kirkaldy-Willis (1992:124-125) model included Patrick Fabers test, Gaenslen's test and Yeomann's or Extension test.

Kirkaldy-Willis (1992:124-125) considered two out of three positive tests a likely possibility of sacroiliac syndrome. However, Laslett (1997:293) considered three out of four positive sacroiliac stress tests a more reliable model and this ratio was considered appropriate for this trial. Gaenslen's test and the Thigh Thrust or Posterior Shear test were evaluated by Laslett and Williams (1994), for inter-examiner reliability and both were found to have substantial reliability between therapists (88.2% and 94.1% respectively, with a $p < 0.001$ level of significance). The Kappa coefficient was used when evaluating the results to effectively rule out proportion of agreement expected by chance.

The Thigh Thrust Test, was later evaluated by Broadhurst (1997:547) in terms of sensitivity and specificity. The trial was double-blinded, placebo-controlled, and evaluated both Patrick Faber and the Thigh Thrust test on forty patients. Using the criterion that the patients pain was diminished by 75% following an injection of the joint with 1% lidocaine, the two tests were found to have high levels of sensitivity and specificity (at a 0.005 level of significance) and were considered to be more than adequate to diagnose pain of sacroiliac origin. As a result, for purposes of this study,

the Thigh Thrust test was added to the Kirkaldy-Willis model, with three out of four positive tests required in order to confirm the diagnosis of sacroiliac syndrome in the present trial.

Laslett (1997:288) felt that pain provocation tests (that mechanically stress the sacroiliac joint), have better potential, than motion palpation tests, when diagnosing sacroiliac syndrome, since the symptoms that led the patient to seek help are being used to indicate positivity or negativity of the tests. Van der Wurff *et al.* (2000) conducted a methodological review, concerning the reliability of eleven clinical tests of the sacroiliac joint. The authors came to the same conclusion as Laslett (1997), stating that there was no evidence to support the use of mobility tests for the diagnosis of sacroiliac syndrome, but accepting the reliability of both Gaenslens and Thigh Thrust tests to demonstrate provocation of sacroiliac joint pain.

Radiographic changes were not usually detected in the sacroiliac syndrome, (Kirkaldy-Willis *et al.* 1992; Laslett and Williams 1994), but blurring or erosion of the joint surface indicated the possibility of sacroilitis. Kirkaldy-Willis *et al.* (1992) also noted that degenerative changes in the joint were common in later life, including subchondral sclerosis (more marked on the iliac side), and osteophytes at the lower margins of the joint.

Therefore, while radiographs do not assist the physician in making a specific diagnosis, they do help in excluding other conditions, and should be considered when a definitive diagnosis is questionable. As a result, in the present trial radiographs

were not used routinely in making a diagnosis. Patients who had been recently involved, in significant traumatic injury (eg. Fall or MVA) or whose clinical examination indicated the possibility of a condition other than sacroiliac syndrome, were not included into the trial.

2.7 MANAGEMENT OF SACROILIAC SYNDROME

2.7.1 MANIPULATION

The definition of manipulation is broad and includes both mobilisation techniques and the more specific chiropractic adjustment. The adjustment is described by Gatterman (1990:112), as a short lever, high velocity thrust, of controlled amplitude, directed to restore mobility to individual articulations.

Manipulation is rendered effective by a combination of mechanical, neurophysiologic and psychological mechanisms and the principle purpose of manipulation is to relieve pain and increase function (Paris 1983). Herzog (1995), further discussed the reflex responses in the mechanoreceptors of joint capsules and skeletal muscle, following high velocity manipulation. This reflex reaction lead to reflex inhibition of muscle spasm, and was associated with diminished pain perception.

In a systematic review of the literature Cassidy *et al.* (1992:292) found that there have been more controlled clinical trials of the manipulation for low back pain than for any other treatment approach. The researchers reviewed 25 trials on manipulation, and in the majority of the trials the authors concluded that manipulation was accepted as a more effective conservative treatment when compared to the respective control groups.

While Assendelft et al. (1992) found 30 randomised control trials on manipulation for low back pain in a Medline search between 1966-1990, they only identified five of these as chiropractic trials. The trials were considered poor in terms of methodological quality and yet the authors still supported chiropractic as an effective treatment of back pain.

In a similar review by Manga et al. (1993) it was concluded that chiropractic manipulation was shown to be more effective than many alternative treatments for low back pain. In addition, the authors called for further validation of traditional, medical management of low back pain, which at that time was not supported by the same degree of clinical evidence for the effectiveness of chiropractic.

Meade et al. (1990) conducted a randomised controlled trial comparing chiropractic manipulation to hospital outpatient treatment, and found significantly greater improvement (where $p=0.01$) after a two-year follow up, in the manipulation group compared to the outpatient group. These results were still evident at an extended three year follow up ($p=0.004$) and were supported by greater patient satisfaction in the chiropractic group (Meade et al. 1995). It was noted, that the outpatient treatment conducted in this trial, included mostly mobilizations and manipulation performed by physiotherapists. This was not considered to be a commonly implemented management of low back pain in a hospital based outpatient center, and the researcher of the present trial was reluctant to draw conclusions about the superiority of chiropractic management over medical management of low back pain, in this instance. However, this opinion did not challenge the principle findings of the

trial and medical reviews by Assendelft et al. (1992), found the trial to be one of the superior trials in this field.

In contrast to the two and three-year follow up results in the study by Meade et al. (1995), Cassidy et al. (1992:292) found that earlier results of controlled clinical trials suggested that manipulation was successful in speeding recovery from low back pain but claims of long term effects were unsupported.

Twomey and Taylor (1995) stated that spinal manipulative therapy had become one of the most widely used methods of treating vertebral column pain, and would continue to be a popular choice for many people.

van Tulder et al. (1997) conducted a systematic review of randomised control trials on the most common conservative, low back pain interventions. The results were based on generally accepted criteria used to evaluate intervention research, and indicated that there was no evidence to support the use of manipulation in acute low back pain, mainly due to contradictory results of the different trials. However, there was strong evidence to advocate the use of manipulation in chronic low back pain. Interestingly, in the same review, the authors identified only one low quality trial on the use of a low back orthotic, indicating that there is no evidence of its effectiveness in the treatment of low back pain.

Following the systematic review of randomised controlled trials, conducted by van Tulder *et al.* (1997), which found no evidence to support the use of manipulation in acute low back pain, a trial was conducted by Morton (1999), which challenged these findings. Convenience sampling was used, and twenty-nine patients with acute low back pain were randomly assigned to two groups each receiving a low back and abdominal muscle exercise program, but only one group received manipulation. Results were based on pain, range of motion and disability measurements and indicated that the manipulation group improved faster and to a greater degree than the group who received the exercise program alone. The difference between the groups was significant ($p < 0.0005$) and was established with a small sample population, early in the trial.

A randomised, controlled trial by Broughton and Kretzmann (2000) compared manipulation of the low back to manipulation combined with low back strapping, for the treatment of low back pain in the dysfunctional stage. Sixty patients were treated over a two-week period and both groups responded favorably to treatment. Despite subtle clinical differences favouring the strapping group, the two groups were found to be equally effective, in the treatment of low back pain in terms of subjective and objective clinical findings, at a 95% confidence level.

2.7.1.1 MANIPULATION OF THE SACROILIAC JOINT

Manipulation has received further recognition in the specific treatment of the sacroiliac joint and Cassidy and Mierau (1992) considered manipulation as the first line of treatment for sacroiliac syndrome. Kirkaldy-Willis and Burton (1992:249) stated that manipulation was the most certain way of relieving pain in this condition. In a review article, Hendler *et al.* (1995) agreed that sacroiliac subluxations are dramatically relieved by manipulation.

A pilot study by Reid and Peers (1996) added support to the above statements. The trial involved thirty patients diagnosed with sacroiliac syndrome. The patients were randomly divided into two groups, where one group received a side posture adjustment and the other received prone-drop mechanism manipulation. The results indicated that the two different manipulative techniques were equally effective in showing significant improvement in clinical signs and symptoms over ten treatments (a 95% confidence level was employed in the trial).

2.7.1.2 CONTRAINDICATIONS AND SIDE EFFECTS OF MANIPULATION

General contraindications to manipulation include diseases of the spine: tuberculosis, metastasis, osteomyelitis, acute inflammatory joint disease, bleeding disorders and advanced osteoporosis (Paris 1983). Specific contraindications include instability,

spondylosis, fracture or dislocation, cauda equina syndrome, large abdominal aneurysm, visceral referred pain (Cassidy et al. 1992)

Senstad et al. (1996), discussed side effects to manipulation, in terms of common reactions (i.e. local or radiating discomfort, headache or tiredness) and uncommon reactions (i.e. dizziness, nausea, hot skin, and other complaints). The authors conducted a prospective, clinic-based survey in Norway, receiving responses from 102 chiropractors, regarding 1058 patients who attended 4712 treatments. The authors noted, that reactions to spinal manipulation, were more typically reported by females, after the first two treatment sessions. Treatment reactions were shown to increase with an increase in the number of spinal areas adjusted, and the treatment of the thoracic spine, induced the highest number of reported reactions treated (95% confidence interval). A similar prospective study was conducted by Leboeuf-Yde et al. (1997) in Sweden, to investigate whether the characteristics of unpleasant side effects after spinal manipulative therapy, would coincide with the Norwegian study above. Leboeuf-Yde et al. (1997) concluded that while the study design was weak, the similarities between the results of the two studies was sufficient to validate the findings. The latter study found that reactions to spinal manipulation were common, but benign and short-lasting, appearing soon after treatment and disappearing within 48 hours. The most common reaction was local discomfort, less commonly patients reported pain distant to the area of treatment or fatigue, and very rarely reported uncommon reactions such as nausea, dizziness or other complaints. (A 95% confidence interval was employed in the trial).

2.7.2 ORTHOTICS

Paris (1983) noted that few practitioners use manipulation as a sole treatment method. The use of an orthotic will be discussed below in terms of its application in combination with manipulation.

Levine (1984) describes a corset as a type of orthotic which functions by increasing intra-abdominal pressure, and a brace as an orthotic which functions by reducing mobility. This description of a brace applies to the sacroiliac stabilising orthotic used in this research study as it functions to reduce the mobility of the pelvis. This type of orthotic has been described in the literature by various names, including, trochanteric belt, sacroiliac belt, lumbar-sacral brace and sacroiliac brace.

Due to the paucity of available literature on low back pain treatment, excluding manipulation, the same acceptance of alternative management protocols, is not evident, especially when considering orthotics.

Despite the widespread use of orthotics for lower back pain, some authors have still questioned their prescription. The comprehensive Quebec Task Force Report (Le Blanc *et al.* 1987) concluded that there is no documented evidence to indicate, that orthotics reduce the period of disability due to low back pain. In addition, Flor and Turk (1984) concluded that corsets and braces, although widely used, have no proven effect.

However, despite these negative statements, two outcome-based studies, published prior to the Quebec Task Force Report, had favourable results, with regard to the use of low back orthotics. A randomised, controlled study by Coxhead *et al.* (1981), assessed the application of four different therapies, in the management of pain in the sciatic distribution. The study design, enabled a comparison between patient response to individual therapies and a combination of therapies. This study included manipulation, low back orthotics, traction and exercises. Each of the therapies were associated with a small degree of benefit over and above spontaneous recovery, and for manipulation the benefit was statistically significant, where $p < 0.05$. There was good evidence that a significant trend existed in favour of combining treatments, which was found to be more effective than using a single treatment protocol, where $p < 0.01$.

In an earlier study by Doran and Newell (1975), on 456 lower back pain patients, the patients were randomly allocated to one of four treatments: manipulation, physiotherapy, low back orthotic or analgesic tablets. The orthotic was found to be less expensive than manipulation and physiotherapy, safer than drugs and as effective as the other treatments, (there were no significant differences between treatment groups at the 5% level of significance).

In a prospective, randomised trial by Pope *et al.* (1994), it was found that patient confidence levels were significantly lower in the corset group ($p < 0.05$) compared to the massage, transcutaneous muscle stimulation, and manipulation groups. (The

latter, having the highest level of patient confidence and satisfaction). The results showed a significant decrease in pain, increase in flexibility and strength and increase in time to fatigue, in seconds ($p < 0.05$), in the manipulation group. Although no significant difference was demonstrated between the four groups, significant improvement for each individual therapy was noted. The corset group demonstrated significant improvement in pain levels and surprisingly, in voluntary extension effort (strength). In addition, the authors had hypothesised a decrease in flexibility in the corset group, but this did not occur over the three-week treatment period.

According to Pope (1991), back orthotics have enjoyed great acceptance by physicians and yet there are few prospective clinical trials on low back orthotics, which used controlled selection of the sample population prior to treatment. In the United States, a national survey indicated that only one percent of orthopaedic surgeons had never made use of appliances (orthotics) in the treatment of lower back pain (Perry 1970). It is not known, whether this trend still exists, but Margo (1994) stated that back braces were being used with no studies to clearly demonstrate their efficacy. For this reason it is important to establish the effect which low back orthotics have in the treatment of the condition under investigation as well as the cost-effectiveness when compared to other available therapies.

2.7.2.1 SIDE EFFECTS OF ORTHOTICS

As with other methods of treatment, the use of back supports, is not, without drawbacks, and possible side effects include reduced muscle function leading to disuse atrophy, local skin irritation and psychological dependency (Sypert 1987). Consequently, the author emphasised that the goal of treatment should be to terminate the use of the orthotic as soon as it's therapeutic value has been achieved. Levine (1984) had previously emphasised that braces (orthotics) should not be prescribed for indefinite use. He indicated that after only two to three weeks of use, the patients may develop both psychological and physiological dependence on the support, and prolonged use may result in musculature atrophy, weakness and further injury.

2.7.2.2 STABILISING SACROILIAC ORTHOTIC

The proposed mechanism of action of the sacroiliac stabilising orthotic includes:

- support to the pelvic ring
- physical limitation of range of motion therefore decreasing stress to painful structures in the back
- insulation of the skin, increasing warmth and decreasing pain sensation
- tactile stimulation of the device affording beneficial modification of muscle action with decreased stress to the back. Pope (1991).

- Sybert (1987) included the benefit of the brace as a psychological reminder to the patient to avoid activities, which may aggravate the back pain.

A publication by Gill and Callaghan (1998) established an association between reduced proprioception and chronic low back pain ($p < 0.05$). The trial compared spinal positioning in twenty patients with low back pain and twenty patients without low back pain. It was not established whether reduced proprioception was a result of the low back pain or a possible cause of the low back pain in this sample population. Indahl *et al.* (1999) agreed, as a result of their muscle activation study on the sacroiliac joints of porcine specimens, that lesions in the joint capsule, may disrupt the proprioceptive function of different receptors, resulting in prolonged muscle contraction. Proprioceptive enhancement through lumbar spine bracing was demonstrated recently by McNair and Heine (1999). Forty blind-folded, asymptomatic patients showed less error in trunk positioning when using the neoprene lumbar spine orthotic as a result of improved somatosensory information received by the central nervous system. The results were more significant when the patient was not already adept at the task ($p < 0.05$). Intuitively, an awareness of the trunk position during movement, may be an important factor that influences possible injury. The researchers speculated, that back injury could possibly result in damage to structures that provide proprioceptive feedback to the central nervous system and, that this would reduce the patients awareness of his or her trunk position.

With these studies in mind, it could be concluded that wearing an orthotic during the early period of rehabilitation would allow the patient to move more safely and with less pain activation, as a result of enhanced proprioception in the injured spine.

In a case study on sacral load displacement in a weightlifter, Gosselin *et al.* (1998) used a linear potentiometre to record in vivo measurements of the sacrum on the ilia. Loads were added from 0-200 Newton's (N), and measured after 30 seconds to allow for creep. The least amount of movement (<1mm) occurred with 30 degrees hip flexion and the use of a pelvic belt. The situation of most displacement (9.2mm) was at 0 degrees hip flexion without the pelvic belt. The flexed position did not allow more than 6mm displacement. The stabilisation of the sacroiliac joint during hip flexion was explained by the increased tension, which this position places on the thoracolumbar fascia.

Vleeming *et al.* (1997) proposed the self-locking mechanism, induced by load transfer as the thoracolumbar fascia contracts and in conjunction with gluteal muscle contraction, forms a stabilising force on the pelvis. This mechanism would have a similar effect as a sacroiliac stabilising orthotic, suggested by Jayson (1992) who stated that it would provide sufficient restriction of sacroiliac mobility to allow pain control in certain patients.

A combination of manipulation followed by the application of a sacroiliac orthotic has been suggested by a number of authors. Paris (1997:325) found that the sacroiliac joint was usually found to be hypermobile after manipulation and stated

that it would benefit from support. In a study of 100 patients diagnosed with sacroiliac syndrome, the researchers Xiaodong and Yonggang (1994) treated each patient with a manipulation of the subluxated sacroiliac joint followed by fixing the sacroiliac joint with a 10cm width elastic bandage. This study had a 100% recovery rate, which seems extraordinarily high and the validity of the study is questionable due to the apparent lack of a control group.

Dontigny (1997:473-474) also suggested the use of a lumbosacral belt, following correction of sacroiliac joint dysfunction, using a muscle energy technique to correct the functional leg length difference commonly found with sacroiliac joint dysfunction, and believed that if the support is applied without correction of the dysfunction, it may actually increase the pain by increasing pressure on uncorrected joints. However, Dontigny placed far more emphasis on the use of a 'self-bracing' mechanism, involving active contraction and strengthening of abdominal and gluteal muscles, than he did on the extrinsic support of the belt.

2.7.2.3 NON-STABILISING SACROILIAC ORTHOTIC

The mechanism of action of the non-stabilising sacroiliac orthotic (strapping), would include the three points stated below, without providing support to the pelvic ring or a relative immobilisation to the sacroiliac joints.

- insulation of the skin, increasing warmth and decreasing pain sensation. Pope (1991).

- tactile stimulation of the device affording beneficial modification of muscle action with decreased stress to the back. Pope (1991).
- Sybert (1987) included the benefit of the brace as a psychological reminder to the patient to avoid activities, which may aggravate the back pain.

For the present study, a very rudimentary comparison of the stabilising and non-stabilising orthotic, would be that the stabilising orthotic provided support to the joint and ligamentous structures, while the latter provided support to the soft tissue and musculature.

Davis (1995:3-1) indicated a number of situations in which taping would be inappropriate:

- when further assessment is indicated, and the nature and severity of the injury has not yet been established.
- after an acute injury, in order to allow the patient to continue with the activity in which he/she was injured.
- if there is functional disability causing obvious limitations in the patients movement patterns, strength, stability, balance and coordination.

Davis (1995:3-2) added that prolonged restricted range of motion, due to strapping, may weaken muscles and tendons, and in addition the strapping may provide a false

sense of security for the patient, who may develop psychological dependency on the support.

There is currently an abundance of orthotics available for prescription by practitioners. However, according to Grieve (1994:839) the advertising of (spinal) orthotics is rarely if ever accompanied by research data to validate the claims made by the supplier of the equipment.

This study will serve to establish the clinical efficacy of an orthotic which is a readily available adjunct to the treatment of a very common cause of lower back pain.

2.8 SUMMARY

In summary, sacroiliac joint syndrome, has been accepted by many practitioners, as a commonly occurring cause of low back pain (Bernard and Cassidy 1991; Kirkaldy-Willis 1992; Fortin *et al.* 1994b; Schwarzer *et al.* 1995)

Scientific evidence exists in the form of controlled, clinical trials on the efficacy of the various treatment protocols applied in this condition. As a result manipulation of the joint is a well-recognised approach to treatment (Cassidy *et al.* 1992) and manipulation of the joint is considered the first line of treatment for sacroiliac syndrome (Cassidy and Mierau 1992). It has also been suggested that a combination,

of two or more treatments, would have a more positive response to treatment than a single treatment protocol (Coxhead et al. 1981).

The use of an orthotic as a primary therapy for low back pain or as an adjunct to therapy has no documented evidence to support its wide spread acceptance (Le Blanc et al. 1987). However, the use of a sacroiliac stabilising orthotic, following manipulation of the sacroiliac joint, has been proposed, by Paris (1997:325); Jayson (1992:400) and Xiaodong and Yonggang (1994).

This study will serve to establish the efficacy of this protocol relative to using a non-stabilising sacroiliac support following manipulation, and help to shed more light on the pathogenesis of the condition.

3. MATERIALS AND METHODS

3.1 INTRODUCTION

This chapter gives a detailed description of the design, primary and secondary data, the subjects and interventions utilised. An overview of each questionnaire is discussed as well as the methods of statistical analysis and the process of evaluation of the data. The study design chosen was a randomised, comparative, clinical trial. This involved two treatment groups, both receiving chiropractic manipulation followed by the application of a stabilising orthotic in one group and a non-stabilising orthotic in the other group.

3.2 THE DATA

The data consisted of primary and secondary data.

3.2.1 THE PRIMARY DATA

- The case history (Appendix A), physical examination (Appendix B), lower back regional examination (Appendix C)
- The patient's perception of their pain level (Numerical Pain Rating Scale 101 : Appendix E)

- The patient's perception of their disability (Oswestry Low Back Disability Index : Appendix F)
- The patient's response to a questionnaire, regarding compliance, comfort and attitude to the stabilising orthotic (Appendix G).
- The patient's pressure threshold in terms of pain (Wagner Algometer).
- Orthopaedic testing including the results of four sacroiliac provocation/stress tests (Appendix D)

3.2.2 THE SECONDARY DATA

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

3.3 THE SUBJECTS

Subjects were drawn from the greater Durban area by means of mini advertisements, distributed locally and advertisements placed on noticeboards in gyms, corporate offices, and at tertiary institutions. Sixty patients were selected from those who responded, using purposive sampling. No stratification of the patients took place and they were accepted without criteria regarding gender, occupation, race, severity or chronicity of the condition.

Patients who responded to the advertisements by phone- call were only excluded from the study if they didn't fit the age criteria of 18-49 years, or if there was evidence of previously diagnosed spondylolisthesis (with or without instability), lumbar spine disc injury or other cause of hard neurological signs. All other patients were subjected to a case history, physical exam, low back regional examination and orthopaedic sacroiliac tests.

3.4 INCLUSION AND EXCLUSION CRITERIA

1) Due to the possible development of fibrous ankylosis in the sacroiliac joint after the sixth decade (Kirkaldy-Willis et al. 1992:123), only patients 18-49 years were accepted for the trial. This chronological range represents patients most likely to consult a chiropractor.

2) Any mechanical conditions associated with but secondary to sacroiliac syndrome (eg. latent myofascial involvement, facet syndrome) were assessed and noted in the lower back regional examination, but no treatment for these conditions were administered.

3) Patients presenting with active myofascial trigger points (Travell and Simmons 1983) which were symptomatic and referring pain in a similar distribution to sacroiliac syndrome, were excluded from the trial.

4) Patients presenting with lumbar spine facet syndrome as the primary causative factor, with the emphasis of the objective and subjective clinical signs in the lumbar spine, were not accepted into the trial.

5) Patients presenting with signs of nerve root entrapment were not considered for the trial.

6) Any additional low back pain treatment received during the treatment period of the trial resulted in exclusion of the subject. This included the use of analgesics, anti-inflammatory medication, muscle-relaxants, alternative orthotics or forms of manual therapy.

7) Patients who were currently on medication mentioned in criteria 6, were permitted into the trial on request 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.

8) Each patient who was allocated to group 2 was required to fill out a daily compliance diary regarding the wearing of the brace. Non-compliance regarding wearing of the brace resulted in exclusion of that patient's data from the trial.

9) Patients suspected of having contra-indications to spinal manipulation were not permitted into the trial. General contraindications to manipulation include diseases of

the spine: tuberculosis, metastasis, osteomyelitis, acute inflammatory joint disease, bleeding disorders and advanced osteoporosis (Paris 1983). Specific contraindications include instability, spondylosis, fracture or dislocation, cauda equina syndrome, large abdominal aneurysm, visceral referred pain (Cassidy *et al.* 1992). These were excluded on the grounds of clinical history and examination, and no further investigations were performed (eg. Radiographs or scans).

10) Pregnant females were not considered for the trial, due to the hormonal changes occurring during pregnancy, resulting in relaxin-induced ligament laxity and possibly instability of the sacroiliac joints which would contra-indicate an adjustment (Vleeming *et al.* 1990). This group was also considered more likely to respond to the effects of the sacroiliac stabilising orthotic and would have required stratification within the sample group, which was not implemented in this study.

11) Patients were requested to refrain from engaging in any new lifestyle or physical activities for the duration of the trial. Failure to comply, to these instructions resulted in exclusion from the trial.

3.5 DELIMITATIONS

This study was limited to the treatment of sacroiliac syndrome. The diagnosis of sacroiliac syndrome was made according to the clinical picture described in sections 2.4 and 2.5 above.

However, it was decided that the definitive diagnosis would be confirmed by the consulting clinician only if three out of four orthopaedic tests were positive. The four tests were all sacroiliac provocation/stress tests and included Patrick Faber's test, Gaenslaen's test and Yeomann's Extension test of the Kirkaldy-Willis (1992:123) model, and the Thigh Thrust or Posterior Shear test evaluated favourably by Laslett and Williams (1994) and Broadhurst (1997) for inter-examiner reliability, and sensitivity and specificity.

3.6 ETHICS

After an explanation of the trial, each patient had to complete and sign an informed consent form, prior to treatment commencing. Patients were told the precise nature of the study and were informed that they had a 50% chance of receiving a non-stabilising sacroiliac orthotic instead of a stabilising orthotic.

Both groups received an established and widely used form of treatment for low back pain in terms of the adjustment. While the use of orthotics and supports has not received the same level of acceptance as the adjustment for low back pain, they are still considered an appropriate form of therapy for this condition. (Haldeman et al. 1993).

The patients were informed that they were free to withdraw from the study at any stage. All patient information was treated confidentially.

3.7 THE SAMPLE GROUP

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

Group one was the control group and received chiropractic manipulation followed by the application of a non-stabilising sacroiliac orthotic (strapping).

Group two was the experimental group and patients in this group received chiropractic manipulation of the sacroiliac joint followed by the application of a stabilising sacroiliac orthotic.

3.8 MEASUREMENTS

Patients selected for the trial were required at the initial consultation, to complete a Numerical Pain Rating Scale 101 (Jenson et al. 1986), and an Oswestry Low Back Pain Disability index (adapted from Fairbank et al. 1980). Pressure readings, using an algometer were recorded (as kilograms per centimeter squared), using Wagner FDK20 model, and the results of four sacroiliac stress tests were recorded.

Patients from group two were required in addition to complete a compliance diary (Appendix I) regarding hours spent using the orthotic and types of activity

performed with and without the orthotic, for the duration of the treatment. The application of this diary was intended to encourage compliance and the information in the questionnaire was not used for any form of statistical analysis.

After the third consultation the above measurements were all repeated and recorded. In addition the compliance questionnaire was administered at this consultation, to patients from group two, to assess the patient response to the sacroiliac stabilising orthotic.

After the final consultation the measurements were repeated once again, including the compliance questionnaire.

3.8.1 SUBJECTIVE MEASUREMENTS

Subjective measurements were recorded from three questionnaires completed by the patients in writing. The questionnaires used were the Numerical Pain Rating Scale 101 (Jenson et al. 1986), an Oswestry Low Back Pain Disability index (Fairbank et al. 1980) and a compliance questionnaire (Appendix G) constructed specifically for this trial. The Numerical Pain Rating Scale (Appendix E) and the Oswestry Low Back Disability (Appendix F) questionnaires were completed before the first treatment and after the third and final treatments. The compliance questionnaire was completed at the third and final consultations.

3.8.1.1 NUMERICAL PAIN RATING SCALE 101

Subjective pain is still considered to be one of the most important measurements available to both researchers and clinicians (Jenson et al. 1986). The 101-point Numerical Pain Rating Scale is a questionnaire used to measure the intensity of pain a patient is experiencing. The patient was required prior to treatment, to indicate by means of a percentage the intensity of pain on a scale of 0 to 100, where 0 represents 'no pain' and 100 represents 'pain as bad as it could be'. Two values were recorded to indicate firstly the pain intensity when it is at it's worst and secondly the pain intensity at it's least. The average between these two figures is an indication of the patients pain level.

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

- ease of administration of the scoring
- relative rate of incorrect responding
- sensitivity with regard to questions
- sensitivity of statistical analysis
- relationship to a combination of pain intensity indices

The results of this study concluded that the Numerical Pain Rating Scale was superior to the other measures due to it's simple and practical method of

administering and scoring, which may be in written or verbal form and it's results did not seem to be dependant on age. These findings were in agreement with Downie et al. who as early 1978 had identified the Numerical Pain Rating Scale as having advantages over three other rating scales, in terms of accuracy.

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

3.8.1.2 THE OSWESTRY LOW BACK DISABILITY INDEX

This questionnaire is designed to give the researcher an indication of how the low back pain affects the patient's ability to manage in every day life. There are ten questions, with a possible six answers to each question. This gives each answer a maximum score of five and a minimum score of zero. The total score is then multiplied by two and represents a percentage of disability. (Fairbank et al. 1980).

The interpretation of the results were outlined 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

Tibbles et al. (1998) considers the functional status of the patient the most desirable outcome measure for both clinical use and research. Beurskens et al. (1995) evaluated the quality of four disease- specific questionnaires used in outcome based trials and concluded the Oswestry was a valuable outcome measure for the assessment of back pain within clinical trials. The Oswestry questionnaire along with a second disability questionnaire (Rolands), had been more frequently used and evaluated than the other outcome based questionnaires and as a result the authors were more certain about its responsiveness and validity.

A possible drawback of the Oswestry questionnaire was that it contained both performance based and capacity based questions making it unclear for the patient to answer whether they can perform the action or whether they think they can perform the action Beurskens et al. (1995). A second problem identified by Beurskens et al. (1995) and later by Enebo (1998) is that the time frame regarding the pain and disability is left undefined.

In the present research study, this problem was dealt with by verbally informing the patient about the respective time frames. The patient was asked to fill in the first

Oswestry questionnaire with regard to the pain experienced during their present low back pain episode. The second questionnaire, administered on the third visit, was with regard to their pain since the first treatment and the third questionnaire, administered at the sixth visit was with regard to their pain since the third visit. This method was used in an attempt to highlight changes in disability between the initial, third and final visits.

Tibbles *et al.* (1998) evaluated the Oswestry questionnaire concluding that it possessed stable psychometric properties. The authors established favourable results, identifying no evidence of set bias response (the responses to questions did not seem to be a result of format of the questionnaire), good construct validity (the results were consistent with the expected response to treatment) and strong internal consistency (there was no evidence of an exaggerated outcome as a result of redundancy of the questions).

3.8.1.3 COMPLIANCE QUESTIONNAIRE

This questionnaire was constructed specifically for use in the present trial, relating to the use of the sacroiliac stabilising orthotic. The questions covered information regarding the compliance to instructions about wearing the orthotic, comfort and attitude towards the orthotic and awareness of the back problem as a result of the orthotic. There were nine questions in total and were either dichotomous (two possible answers) or multiple-choice (three possible answers). Each question had a maximum score of three and a minimum score of one, with a possible total between

nine and twenty-seven. This scoring system gave an overall response to the orthotic according to three categories:

- Poor: 9 - 14
- Moderate: 15 - 20
- Favourable: 21 - 27

EXPLANATION OF EACH QUESTION IN THE QUESTIONNAIRE

- 1) This was a direct question regarding patient compliance to brace-wearing instructions. The response was dependant upon each patients honesty, when answering the question.
- 2) This question assessed whether the patient had a beneficial emotional or psychological response to the brace and felt more secure when wearing it.
- 3) The general comfort of the brace will have obvious effects on compliance to instructions and needed, to be considered, to establish how likely it was that a patient would follow the instructions. This was a direct question regarding comfort.
- 4) This question was evaluating how practical the brace was to wear during the normal activities of daily life. In a similar way to question three, a patient who felt that his or her normal and everyday activities were being restricted, may have decided that the benefits of wearing the brace did not outweigh the

disadvantage of its limitations. In this case restriction from normal activity would have had a negative effect on compliance and attitude towards the brace.

- 5) This question is of value because it suggests that being able to do greater activity is beneficial, when in fact this attitude is more likely to encourage over-confidence in a patient, who should actually be avoiding activities, which may aggravate the condition. This was the only question, which was not straightforward and was included to evaluate whether patients were trying to answer the questions to please the examiner.
- 6) A positive response to this question reflects the opposite attitude, which is that wearing the brace elevated patient awareness of their condition and reminded them to avoid activity, which may overload the lower back.
- 7) A positive response to this question suggested a physical restriction of activity due to the brace, with a more direct benefit than elevated awareness in terms of injury prevention by physical limitation of activity.
- 8) This is a direct question regarding awareness.
- 9) This question will obviously elicit an entirely subjective response and as a result will give a good indication of the patients overall attitude towards the brace. A

positive subjective response to any therapy will increase the possibility of a favourable outcome.

3.8.2 OBJECTIVE MEASUREMENTS

Objective measurements were recorded from the results of algometer readings and four orthopaedic tests, which stress the sacroiliac joints. These measurements were recorded before the first treatment and after the third and the final treatment.

3.8.2.1 THE ALGOMETER

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

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

Fischer (1987) defines pressure threshold as the maximum pressure inducing pain or discomfort. The algometer can be used to quantify response to treatment such as

manipulation and provides a means of measuring the patients improvement Fischer (1986:837).

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

3.8.2.2 ORTHOPAEDIC TESTS

Four orthopaedic tests were used to confirm the diagnosis of sacroiliac joint syndrome. These included the three sacroiliac joint stress tests of the Kirkaldy-Willis (1992:123-125) model of classifying sacroiliac joint syndrome, and a fourth sacroiliac stress test, called the Posterior shear or Thigh thrust test (Laslett and Williams 1994). To be accepted into the trial, the patient had to have at least three out of four tests positive.

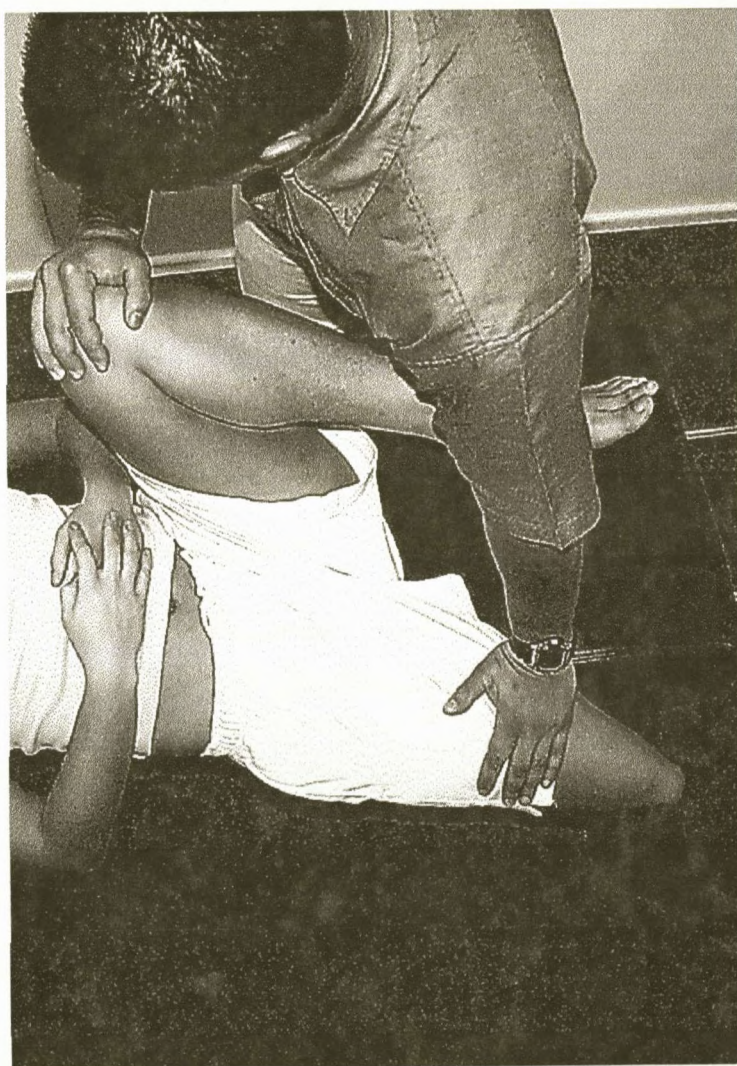
- Patrick Faber's: patient supine. The right leg, near the ankle is placed in front of the left thigh above the knee. The examiner places his right hand over the patients left iliac crest, while the examiners left hand pushes downward on the medial aspect of the right knee. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint. Kirkaldy-Willis (1992:123-125)

FIGURE 3.1 PATRICK FABER'S TEST



- Gaenslaen's: patient supine. The examiner flexes the patients left knee and hip, while pressing downward over the right thigh to hyperextend the right hip. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint. Kirkaldy-Willis (1992:123-125)

FIGURE 3.2 GAENSLAENS TEST



- Yeomann's: patient prone. The examiner places one hand under the right thigh above the knee on the affected side, to extend the right hip. The examiner's other hand presses downward over the crest of the right ilium. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint.

Kirkaldy-Willis (1992:123-125).

FIGURE 3.3 YEOMANNS TEST



- Thigh Thrust: patient supine. Patients right hip and knee is flexed and slightly adducted. The examiner places one hand under the right sacroiliac joint while exerting a posterior shearing force downward on the right knee through the femur, while feeling for excessive joint motion with the opposite hand. A positive test was recorded if this position elicited pain over the region of the right sacroiliac joint. Kirkaldy-Willis (1992:123-125).

FIGURE 3.4 THIGH THRUST TEST



The same four tests were used to evaluate the patient's initial presentation and progress throughout the treatment period. The tests were performed bilaterally and scored with a possible maximum of ten points.

Each test of the Kirkaldy-Willis (1992:1223-125) model would score one point if it induced pain over either sacroiliac joint, while due to its apparent reliability the Thigh Thrust test would score two points, if pain was induced at the sacroiliac joint. A negative result was recorded as zero points when the patient reported 'no pain' or pain in the lumbar spine, hip joint, anterior thigh or inapplicable site. The score was recorded as a proportion of pain of sacroiliac origin, and the score was obviously inflated, in patients with bilateral symptoms. It was emphasised that the score was not an indication of pain intensity, and patients with a high score as a result of bilateral symptoms did not necessarily have a higher pain intensity than a patient with a low score, with only unilateral symptoms.

3.9 INTERVENTIONS

Each patient who entered the trial, attended up to six consultations over a two-week period. Group one and two received treatment, until the condition had resolved both subjectively and objectively, or for a maximum of six treatments. According to Gatterman (1990), a sacroiliac syndrome can resolve with one adjustment, but may require up to six treatments over a two-week period. If a patient became asymptomatic, in terms of subjective clinical findings, before the sixth treatment, the

patient continued to be evaluated for the remainder of the treatment period, but received no further treatment.

If a patient developed local skin irritation, due to the orthotic or their condition became subjectively worse as a result of treatment, their condition was re-evaluated before continuing treatment, and if necessary that patients treatment was terminated and their data was excluded from the trial. The data was then used only demographically.

3.9.1 SPINAL MANIPULATIVE THERAPY

Both groups received spinal manipulative therapy. Once the diagnosis of sacroiliac syndrome was confirmed by use of the four orthopaedic tests (Gaenslaens, Yeomanns, Patrick Faber's and Thigh Thrust), the manipulable lesion was determined by motion palpation (Bergmann 1993; Schaefer and Faye 1990). The following listing system was used: upper flexion, lower flexion, upper extension, lower extension.

3.9.1.1 MOTION PALPATION

A recent study by Meinje et al. (1999) found that the commonly used Gillet motion palpation test, did not appear to have intra or inter-examiner reliability ($p=0.05$). The study sample had a small symptomatic group, (less than fifteen patients) and the

examiners were inexperienced final year physiotherapy students, but the results followed the trend later established by van der Wurff et al. (2000) who reviewed eleven clinical sacroiliac tests, and found no evidence to support the use of mobility tests as an objective outcome measure.

However, despite these negative findings, practioners using spinal manipulation, place major emphasis on the use of palpation of intersegmental spinal motion (Evans 1994). Walker and Buchbinder (1997) conducted a survey of all registered chiropractors in Victoria, Australia, and found that motion palpation was commonly used and considered the most reliable diagnostic method for detecting the spinal entity that they manipulate.

Motion palpation was therefore used only to establish the manipulable lesion, and not as an outcome measurement.

Motion Palpation of the sacroiliac joint was conducted using the Standing Flexed-Knee-Raising Test, similar to the Gillet test, described by Schaefer and Faye (1990).

- a) Superior joint motion palpation: The left thumb is placed on the patient's sacral apex, the right thumb is placed on the patient's right posterior superior iliac spine. The patient is asked to raise the right flexed knee as if taking a high step. Separation of the thumbs is noted. Normally the posterior superior iliac spine will move downward and backward causing the right thumb to separate from the left thumb. The test is then repeated with the patient raising the left knee, normally causing the left thumb to move downwards. If the superior sacroiliac joint or the

symphysis pubis is locked, the pelvis will move as a unit, and the thumbs will not separate.

- b) Inferior joint motion palpation: The left thumb is placed on the patient's sacral apex and the right thumb on the patient's right ischial protuberance. The patient is asked to raise the right flexed knee. The ischium should be felt to move anteriorly- superiorly and slightly lateral on the sacrum. If the inferior sacroiliac joint is locked, the ischium and sacral apex move as a unit.

3.9.1.2 MANIPULATION

The involved area will be manipulated according to the Diversified Technique (Schaefer and Faye 1989; Bergmann 1993). The applicable side posture adjustment, with the patient in the lateral recumbent position, with a thenar or hypothenar contact, was delivered to the fixated area of the right or left sacroiliac joint depending on the motion palpation findings. A record will be kept of the motion palpation findings, and the applicable adjustment delivered to each patient on each visit.

3.9.2 ORTHOTICS

3.9.2.1 NON-STABILISING SACROILIAC ORTHOTIC

Patients within group one received a non-stabilising sacroiliac orthotic, in the form of Smith and Nephew elastoplast rigid strapping (supplied by Smith and Nephew limited, 30 Gillits road, Pinetown), applied after the adjustment of the sacroiliac joint and removed by the examiner at the next consultation. The strapping was worn for a maximum of three days after each application, to avoid local skin irritation. The strapping was a form of placebo treatment in this trial because it provided no stabilising function for the pelvis.

Its effects were limited to support of the local musculature and enhanced proprioceptive response McNair and Heine (1999). The strapping was applied posteriorly between the right and left posterior superior iliac spine, between the iliac crests superiorly, and just above the gluteal cleft inferiorly. (adapted from Broughton and Kretzmann 2000).

3.9.2.2 STABILISING SACROILIAC ORTHOTIC

Patients within group two received a sacroiliac stabilising orthotic (supplied by Chiropractic Equipment Suppliers, P.O. Box 22349, Fish Hoek, Cape Town, S.A., 7974. Tel. 7823540) and precise instructions (Appendix H) on when and how to use it. It is made of strong, supportive, elastic, neoprene material, that fastens with

velcro, with a second rigid portion that is secured over the elastic portion that is tightened with a loop mechanism and also fastens with velcro. The orthotic, was to be worn between the greater trochanters inferiorly and iliac crests superiorly.

Patients in this group were reminded by the researcher at each treatment how and when to use the orthotic. In addition they received a compliance diary (Appendix I) to be filled in each day regarding adherence to the instructions of when to wear the orthotic. This served as a reminder to the patient and was implemented to encourage compliance to instructions. It also allowed the researcher a structured method of assessing compliance regarding wearing of the orthotic, in order to exclude non-compliant patients from the trial. The information from the compliance diary was not recorded for statistical or data analysis.

3.10 TREATMENT OF THE SUB PROBLEMS

The purpose of this study is to investigate the relative effectiveness of manipulation, used in conjunction with a non-stabilising sacroiliac orthotic versus manipulation, used in conjunction with a stabilising sacroiliac orthotic in terms of objective and subjective clinical findings, in the treatment of sacroiliac syndrome.

3.10.1 THE FIRST SUBPROBLEM

The first subproblem was to evaluate the efficacy of manipulation used in conjunction with a non-stabilising sacroiliac orthotic and manipulation used in conjunction with a stabilising sacroiliac orthotic in the treatment of sacroiliac syndrome in terms of subjective clinical findings.

3.10.2 THE SECOND SUBPROBLEM

The second subproblem was to evaluate the efficacy of manipulation used in conjunction with a non-stabilising sacroiliac orthotic and manipulation used in conjunction with a stabilising sacroiliac orthotic in the treatment of sacroiliac syndrome in terms of objective clinical findings.

3.11 STATISTICAL ANALYSIS

3.11.1 TREATMENT OF THE DATA

3.11.1.1 SUBJECTIVE DATA

The subjective data was treated as follows:

- Questionnaires that the patients completed were screened to ensure they had been completed correctly.
- Raw data from the three questionnaires was converted into percentages and recorded separately for each group.
- The data was analysed using a 95% confidence level.

3.11.1.2. OBJECTIVE DATA

The objective data was 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 was statistically analysed using a 95% level of confidence.

3.11.2 STATISTICAL ANALYSIS OF THE DATA

The Technikon Natal statistician was consulted for advice on how to statistically analyse the data obtained from this research study. Due to the sample size ($n_1 = 30$ and $n_2 = 30$) both parametric and non-parametric tests were used to analyse the data. Data was transferred to a spread-sheet and statistical analysis was conducted at a 95% confidence level.

3.11.2.1 NON-PARAMETRIC TESTING

Non-parametric testing was used to analyse the categorical variables (Fisher 1993).

The categorical variables include results from:

- The Oswestry Low Back Disability Index
- The four orthopaedic tests (Patrick Faber's, Gaenslaen's, Yeomann's and Thigh Thrust)
- The compliance questionnaire

Frequencies and percentages were be collected for analysis.

A) Mann-Whitney Unpaired Test

Subjective and objective data, from the results of the Oswestry Disability questionnaire and the orthopaedic tests, were analysed using the Mann-Whitney Unpaired Test for inter-group comparison. This was in order to determine whether any significant difference existed between the median values in the control and experimental groups at the first, third and sixth consultations.

Confidence levels were conducted at a 95% confidence interval ($\text{Alpha} = 0.05$).

B) Wilcoxon Signed Rank Test

Subjective and objective data, from all three categorical variables was analysed using the Wilcoxon Signed Rank Test for intra-group comparison. This was in order to determine whether any significant change occurred between the median values within each group between the first, third and sixth consultations.

Confidence levels were conducted at a 95% confidence interval ($\text{Alpha} = 0.05$).

3.11.2.2 PARAMETRIC TESTING

Parametric testing was used to analyse the continuous variables (Fisher 1993). The continuous variables include results from:

- The algometer measurements
- The Numerical Pain Rating Scale 101

Medians, ranges and standard deviations will be used for analysis.

A) Two Sample Unpaired t-test

Subjective and objective data, from the results of the continuous variables, were analysed using the Two sample Unpaired t-test for inter-group comparison. This was in order to determine whether any significant difference existed between the median values within the control and experimental groups at the first, third and sixth consultations.

Confidence levels were conducted at a 95% confidence interval ($\text{Alpha} = 0.05$).

B) Two Sample Paired t-test

Subjective and objective data, from the continuous variables was analysed using the Two Sample Paired t-test for intra-group comparison. This was in order to determine whether any significant change occurred between the median values within each group of the first, third and sixth consultations.

Confidence levels were conducted at a 95% confidence interval ($\alpha = 0.05$).

3.11.2.3 HYPOTHESIS TESTING

The null hypothesis (H_0) for subproblem one stated that within each group there was no significant improvement in the patient's condition in terms of subjective clinical findings.

The alternative hypothesis (H_1) for subproblem one stated that within each group there was a significant improvement in the patient's condition in terms of subjective clinical findings.

The null hypothesis (H_0) for subproblem two stated that there was no statistically significant improvement within group one and two in terms of objective clinical findings.

The alternative hypothesis (H 2) for subproblem two stated that there was a statistically valid improvement in group one and two in terms of objective clinical findings.

3.11.3.4 SUMMARY STATISTICS

If the Parametric or Non-Parametric tests determined by way of calculation that there was a significant difference between the two groups in terms of subjective or objective clinical findings, the mean was used to identify the superior treatment group. The standard deviation could then be used to measure the reliability of the mean by measuring the spread of data around the mean. Both parametric and non-parametric tests used the median within the calculations.

Power analysis was conducted to determine whether the results were valid and reliable.

4. THE RESULTS

4.1 INTRODUCTION

This chapter covers the results obtained from the statistical analysis of the subjective and objective data recorded in the trial. It also includes demographic information of all patients accepted into the trial.

4.2 DISCUSSION OF RECRUITMENT

One hundred and seventy patients, from the greater Durban area responded to the advertisement for the treatment of low back pain. Patients were screened telephonically to ensure they met the age criteria, and were excluded from further evaluation if they had been experiencing obvious signs of nerve root entrapment or had been previously diagnosed with instability, fracture, or arthritis of the lumbar spine and pelvis, or if symptoms appeared to be within the lumbar spine and not the sacroiliac joints. One hundred and nine patients were further assessed at the Chiropractic Day Clinic of which, sixty-four patients met all the selection criteria and were accepted into the trial. (Table 4.1)

Three patients were excluded during the course of the treatment period due to non-compliance, while one patient was excluded as a result of progressing low back pain which required analgesic medication.

Sixteen patients with low back pain who responded to the trial did not attend the screening appointment for personal reasons, time or transport constraints. Six patients were referred to the clinic as regular patients because it became apparent during the telephonic screening that their condition was very acute, and that they would benefit from a more intensive treatment program than was available on the research program, possibly with the addition of anti-inflammatory medication. The remaining patients were excluded either during the telephonic screening or the initial screening appointment, according to the reasons tabulated below.

TABLE 4.1

Reasons for research patients not meeting selection criteria (N = 170)

EXCLUSION CRITERIA	NUMBER	PERCENTAGE
AGE < 18Y	1	0.5%
AGE > 50Y	20	12%
SIGNS OF N.R.E	11	6%
FACET SYNDROME OR MYOFASCITIS	20	12%
SPONDYLOLISTHESIS	1	0.5%
HIP PATHOLOGY OR OA	4	2%
SACROILIAC SYNDROME (DID NOT MEET ORTHOPAEDIC TEST CRITERIA)	27	16%

The last criteria (orthopaedic tests), refers to the sacroiliac stress tests which were used as the diagnostic criteria required to allow patients into the trial. Three out of four positive tests were required for selection into the trial. It is important to note that the percentage of patients excluded due to this criteria, has been shown as a

percentage of one hundred and seventy patients, who responded to the trial. However, only one hundred and nine patients were actually screened in the clinic and sacroiliac stress tests were performed on patients whose case-history and low back regional examination suggested the diagnosis of sacroiliac syndrome. Using this system, 30 % of patients were excluded from the trial as a direct result of orthopaedic testing. This resulted in a reasonably high prevalence of 38 % of patients being diagnosed with sacroiliac syndrome in this low back pain population (N=170). According to Schwarzer *et al.* (1995), prevalence estimates for sacroiliac syndrome would be up to 30%, in a population of patients with pain below L5-S1. It was mentioned earlier that the population of patients in the study by Schwarzer *et al.* (1995), could be considered minimum values because the study had selected patients from a population with severe low back pain which warranted further, invasive investigation. It is possible that the population of patients in the present study, who presented as a milder group of low back pain patients, resulted in the presence of sacroiliac syndrome being more likely to occur. As a result the prevalence findings in the present study are higher than expected, but could be considered close enough to previous prevalence estimates (Schwarzer *et al.* 1995), to be considered an adequate method of diagnosing this condition.

4.3 DEMOGRAPHIC DATA

Demographic data was recorded for all patients accepted into the trial, including patients whose statistical data was later excluded. The demographic data of all

patients who responded to the trial advertisements, complaining of low back pain, includes one-hundred and seventy patients. The total number of patients accepted into the trial was sixty-four, and the number of patients who completed the trial and contributed to the statistical data was sixty.

4.3.1 GENDER

TABLE 4.2

Gender distribution of source population (N = 170)

GENDER	NUMBER	PERCENTAGE
MALES	76	44%
FEMALES	94	56%
TOTAL	170	100%

The number of males and females who responded to the trial was relatively weighted, with 12 % more females complaining of low back pain. There was no trend favouring a male or female distribution of patients diagnosed with sacroiliac syndrome. This was in contrast to earlier studies demonstrating a distinct female predominance of sacroiliac syndrome (Schwarzer *et al.* 1995; Gemmel and Jacobson 1990; Cibulka and Koldehoff 1999).

TABLE 4.3

Gender distribution of sample population (n = 64)

GENDER	GROUP 1	GROUP 2
MALES	18 (56%)	13 (41%)
FEMALES	14 (44%)	19 (59%)
TOTAL	32	32

Overall the male : female ratio was fairly equal at 31 : 33. Group II had a predominance of females to males at a ratio of 60 : 40.

4.3.2 AGE

TABLE 4.4

Age distribution (n = 64)

AGE GROUP	GROUP 1	GROUP 2
18 - 25	14 (44%)	5 (16%)
26 - 35	11 (34%)	7 (22%)
36 - 50	7 (22%)	20 (63%)
18 - 50	32	32

The average (mean) age of Group I was 28.8. The median was 26.

The average (mean) age of Group II was 36.5. The median was 37.5.

The average (mean) age of Group I and II was 32.65.

The difference between the median scores of the two groups shows that there was a clear trend towards an older group of patients, in Group II.

4.3.3 SYMPTOMATIC PRESENTATION

TABLE 4.5

Presence of extremity pain

EXTREMITY PAIN	GROUP 1	GROUP 2
BUTTOCK	2	2
HIP	0	2
GROIN	3	0
POST THIGH	1	3
BELOW KNEE	2	2
TOTAL	8	9

The referral patterns in the table above are common areas of involvement in sacroiliac syndrome (Kirkaldy-Willis et al. 1992). The results indicate that 27% of the patients accepted for the trial experienced pain in regions below the sacroiliac joint and 6% experienced symptoms below the knee. Both groups had a similar distribution of patients with extremity pain. Schwarzer et al. (1995) considered groin pain the only distinguishing factor between patients with sacroiliac pain and those without.

4.3.4 HISTORY OF SMOKING AS A LOW BACK PAIN RISK FACTOR

TABLE 4.6

Number of smokers in each group

	GROUP 1	GROUP2
SMOKERS	9(28%)	13(41%)

Burton and Cassidy (1992) list smoking as one of the individual risk factors for low back pain and this information was recorded purely for interest. Group II had a high proportion of smokers. There was very little statistical indication, that Group II was significantly more severe on presentation than Group I. However the mean and median results of all objective and subjective tests were in fact slightly more severe for Group II, at the initial consultation, indicating that this group was possibly more severe at a lower statistical confidence level.

4.4 MANIPULATION DATA

TABLE 4.7

Comparison of pain distribution and side of sacroiliac joint dysfunction (SIJD)

LOCATION	PAIN DISTRIBUTION	SIJD
BILAT	38 (63%)	7 (12%)
RIGHT	16 (26%)	33 (55%)
LEFT	6 (10%)	20 (33%)
TOTAL	60	60

The pain distribution was predominantly bilateral, in 63% of patients and more often on the right than the left side, when unilateral. A right-sided predominance was noted in the present trial, for sacroiliac joint dysfunction, and if the relatively small percentage of bilateral results are disregarded, the right to left ratio is 62:38.

4.5 THE ANALYSED DATA

P-VALUE $\alpha = 0.05$

Reject H_0 if $P \leq \alpha / 2$

Accept H_0 if $P > \alpha / 2$

P was the observed level of significance

As $\alpha / 2 = 0.025$, the p-value must be equal to or less than 0.025 in order to reject H_0 (there is a significant difference).

4.6 PARAMETRIC AND NON-PARAMETRIC PAIRED HYPOTHESIS

TESTS

Objective and subjective measurements from Group I were tabulated to compare the results of the initial and third consultation, the third and final consultation, and lastly, the initial and final consultation. This process was then completed for the data obtained for Group II. P-values were calculated at a 5% level of significance, using the Two Sample Paired t-test, for the continuous variables (algometer and Numerical Pain Rating Scale), and the Wilcoxon Signed Rank Test for categorical variables (Oswestry Disability Index, the orthopaedic tests, and the compliance questionnaire).

TABLE 4.8

Statistical results of the subjective and objective data comparing the first and third consultation in group I

GROUP I									
	FIRST CONSULTATION					THIRD CONSULTATION			
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	4.3	4.4	1.04	0.19	0.0001	5.1	4.75	1.29	0.24
NRS 101	39.08	38.75	14.35	2.62	0.0001	27.85	30	13.68	2.5
SI TESTS	5.93	6	1.8	0.33	0.0001	2.83	2.5	2.12	0.34
OSWESTRY	19.27	16	11.14	2.03	0.0001	13.73	10	10.51	1.92

Two Sample Paired t-test : Algometer and NRS 101

Wilcoxon Signed Rank : Sacroiliac tests and Oswestry Disability Questionnaire

Table 4.8 gives an indication of the initial response to treatment, in Group I. When comparing subjective and objective data between the first and third consultation it can be seen that there was a significant improvement within Group I. for all measurements. The null hypothesis was therefore rejected for all results.

TABLE 4.9

Statistical results of the subjective and objective data comparing the third and final consultation in group I

GROUP I									
THIRD CONSULTATION					FINAL CONSULTATION				
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	5.1	4.75	1.29	0.24	0.0001	5.7	3.55	1.32	0.24
NRS 101	27.85	30	13.68	2.5	0.0001	18.2	11.25	18.38	3.36
SI TESTS	2.83	2.5	2.12	0.34	0.0001	1.53	1	1.81	0.33
OSWESTRY	13.73	10	10.51	1.92	0.0001	9.4	8	7.5	1.37

Two Sample Paired t-test : Algometer and NRS 101

Wilcoxon Signed Rank : Sacroiliac tests and Oswestry Disability Questionnaire

Table 4.9 gives an indication of whether any further improvement occurred as a result of on-going treatment. (Between one and six treatments were administered depending on the patients response to treatment). Initial response to treatment, was measured at the third consultation, further response to treatment was measured at the sixth consultation, or following resolution of the patients condition, depending on which occurred first. When comparing subjective and objective data between the

third and final consultation, it can be seen that there was further improvement, which was statistically significant, within Group I for all measurements. The null hypothesis was therefore rejected for all results.

TABLE 4.10

Statistical results of the subjective and objective data comparing the first and final consultation in group I

GROUP I									
FIRST CONSULTATION					FINAL CONSULTATION				
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	4.3	4.4	1.04	0.19	0.0001	5.7	5.5	1.32	0.24
NRS 101	39.08	38.75	14.34	2.62	0.007	18.2	11.25	14.46	2.64
SI TESTS	5.93	6	1.8	0.33	0.0001	1.53	1	1.81	0.33
OSWESTRY	19.27	16	11.14	2.03	0.001	9.4	8	7.5	1.37

Two Sample Paired t-test : Algometer and NRS 101

Wilcoxon Signed Rank : Sacroiliac tests and Oswestry Disability Questionnaire

Table 4.10 gives an indication of the overall response to treatment after the final consultation in Group I. When comparing subjective and objective data between the first and final consultation, it can be seen that there was a significant overall improvement within Group I, for all measurements. The null hypothesis is therefore rejected for all results.

TABLE 4.11

Statistical results of the subjective and objective data comparing the first and third consultation in group II

GROUP II									
	FIRST CONSULTATION					THIRD CONSULTATION			
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	3.79	3.55	1.39	0.25	0.0001	4.6	4.4	1.37	0.25
NRS 101	41.08	40	18.38	3.36	0.0001	28.15	23.75	20.5	3.7
SI TESTS	6.3	6	2.2	0.4	0.0001	2.67	2	2.11	0.39
OSWESTRY	21.67	17	13.42	2.45	0.0001	15.27	12	13.16	2.4

Two Sample Paired t-test : Algometer and NRS 101

Wilcoxon Signed Rank : Sacroiliac tests and Oswestry Disability Questionnaire

Table 4.11 gives an indication of the initial response to treatment, in Group II. When comparing subjective and objective data between the first and third consultation it can be seen that there was a significant improvement within Group II for all measurements. The null hypothesis is therefore rejected for all results.

TABLE 4.12

Statistical results of the subjective and objective data comparing the third and final consultation in group II

GROUP II									
THIRD CONSULTATION					FINAL CONSULTATION				
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	4.6	4.4	1.37	0.25	0.0001	5.48	5.15	1.45	0.26
NRS 101	28.15	23.75	20.5	3.7	0.0001	21.83	12.5	21.24	3.88
SI TESTS	2.67	2	2.11	0.39	0.0001	1.57	1	1.63	0.3
OSWESTRY	15.27	12	13.16	2.4	0.152	14.9	9	16.58	3.03
COMPLIANCE	19.9	20.5	3.21	0.59	0.343	19.6	19	2.46	0.45

Two Sample Paired t-test : Algometer and NRS 101

Wilcoxon Signed Rank : Sacroiliac tests, Oswestry Disability Questionnaire and Compliance Questionnaire

Table 4.12 gives an indication of whether any further improvement occurred as a result of on-going treatment. When comparing subjective and objective data between the third and final consultation, it can be seen that there was a significant improvement within Group II for all measurements, except the Oswestry

Questionnaire. The null hypothesis is therefore accepted for the Oswestry results and rejected for all other results.

The last entry on the Table is a comparison of the difference, in patient's responses to a compliance questionnaire, between the third and final consultations. Although, no significant difference could be found statistically, there was a slightly more positive response, earlier in the treatment (third consultation), when comparing the mean and median values directly.

TABLE 4.13

Statistical results of the subjective and objective data comparing the first and final consultation in group II

GROUP II									
FIRST CONSULTATION					FINAL CONSULTATION				
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	3.79	3.55	1.39	0.25	0.0001	5.48	5.15	1.45	0.26
NRS 101	41.08	40	18.38	3.36	0.0001	21.83	12.5	21.24	3.88
SI TESTS	6.3	6	2.2	0.4	0.0001	1.57	1	1.63	0.3
OSWESTRY	21.67	17	13.42	2.45	0.001	14.9	9	16.58	3.03

Two Sample Paired t-test : Algometer and NRS 101

Wilcoxon Signed Rank : Sacroiliac tests, Oswestry Disability Questionnaire

Table 4.13 gives an indication of the overall response to treatment after the final consultation, in Group II. When comparing subjective and objective data between the first and final consultation it can be seen that there was a significant improvement within Group II for all measurements. The null hypothesis is therefore rejected for all results.

4.7 PARAMETRIC AND NON-PARAMETRIC UNPAIRED HYPOTHESIS TESTS

Objective and subjective data from the first consultation was tabulated to make comparisons, regarding the initial presentation of patients from Group I with patients from Group II. This process was repeated for the third consultation and then the final consultation. Data was analysed at a 95% level of confidence, using the Two Sample Unpaired t-test to obtain a p-value for continuous variables, and the Mann-Whitney Unpaired test to obtain a p-value for categorical variables.

TABLE 4.14

Statistical results of the subjective and objective data comparing group I and II at the first consultation

FIRST CONSULTATION									
	GROUP I					GROUP 2			
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	4.3	4.4	1.04	0.19	0.111	3.79	3.55	1.39	0.25
NRS 101	39.08	38.75	14.35	2.62	0.378	41.08	40	18.38	3.36
SI TESTS	5.93	6	1.8	0.33	0.615	6.3	6	2.2	0.4
OSWESTRY	19.27	16	11.14	2.03	0.514	21.67	17	13.42	2.45

Two Sample Unpaired t-test : Algometer and NRS 101

Mann Whitney U-test : Sacroiliac tests and Oswestry Disability Questionnaire

When comparing the subjective and objective data taken from the initial consultations for Group I and II (Table 4.14), it can be seen that there is no statistically significant difference between the two groups. The null hypothesis is therefore accepted for all variables. This is a fair indication that the groups were similarly matched on initial presentation, when variables are compared separately. While no statistically relevant differences were found, it was noted that the mean

values of all the variables were slightly higher, in Group II, indicating a greater degree of severity in this group. According to the grading system used by Fairbank et al. (1980), the mean values of the Oswestry Disability Questionnaire, would result in patients from Group I being defined as a group with minimal disability, while Group II would be defined as a group with moderate disability.

TABLE 4.15

Statistical results of the subjective and objective data comparing group I and II at the third consultation

THIRD CONSULTATION									
	GROUP I					GROUP 2			
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	5.1	4.75	1.29	0.24	0.999	4.6	4.4	1.37	0.25
NRS 101	27.85	30	13.68	2.5	0.27	28.15	23.75	20.5	3.7
SI TESTS	2.83	2.5	2.12	0.34	0.781	2.67	2	2.11	0.39
OSWESTRY	13.73	10	10.51	1.92	0.667	15.27	12	13.16	2.4

Two Sample Unpaired t-test : Algometer and NRS 101

Mann Whitney U-test : Sacroiliac tests and Oswestry Disability Questionnaire

When comparing the objective and subjective readings taken from the third consultations for Groups I and II (Table 4.15), it can be seen that there was no statistically significant difference between the two. The null hypothesis was therefore accepted for all readings, indicating that there is no indication that the efficacy of either treatment, is greater than the other, at the third consultation.

TABLE 4.16

Statistical results of the subjective and objective data comparing group I and

II at the final consultation

FINAL CONSULTATION									
GROUP I					GROUP 2				
	MEAN	MEDIAN	S.D.	S.E.	P-VALUE	MEAN	MEDIAN	S.D.	S.E.
ALGOMETER	5.7	3.55	1.32	0.24	0.726	5.48	5.15	1.45	0.26
NRS 101	18.2	11.25	18.38	3.36	0.137	21.83	12.5	21.24	3.88
SI TESTS	1.53	1	1.81	0.33	0.719	1.57	1	1.63	0.3
OSWESTRY	9.4	8	7.5	1.37	0.432	14.9	9	16.58	3.03

Two Sample Unpaired t-test : Algometer and NRS 101

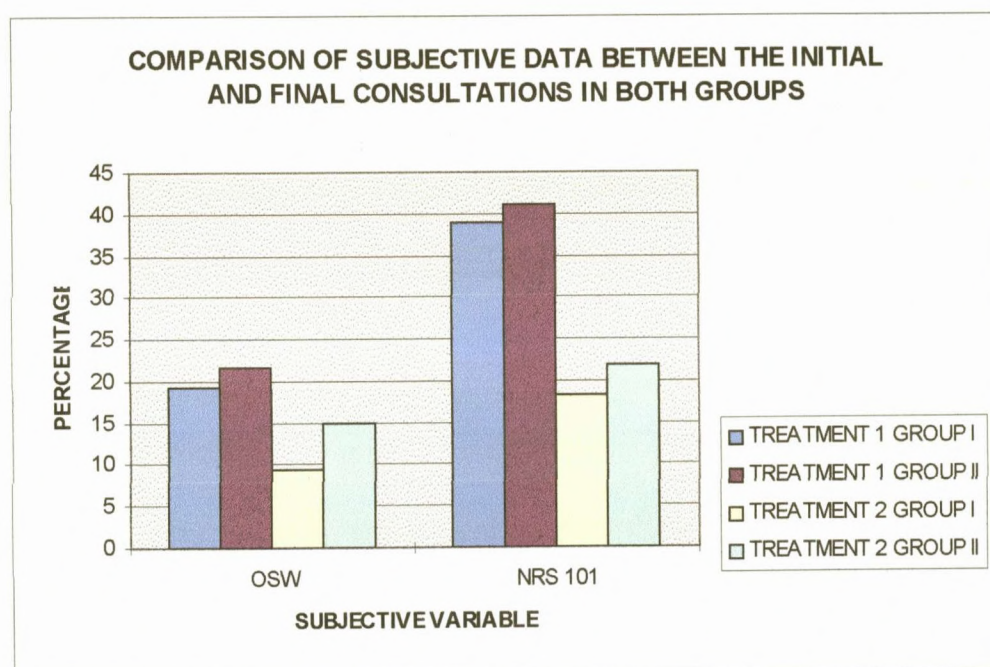
Mann Whitney U-test : Sacroiliac tests and Oswestry Disability Questionnaire

When comparing the objective and subjective readings taken from the final consultations for Groups I and II (Table 4.16), it can be seen that there was no statistically significant difference between the two groups. The null hypothesis is therefore accepted for all readings. There was no evidence that manipulation used in conjunction with a stabilising sacroiliac orthotic was statistically superior to manipulation used in conjunction with a non-stabilising sacroiliac orthotic for the

treatment of sacroiliac syndrome, in terms of subjective and objective findings. A comparison of the overall improvement in both groups can be seen in the figures below.

FIGURE 4.1

The subjective results of both groups, comparing the initial and final consultations

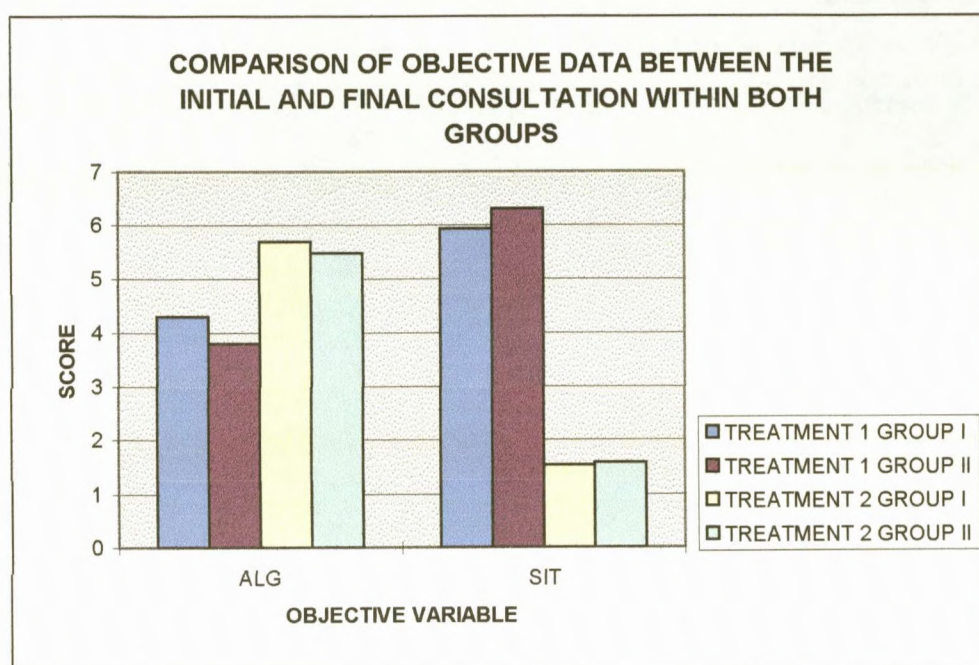


Treatment 1: Initial consultation

Treatment 2: Final consultation

FIGURE 4.2

The objective results of both groups, comparing the initial and final consultations



Treatment 1: Initial consultation

Treatment 2: Final consultation

ALG: the algometer results

SIT: the orthopaedic sacroiliac joint stress tests

It must be noted that the algometer results, were a recording of pressure pain tolerance. As a result the values throughout the treatment period are expected to increase, which is in contrast to the orthopaedic test results which show a decrease in score with treatment, reflecting a positive response to therapy.

4.8 POWER ANALYSIS

TABLE 4.17

	Consultation 1	Consultation 3	Consultation 6
Algometer	0.35	0.29	0.09
NRS 101	0.08	0.05	0.1

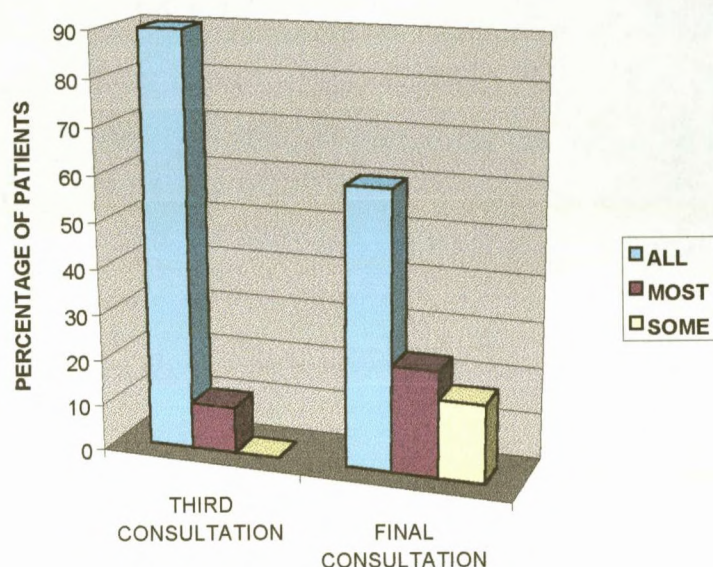
Power analysis was conducted on all continuous variables, for which the null hypothesis was accepted. A high power value is a value which approaches 1.0, where power is equal to $(1 - \beta)$ (Fisher 1993). At each data collecting session, the power value was very low, as a result of the small sample population. A low power value, indicates a high possibility that a Type II error has occurred.

4.9 ANALYSIS OF RESPONSES TO COMPLIANCE QUESTIONNAIRE

The results of the compliance questionnaire were recorded only in Group II, on the third and final consultations. The questionnaire was designed to give a general picture of the patients response to the stabilising sacroiliac orthotic.

Each question of the compliance questionnaire was tabulated individually to compare the frequency of responses between the third and final consultation.

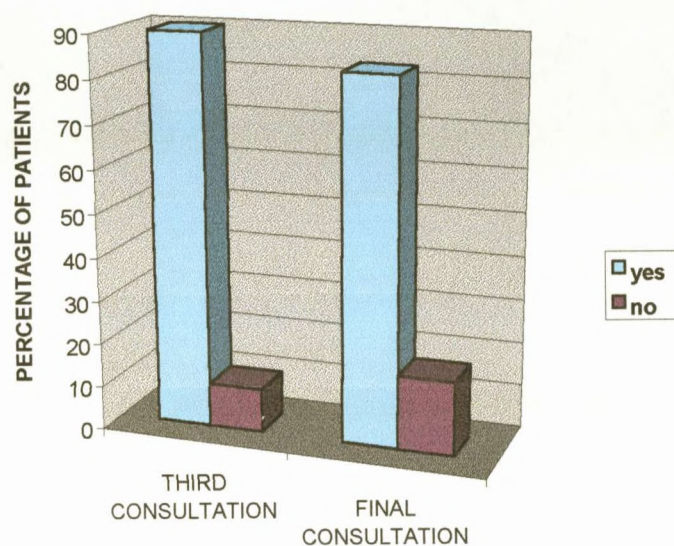
FIGURE 4.3

Question 1Was the brace worn during all activities except lying and sleeping ?

There was steady decline in the amount of time spent using the stabilising orthotic. This was consistent with the treatment protocol, which instructed the patient to use the orthotic until the end of the treatment programme. For some patients this was only until the third consultation. The trend may also have been associated with a slight, and not statistically significant (TABLE 4.12), but evident decrease in the overall response to the orthotic, which could have been the cause of weaning compliance.

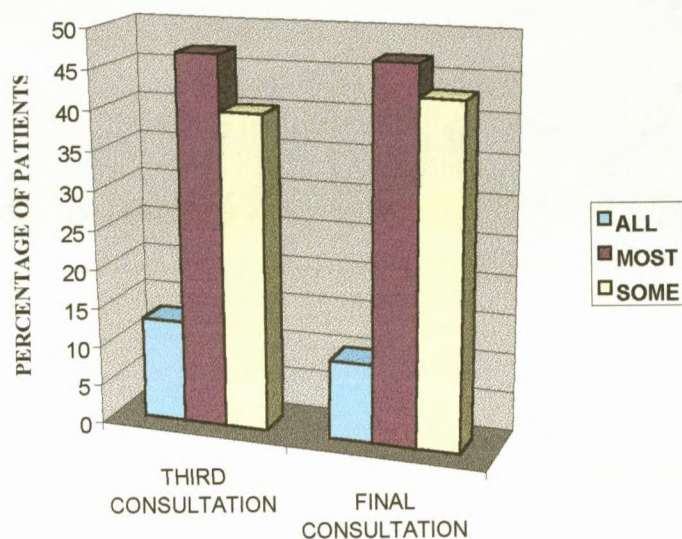
FIGURE 4.4**Question 2**

Did wearing the brace give you a sense of security because of the support it provides ?



There was an overwhelming positive response to this question, suggesting that the application of the brace provided a high level of emotional or psychological benefit.

FIGURE 4.5

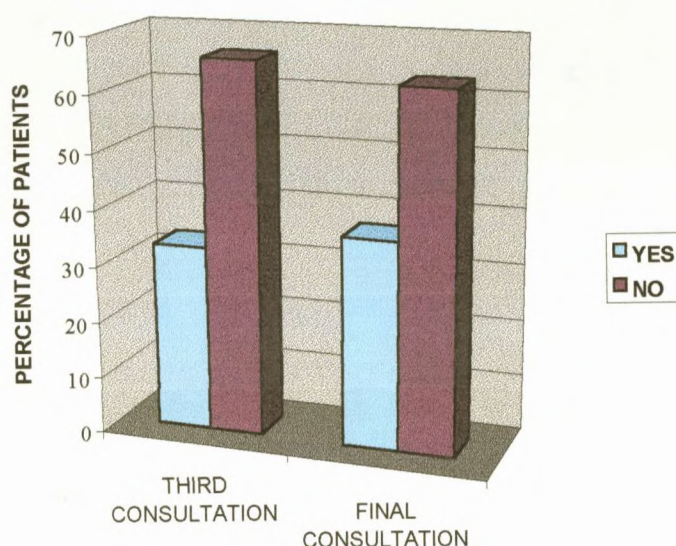
Question 3Was the brace comfortable to wear during your normal activities ?

It was evident from the question above that comfort levels were not high while using the brace. Although almost half the patients in the group found the brace comfortable to wear during most activities, it was not recorded how many patients found the brace uncomfortable to wear during all activities. The question therefore fails to identify patients who found the brace too uncomfortable to wear while performing everyday activities, and this proportion of patients could have been up to forty percent (ie. all the patients who responded to the question with "some"). This is a significant possibility, because lack of comfort would have a negative effect on compliance. If compliance levels are low, the feasibility of using the orthotic as a common adjunct to the adjustment, for the treatment of sacroiliac syndrome, would obviously be negated.

FIGURE 4.6

Question 4

Did you feel the brace restricts you from performing your normal activities properly ?



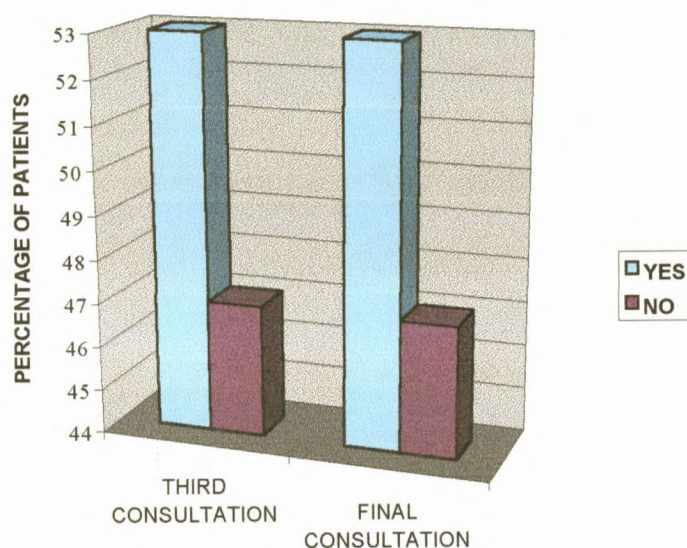
This question has similar implications to question 3, above. If patients felt that the brace would hinder their performance in everyday activities, they would be more likely to be non-compliant, with regards to use of the brace. Throughout the treatment period, 30% of patients found the brace restrictive in terms of performing normal activities. The results of the question may be ambiguous, depending on the patients condition, because it is very often the case that in patients with chronic low back pain, the patients everyday activities, at work or socially, may be aggravating factors in prolonging the condition. In this case the restriction that the brace provided would have been a positive aspect of the brace. However, if the patient felt that the benefit of wearing the brace did not outweigh the restricted lifestyle, then

compliance would be reduced, and the practical value of the brace reduced along with it.

FIGURE 4.7

Question 5

Did wearing the brace make you feel you were able to do more active movements without hurting yourself ?



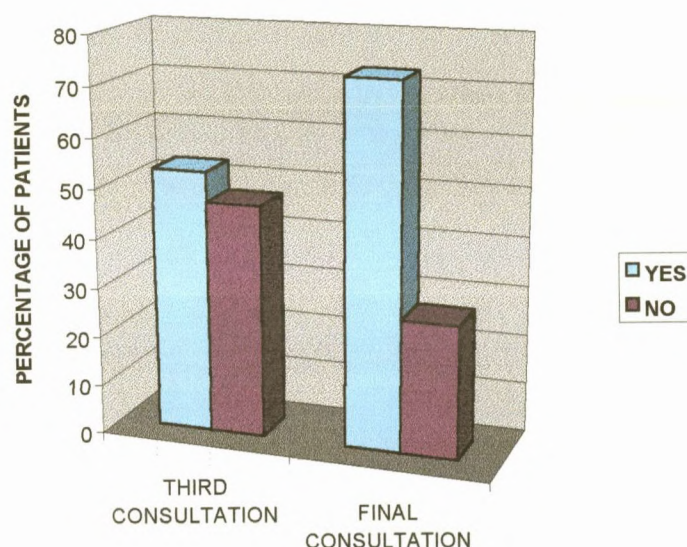
This question was an attempt to establish whether patients were answering questions as honestly as possible or whether answers were swayed towards pleasing the researcher. The question implied that being able to do more active movements without pain was a positive response, while the patient should have been avoiding the more active movements until the back pain had resolved, and did not require the use of the brace. It was noted that the percentage of patients who had felt they could

perform more active movements was only slightly higher than patients who did not feel the brace would make any difference to pain levels during active movements.

FIGURE 4.8

Question 6

Do you think that wearing the brace reminded you that you have a back problem and that it would be better to refrain from activities that that may strain your back ?



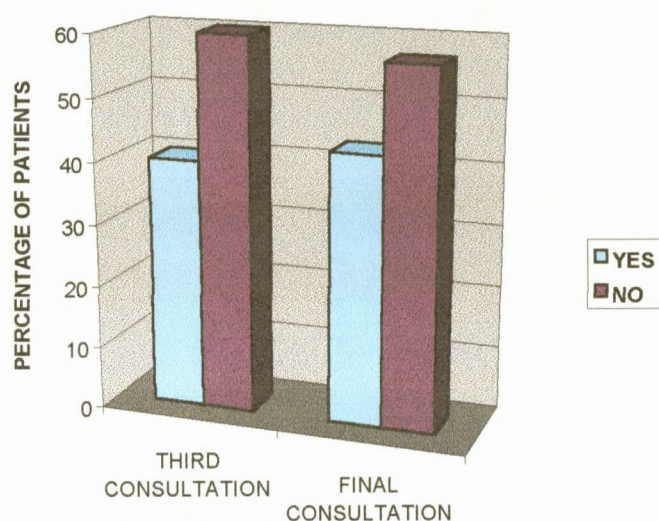
This was a direct question regarding avoidance activity. At the third consultation the responses to the question were exactly matched to question 5 above. Which possibly suggests that while patients did feel they could do more with the brace on, they were consciously avoiding activities that may aggravate their back condition. This increased awareness would have been beneficial to the healing process and was

evident in more than half of the patients wearing the brace. There was no explanation as to why this awareness increased after the third consultation.

FIGURE 4.9

Question 7

Do you feel that wearing the brace restricts you from activities which may aggravate your back pain ?

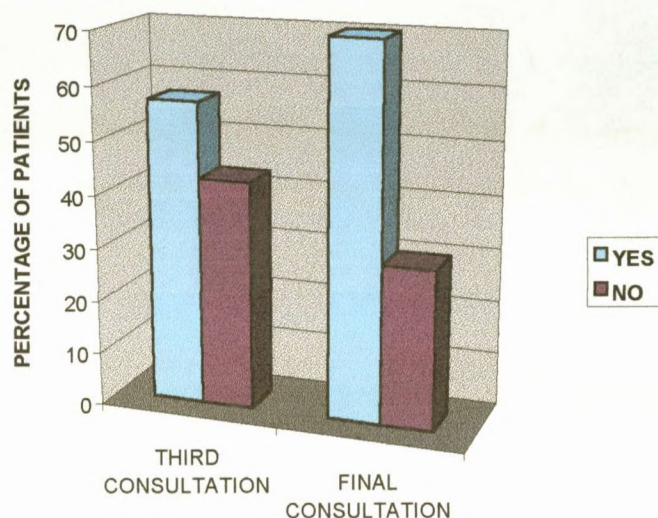


Sixty percent of Group II, felt the brace provided a physical restriction, from harmful activities. This was a more desirable benefit than elevated awareness in terms of re-injury prevention, by physical limitation of the activity.

FIGURE 4.10

Question 8

Did you feel you were more aware of your back problem while wearing the brace than without it ?

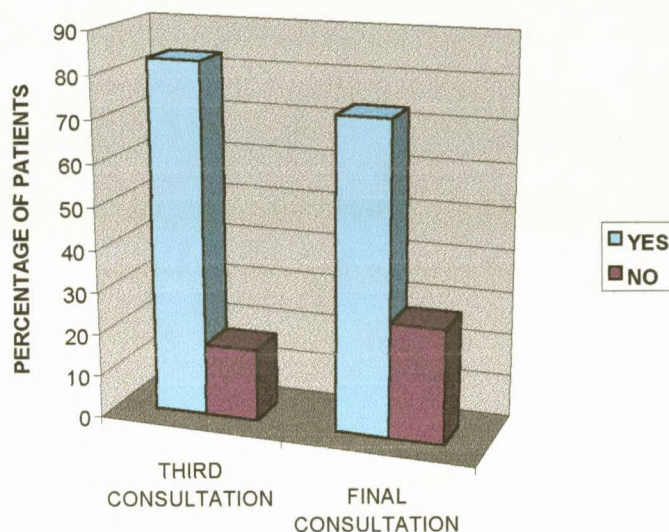


This was a direct question regarding awareness and was expected to give further insight as to whether the patient experienced heightened awareness about their back condition as a result of wearing the brace. In association with question 6, it was possible to deduce that over the treatment period, between 53% and 73% of patients adopted this avoidance activity as a result of heightened awareness. It was interesting that both question 6 and question 8 demonstrated an unexplained increase in positive responses, after the third consultation. This increase was proportional in the two questions, which demonstrates strong consistency for these two questions.

FIGURE 4.11

Question 9

Do you feel that your back pain is relieved by the brace ?



This question was intended to obtain an indication of the patients overall response to the brace. Over the treatment period, between 73% and 80% of patients felt the brace provided relief of the back pain. There was a slight decrease in this opinion after the third consultation. Through the course of the trial, the researcher noted that this trend was evident in certain patients who initially felt the brace was very helpful, but as treatment continued they did not attribute their pain relief to the brace as they had initially. These patients continued to respond favourably to treatment, but found less or no added relief as a result of the brace. This was considered to be a positive trend in light of the fact that long term use of the brace was not advised, and that its benefit was intended to occur early in the treatment programme.

The overall response to the compliance questionnaire was graded using the following system:

- Poor: 9 - 14
- Moderate: 15 - 20
- Favourable: 21 - 27

The responses from each patient who answered the questionnaire at the third and final consultations were added together and divided by two. This allowed the researcher to obtain an average score for each patient. The scores were recorded in the table below.

TABLE 4.18

Overall response to the compliance questionnaire

RESPONSE	MEAN SCORE
POOR	1
MODERATE	19
FAVOURABLE	10

The overall response to the orthotic, seems to be moderate to favourable. The lowest mean score was 14.5, only just missing the moderate category, by 0.5 points.

5. DISCUSSION

5.1 INTRODUCTION

This chapter is concerned with the discussion of the objective and subjective data obtained from the first treatment, third treatment and final treatment.

SUBJECTIVE DATA: Numerical Pain Rating Scale 101, Oswestry Low Back Disability Index and the compliance questionnaire.

OBJECTIVE DATA: algometer and orthopaedic tests

The results are discussed in two sections:

INTRA-GROUP RESULTS: The evaluation of the data obtained before the first, and after the third and final treatments represents the efficacy of the treatment regime. A comparison of the data obtained from the third and final treatments gives an indication of the efficacy of the additional number of treatments applied.

INTER-GROUP RESULTS: The data from the first consultation from both groups is assessed to determine if there was any difference between the two groups in terms of signs and symptoms of the presenting condition. A comparison of the results from

the third and the final treatments of both groups indicates whether either treatment regime showed a higher efficacy in the treatment of sacroiliac syndrome.

5.2 INTRA-GROUP COMPARISON

Intra-group comparison of the subjective and objective data suggests that patients from both Groups I and II, experienced significant overall improvement in pain threshold levels, orthopaedic testing, subjectively reported pain levels and disability due to their low back pain. (Table 4.8 to 4.13)

5.2.1 OBJECTIVE DATA

5.2.1.1 ALGOMETER

The data for intra-group comparison of the algometer readings can be found in tables 4.8 to 4.13.

Comparisons of the first to third consultations, showed that Group I demonstrated a significant improvement in pain threshold. This improvement, was similarly demonstrated by Group II. There was further improvement demonstrated by both Group I and II, at the final consultation. These findings were statistically significant and possibly indicate that more than three treatments provided more benefit when treating this condition than three treatments or less.

5.2.1.2 ORTHOPAEDIC TESTS (SACROILIAC STRESS TESTS)

The data for intra-group comparison, of the results of the sacroiliac stress tests can be found in tables 4.8 to 4.13.

Comparisons of the first to third consultations, showed that Group I demonstrated a significant improvement in test scores. This improvement was, similarly demonstrated by Group II. There was further improvement demonstrated by both Group I and II, at the final consultation. These findings were statistically significant and further indicate that more than three treatments provided more benefit when treating this condition than three treatments or less.

5.2.2 SUBJECTIVE DATA

5.2.2.1 NUMERICAL PAIN RATING SCALE

The data for intra-group comparison, of the results of the Numerical Pain Rating Scale 101 can be found in tables 4.8 to 4.13.

Intra-group comparisons of the first to third consultations, indicated that Group I improved symptomatically, and that the improvement was significant. Similar improvement, was demonstrated, by Group II. Both Group I and II, reported further reductions in pain levels by the final consultation. These findings were statistically significant and correlate with objective findings, that indicate that more than three

treatments provided added benefit when treating this condition than three treatments or less.

5.2.2.2 OSWESTRY LOW BACK DISABILITY QUESTIONNAIRE

The data for intra-group comparison, of the results of the Oswestry Low Back Disability Questionnaire can be found in tables 4.8 to 4.13.

Both groups reported an overall decrease in disability as a result of their back pain during the treatment period. The differences in disability from the first to the third consultations and the first to the final consultations were statistically significant. The decrease in disability from the third treatment to the final consultation was significant only in group I, but indicated no added benefit from additional treatments for this variable in group II, where the P-value ($p = 0.152$) indicated no significant change.

This could be due to the results of two specific patients in group two, whose Oswestry Disability scores did not change between the third and sixth consultations, and had been relatively high, when compared to the other patients in both groups, at the initial consultation. This resulted in a relatively higher disability score when compared with group one who all showed a slightly lower initial score, which continued to decrease at each assessment.

5.2.2.3 COMPLIANCE QUESTIONNAIRE

The Compliance Questionnaire, which was analysed in Table 4.12, was administered at the third and final consultations, in Group II only. Although, no significant difference could be found statistically, there was a slightly more positive response, earlier in the treatment (third consultation), when comparing the mean values directly. The questions included information, about how often the stabilising sacroiliac orthotic was used, comfort, awareness of the back problem while wearing the orthotic and efficiency of the orthotic.

The researcher considered this slight change of attitude in response to the questions, related to two aspects. The patients initial positive response, would possibly be to the novelty of a potential and tangible solution to a painful condition.

However, after practical application of the orthotic, some patients found it either uncomfortable or a nuisance to have to keep applying and removing, during certain activities (for example, bathing). Other negative comments, recorded by the researcher, included that the brace was uncomfortable to use while sitting as it tended to slip upwards and needed to be constantly adjusted; and that the brace was "hot and sweaty" to wear (especially during the first few months of the study, which fell over the summer months).

The orthotic was intended for use in the earlier stages of treatment, and not as a long term solution to the low back pain problem. As a result this slight decrease in the response to the questionnaire at later stages of treatment could be considered

favourable, in terms of the smaller chance of patients developing psychological dependency on the orthotic.

It must be remembered that the compliance questionnaire was used for the first time in this trial, and has not been subjected to any analysis in terms of its validity or reliability.

5.3 INTER- GROUP COMPARISON

Inter-group comparison of the subjective and objective data suggests that patients from both Groups I and II, experienced relatively similar levels of pain during orthopaedic testing, subjectively reported pain levels and disability due to their low back pain, on entry into the trial.

At the third and final consultations there was no evidence that either Group I or II had benefited more from their treatment than the other Group. (Table 4.14 to 4.16). This indicates that at a 95% confidence level, the two treatment regimes are equally effective in improving subjective and objective findings, in patients suffering from sacroiliac syndrome.

5.3.1 OBJECTIVE DATA

5.3.1.1 ALGOMETER

On initial presentation, Group I had statistically similar mean algometer recordings to Group II, indicating pressure pain tolerance levels in both groups were comparable in nature.

After the third and final consultations, there were no statistical differences between the two groups with respect to pressure pain thresholds.

5.3.1.2 ORTHOPAEDIC TESTS

As mentioned previously, baseline measurements for both groups were very similar (Table 4.14). At the third and final consultation, no statistically relevant differences were noted between the two groups, in terms of pain of sacroiliac origin (Table 4.15 and 4.16).

5.3.2 SUBJECTIVE DATA

5.3.2.1 NUMERICAL PAIN RATING SCALE

Statistical analysis of the first consultation revealed no significant differences in the initial level of pain for both treatment groups.

On analysing the data taken from the third consultation, there was no evidence of any statistical difference between the groups. This indicated that both treatment protocols were effective in initial reduction of the severity of pain in sacroiliac syndrome. By the final consultation there was still no statistically significant difference between the two groups.

5.3.2.2 OSWESTRY LOW BACK DISABILITY QUESTIONNAIRE

After the third and final consultations, there were no statistical differences between the two groups with respect to levels of disability due to low back pain. The patients

from both groups entered the trial with statistically similar levels of disability due to low back pain. However, using the grading system established by Fairbank et al. (1980), Group II was graded as slightly more severe, in the group with moderate disability in comparison with Group I, graded with minimal disability.

5.4 DISCUSSION OF THE SUBJECTIVE AND OBJECTIVE DATA

5.4.1 HYPOTHESIS TESTING

From the statistical data it can be seen that both groups improved significantly between the initial treatment and the final treatment. Both treatment regimes were seen to be effective after the third consultation and efficacy was further enhanced as a result of continued treatment at a maximum of six consultations.

The hypothesis (H1) was therefore accepted that there would be a significant improvement in terms of subjective findings, in both groups.

As stated earlier, the only data that did not indicate statistically significant improvement was the change in the Oswestry Disability scores in Group II, as a result of continued treatment, following the initial improvement noted at the third consultation. The overall improvement for this variable, between the initial and final consultations was statistically significant, and warrants rejection of the null hypothesis.

It was hypothesised (H2) that there would be a significant improvement in terms of objective clinical findings, within both groups, demonstrating that both treatment protocols were effective for the treatment of sacroiliac syndrome.

The hypothesis (H2) was accepted for all three data collecting consultations, as both treatment protocols showed statistically significant improvement, between the first and final consultation.

5.4.2 INTER-GROUP COMPARISON OF DATA

No evidence could be found that the use of manipulation in conjunction with a stabilising sacroiliac orthotic was superior to manipulation in conjunction with a non-stabilising orthotic, in terms of subjective and objective findings, for the treatment of sacroiliac syndrome.

Although there was no significant difference between the baseline measurements in Group I and II, recorded at the first consultation, it was apparent from mean and median values, that Group II showed a trend towards consistently more severe values. It was considered possible that, combining the baseline values of all the measurements may have shown that Group II, was in fact more severe on initial presentation than Group I. The sample size may have been too small to register the slight differences between the groups on initial presentation.

In addition the chiropractic manipulation is accepted as an effective treatment approach in the management of sacroiliac syndrome, and the additional benefit

provided by the orthotics may not be significantly large enough to show statistical differences at a 95% level of confidence.

5.5 DISCUSSION OF THE DEMOGRAPHIC DATA

The overall gender distribution was fairly equal, but there was a higher proportion of females, in Group II (Table 4.3).

The gender distribution of the source population, with low back pain was proportionate to the gender distribution of patients diagnosed with sacroiliac syndrome. This was in contrast to earlier studies on sacroiliac syndrome in which females had a higher proportion of pain, of sacroiliac origin than males (Schwarzer *et al.* 1995; Gemmel and Jacobson 1990; Cibulka and Koldehoff 1999). The present research study showed no predominance of sacroiliac syndrome in females in the source population that was assessed.

The age distribution across the groups was almost reversed (Table 4.4). The 18 to 25 year age group had the most patients in group one and very few patients in group two, while the 36 to 50 year age group had a very high proportion of patients in group two and a small proportion in group one.

A right-sided predominance of sacroiliac dysfunction was noted in the present study (Table 4.7), and if the relatively small percentage, of bilateral results, are

disregarded, the right to left ratio is 62:38. This is a remarkably similar ratio to that of Toussaint et al. (1999) who found a 60:40 right-sided predominance of sacroiliac joint dysfunction, in a group of 480 construction workers. No bilateral sacroiliac dysfunction was recorded in that study. Results of a controlled injection study by Schwarzer et al. (1995) suggests that the condition is likely to be unilateral in about 60% of the patients. The symptomatic presentation of patients in the present study did not follow this trend and indicate a bilateral presentation in 60% of patients, accepted for the study.

5.6 STUDY LIMITATIONS

In terms of time and financial constraints, it was not possible to have patients with high homogeneity.

An obvious limitation of the present study is the lack of stratification according to the baseline characteristics, of the selected patients. While the overall distribution of males to females was fairly equal, the distribution within the groups was unbalanced. This was considered relatively important in the light of the available literature. As discussed previously it has been suggested by Cassidy and Mierau (1992), that females may be more vulnerable to the development of ligament laxity in the pelvis and, according to Gatterman (1990) would benefit from stabilisation of the sacroiliac joints during periods of hormonal induced laxity.

The uneven age distribution was another baseline characteristic that could have had an effect on the study, as Burton and Cassidy (1992:4) suggested that low back pain reached a maximal frequency at middle age. The middle age group had a high proportion of patients in group two rendering this group at a higher risk for low back pain.

Patients who were accepted into the study, were instructed not to begin any new lifestyle or exercise activities for the duration of the trial. However, it was not within the researchers control to prevent the patient from continuing with their regular everyday activities at work or socially. This may have impact on the study, as some patients may have returned from the treatment to adopt a stressful position

related to their occupation or sporting activity, possibly negating the relief afforded by treatment.

The subjective measurements which the patients were required to complete are widely used methods of recording pain and disability, but were not designed specifically for the evaluation of sacroiliac syndrome. It is possible that some of the patients did not fully understand the methods of completing each questionnaire, thus affecting their response either negatively or positively. While all patients spoke english fluently, the researcher noted at least seven patients who spoke english as a second language, and may have experienced slight difficulties in understanding the questions completely. It is also possible that some patients may have enhanced their response positively to please the researcher.

Another problem that the researcher noted with the use of orthotics as a therapy, was that the patient would obviously experience different levels of pain when using the orthotic and when not using it. This applied to both groups in the trial. This enhanced improvement while using the orthotic was not necessarily maintained when the patient was not using the orthotic, for example when they removed it before bedtime. As a result patients were asked to answer the subjective questionnaires in terms of overall improvement as opposed to improvement they felt only while using the orthotic.

The objective measurements have the possibility of containing errors due to varying reliability as a result of human error.

Patients in group two were consistently encouraged to comply with the instructions regarding use of the sacroiliac stabilising orthotic. Patients compliance diaries were screened at each appointment and the researcher verbally enquired about the use thereof. However, it is possible that patients may have falsely filled in their diaries, so as not to disappoint the researcher.

Another important limitation of the study, is that the manipulative procedures were performed by a student intern, and not a qualified therapist with years of experience.

5.7 COMPARISON OF THE RESULTS

The results of the present trial have been compared to a number of previous low back pain trials encountered in the literature, in order to determine whether similar trends could be found, within the trials, to further validate the findings.

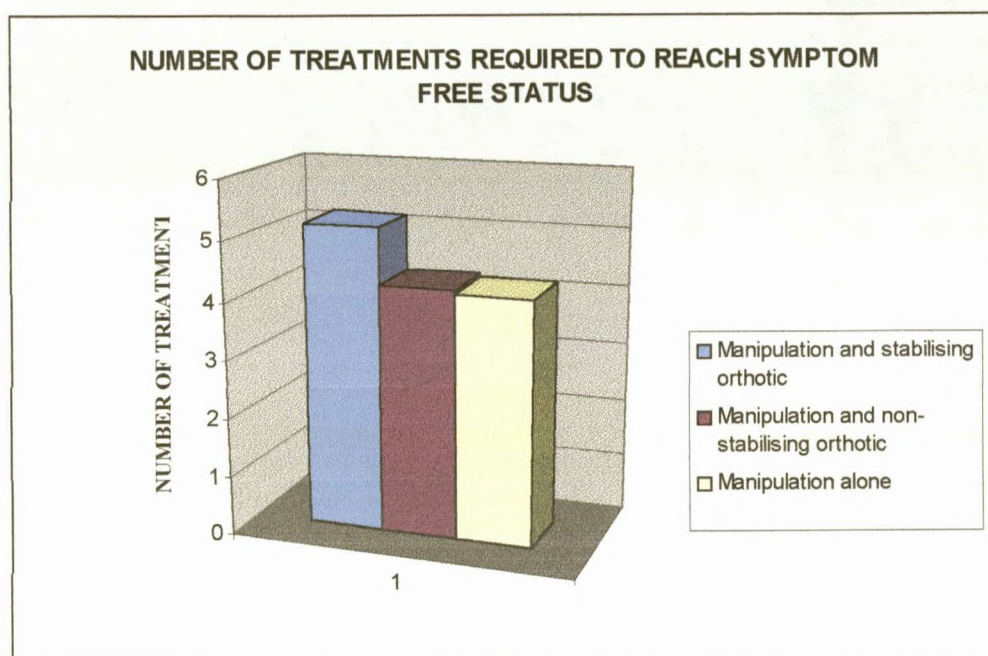
In the present trial, treatment was discontinued once the patient reached symptom-free status. By recording the number of treatments administered to patients in a trial, it is possible to draw conclusions about how quickly patients responded to the specific treatment.

A study by Waagen et al. (1986), compared manipulation to sham manual interventions, in a double-blind, short-term trial. Nineteen patients with chronic low back pain, were treated between four and six times over a two week period, which was a similar regime to the present study. Although no stratification was used for chronicity, the patients in the present trial had all suffered with low back pain for longer than a month. In both trials, treatment was discontinued once the patient became asymptomatic. The figure below demonstrates a comparison between the number of treatments administered in the adjustment group in the trial by Waagen et al., Group I of the present trial (adjustment in conjunction with non-stabilising sacroiliac orthotic) and Group II of the present trial.

FIGURE 5.1

COMPARISON OF No. OF TREATMENTS WITH WAAGEN ET AL. (1986)

No. of treatments administered before patient reached asymptomatic stage.



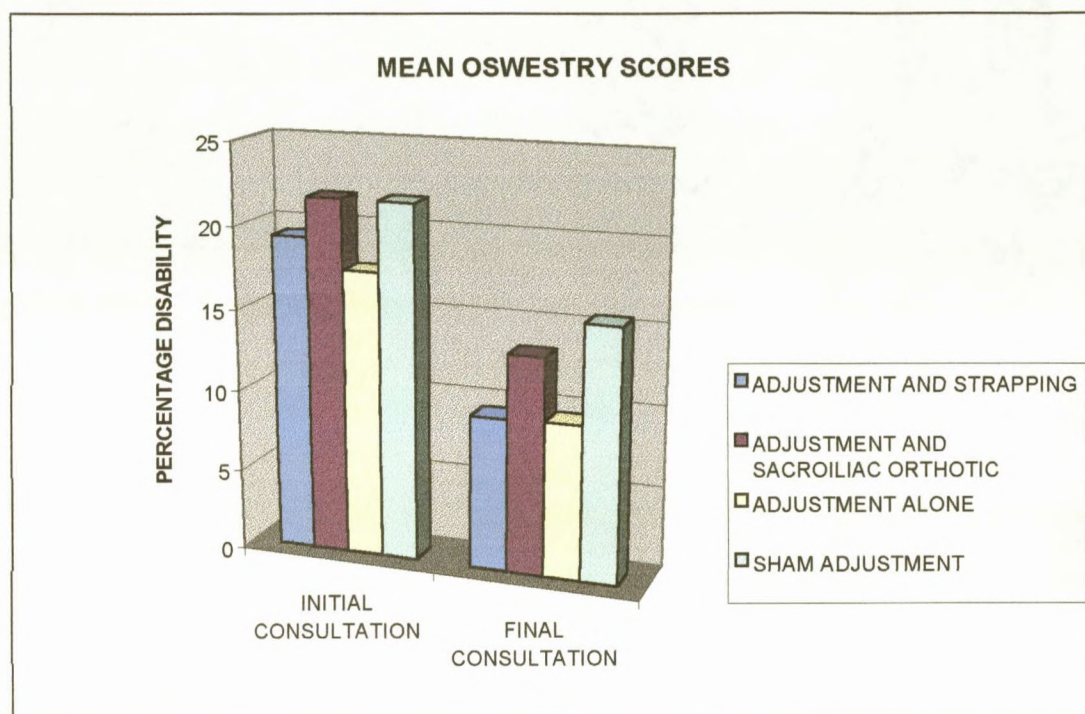
The figure indicates, that on average, patients would require between four to six treatments to reach the asymptomatic stage. The use of the adjustment in conjunction with an orthotic does not seem to add to the effectiveness of the treatment when compared to the adjustment alone.

A randomised trial by Triano *et al.* (1995), compared manipulation, a manipulation mimic, and a back education programme for the treatment of chronic low back pain. Data from 145 patients was collected at the initial consultation, after two weeks of treatment, and two weeks after treatment had ceased. The information from the first two data collecting sessions, was compared with data from the first and final consultations of the present trial. Similarities between the trials included a minimum recruitment age of 18, exclusion due to neuropathy or systemic disease, osteoporosis, fracture or osseous pathology of the spine. Patients receiving additional treatment, for their low back pain, were also excluded. High velocity, low amplitude spinal manipulation was applied, which describes the chiropractic adjustment, in both cases performed by chiropractors.

The main difference between the two trials, is that in the Triano *et al.* (1995) trial, patients were treated a minimum of seven times over two weeks, while in the present trial patients were treated a maximum of six times during the same period. In addition patients in the latter trial were treated only for sacroiliac syndrome, while in the trial by Triano *et al.* (1995), they were treated for non-specific low back pain.

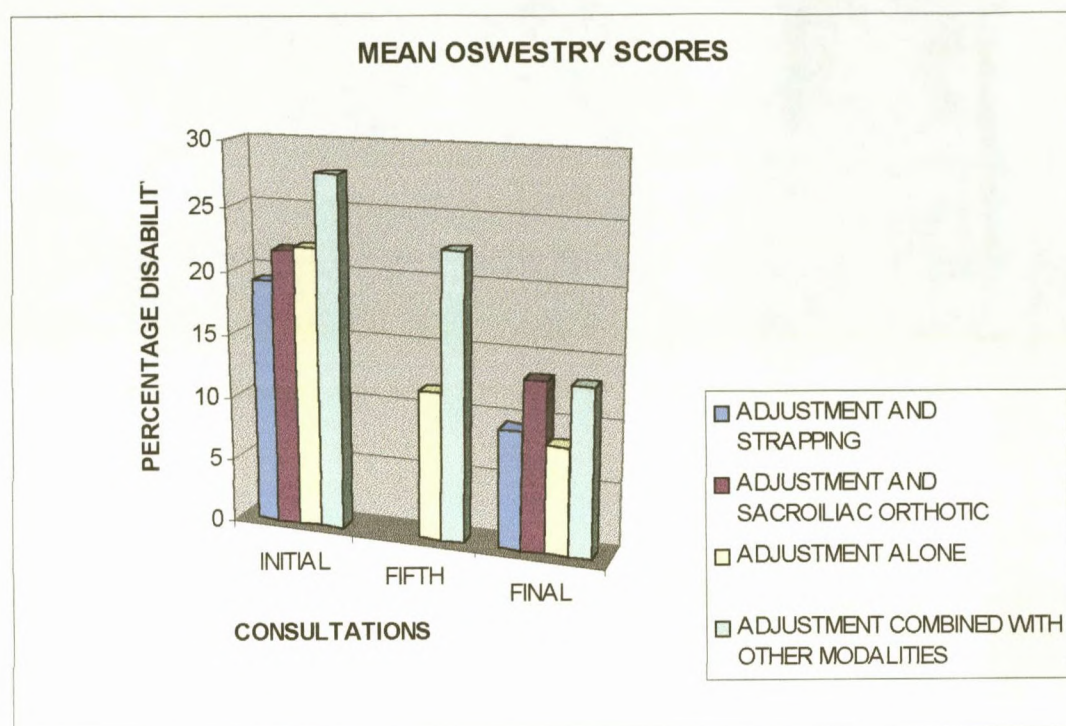
FIGURE 5.2

**COMPARISON OF MEAN OSWESTRY VALUES WITH TRIANO ET AL.
(1995)**



The above comparison shows that manipulation alone is effective in reducing disability due to low back pain, and comparable in efficiency to manipulation used in conjunction with strapping (non-stabilising sacroiliac orthotic) and manipulation used in conjunction with a stabilising sacroiliac orthotic. The sham adjustment used in the Triano et al. (1995) trial, was the least effective in reducing the mean Oswestry scores.

Oswestry scores were again compared to the results of a trial by Urli (1995) who conducted a study on a population of nurses suffering from mechanical low back pain. Thirty patients completed the trial. Fifteen were treated using manipulation in combination with other treatment modalities, (including soft tissue therapy, electrotherapy, ice, and McManis traction). Fifteen were treated using manipulation alone. The nurses received ten treatments each, regardless of whether they became asymptomatic during the treatment programme. In the figure below, the results of the final consultation demonstrate the sixth consultation in the present trial, but the tenth treatment in the trial by Urli (1995). It was interesting to note the continued improvement between the fifth and tenth treatment in the trial by Urli (1995).

FIGURE 5.3**COMPARISON OF MEAN OSWESTRY VALUES WITH URLI (1995).**

The results of Figure 5.3 indicate that it would possibly be more beneficial to extend the treatment programme in the present trial to include up to ten treatments. It is difficult to draw direct conclusions, because once again the trial by Urli (1995), included posterior facet syndromes and myofascial syndromes along with the sacroiliac syndrome of the present trial.

Finally, the results of the present trial were compared with a trial by Broughton and Kretzmann (2000), who compared spinal manipulation and spinal manipulation with low back strapping, in the treatment of low back pain. The study design employed by the authors was very similar to the present trial, with an identical population size,

treatment period and similar statistical methods. One major difference between the two trials was that in the trial by Broughton and Kretzmann (2000), the strapping was applied only until the third treatment, while in the present trial, the stabilising (sacroiliac belt) and the non-stabilising orthotic (strapping), were applied throughout the treatment programme, which in some cases may have been up until the sixth and final consultation. In the trial by Broughton and Kretzmann (2000), the statistical evidence revealed that both groups responded favourably to treatment and by the final consultation no differences were found between the two groups. However, during the period that the strapping was being applied, the strapping group did improve significantly more than the manipulation group. This could be an indication that in the present trial, the use of both the stabilising and non-stabilising orthotic, provided enhanced benefits, while being used, which may not have been long-lasting. Neither orthotic is a long term solution to a patient suffering from sacroiliac syndrome and it is recommended that the use thereof be limited to as short a period as possible. In the present trial, no statistical difference was found between the two groups throughout the trial, and when comparing the results to the trial by Broughton and Kretzmann (2000), there may be evidence to suggest that the use of an orthotic may provide an added benefit while being used, but in terms of practical application is no more beneficial to the patients overall improvement than manipulation alone.

6. RECOMMENDATIONS AND CONCLUSION

6.1 RECOMMENDATIONS

There are a number of recommendations that the author feels could improve future studies investigating the treatment of sacroiliac syndrome in conjunction with stabilising or non-stabilising orthotics. With greater time and financial freedom the following improvements could be implemented.

A large sample size is always desirable in research of this nature. In the present study the population size is large enough to allow for the use of parametric tests, so that more subtle trends in the data could be made apparent. However, a larger sample size is recommended, as it would further minimise the chance of incorrectly accepting the null hypothesis (Type II error). Assendfelt *et al.* (1992) recommended that a sample size of 100 be considered a minimum requirement in research of this nature.

It is recommended that stratification of patients be employed, according to age, sex, occupation, duration and most importantly, severity of the complaint. This would assist homogeneity within groups and lower the impact of these variables on the study. This recommendation does however remain a dilemma, as a highly homogenous group of patients may be subject to selection bias.

It is further recommended that future studies employing the use of the sacroiliac stabilising orthotic be limited to females with similar histories of pregnancy, parity, or stage of menstrual cycle. This is considered the group most likely to respond to pelvic stabilisation, when suffering from sacroiliac syndrome (Gatterman 1990), and a trial of this nature may demonstrate a specific portion of the population who would respond well to this form of therapy.

Furthermore, studies using low back orthotics would be advisable during winter months, if possible due to comfort, which obviously affords compliance.

Blinding of the treatment groups was not possible in the present study due to the nature of the applied therapies. However the validity of the results could have been increased if someone other than the researcher recorded the subjective and objective results, thereby single-blinding the recording of the results, to avoid observer bias.

It is suggested that by adding follow up consultations, at one week or one month, intervals, the long term effects of chiropractic management can be evaluated. In addition, it would provide insight as to the long term benefits, of the short term application of orthotics. There was also evidence to suggest that employing a maximum of six treatments, was a limiting factor in affording certain patients further recovery. The maximum number of treatments should perhaps be increased to twelve consultations.

It would also be recommended to add a third group into the study that receives only placebo treatment, to give an indication of the natural progression of sacroiliac

syndrome. Two earlier trials have implemented the use of sham manipulations, which seem to have provided useful placebo-control groups to strengthen the trial (Waagen *et al.* 1986, Triano *et al.* 1995)

6.2 CONCLUSION

At a 5% level of significance, it was found that both treatment protocols were effective in treating sacroiliac syndrome. Neither group showed any statistically significant advantage over the other in overall treatment efficacy. Consequently, it was accepted that for the present trial, the two treatment regimes were equally effective in improving subjective and objective findings.

One possible reason that the patients in Group II demonstrated no statistical advantage over Group I, by the final consultation, was that the former had a slightly higher level of severity, on initial presentation, indicated by the mean and median data of the subjective and objective variables. This is not conclusive, as it does not fit into the statistical confidence parameter, which this trial employed.

A second possible reason, is that the benefits of the stabilising sacroiliac orthotic could be limited to a more homogenous section of the population, for example, menstruating, pregnant or post partum females, or patients with obvious evidence of hypermobility within the pelvic ring.

The use of an additional therapy along with manipulation, may lead to higher health care costs, and unless the use of orthotics can be shown to shorten the treatment

period, or further reduce pain and disability levels, their use will remain a clinical and ethical dilemma.

Finally, we already know that the use of manipulation alone is effective in the treatment of sacroiliac syndrome. The use of the adjustment, has been the distinction, which has held the chiropractic profession unique from other health professions, and perhaps ensured the survival of chiropractic over the last 105 years. Without further research to demonstrate the efficacy of the sacroiliac orthotic, as well as other spinal orthotics on the market, it will remain within the clinical judgement of the consulting doctor as to whether the use of an orthotic should be implemented.

In conclusion, this study has demonstrated that the use of chiropractic manipulation in conjunction with a non-stabilising sacroiliac orthotic (strapping) was as effective as chiropractic manipulation in conjunction with a stabilising sacroiliac orthotic, in the treatment of sacroiliac syndrome.

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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)

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

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

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:

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

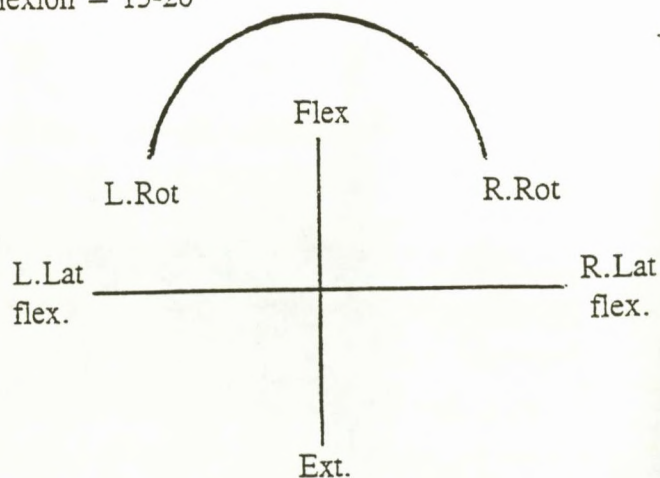
RANGE OF MOTION

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:
Orthopaedic/Neuro/
Vascular:

Observ/Palpation:

Patient Name: _____ File no: _____ Date _____

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

Section 1 - Pain Intensity

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

Section 6 - Standing

- ☐ I can stand as long as I want without extra pain.
☐ I can stand as long as I want, but it gives extra pain.
☐ Pain prevents me from standing for more than 1 hour.
☐ Pain prevents me from standing for more than ½ hour.
☐ Pain prevents me from standing for more than 10 minutes.
☐ Pain prevents me from standing at all.

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

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

Section 7 - Sex life

- ☐ My sex life is normal and causes no extra pain.
☐ My sex life is normal but causes extra pain.
☐ My sex life is nearly normal but it is very painful.
☐ My sex life is severely restricted.
☐ My sex life is absent because of pain.
☐ Pain prevents any sex life at all.

Section 3 - Lifting

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

Section 8 - Social life

- ☐ My social life is normal and gives no extra 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, for example dancing.
☐ Pain has restricted my social life and I do not go out as often.
☐ Pain has restricted my social life to my home.
☐ I have no social life because of pain.

Section 4 - Walking

- ☐ Pain does not prevent me walking any distance.
☐ Pain prevents me walking more than 1 mile (2.2km).
☐ Pain prevents me walking more than ½ mile (1.1km).
☐ Pain prevents me walking more than ¼ mile (0.5km).
☐ I can only walk using a stick or crutches.
☐ I am in bed most of the time and have to crawl to the toilet.

Section 9 - Sleeping

- ☐ I have no trouble sleeping.
☐ I can sleep well only by using pills.
☐ Even when I take pills I have less than 6 hours sleep.
☐ Even when I take pills I have less than 4 hours sleep.
☐ Even when I take pills I have less than 2 hours sleep.
☐ Pain prevents me from sleeping at all.

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 sitting for more than 1 hour.
☐ Pain prevents me from sitting for more than ½ hour.
☐ Pain prevents me from sitting for more than 10 minutes.
☐ Pain prevents me from sitting at all.

Section 10 - Traveling

- ☐ I can travel anywhere without extra pain.
☐ I can travel anywhere but it gives extra pain.
☐ Pain is bad but I manage trips over 2 hours.
☐ Pain restricts me to trips less than 1 hour.
☐ Pain restricts me to trips under 30 minutes.
☐ Pain prevents me from traveling, except to the doctor and / or hospital.

APPENDIX G

NAME:

FILE NO:

DATE:

- 1.) WAS THE BRACE WORN DURING ALL ACTIVITIES (EXCEPT LYING/SLEEPING)? ALL _ MOST _ SOME _
- 2.) DID WEARING THE BRACE GIVE YOU SENSE OF SECURITY BECAUSE OF THE SUPPORT IT PROVIDES? YES _ NO _
- 3.) WAS THE BRACE COMFORTABLE TO WEAR DURING YOUR NORMAL ACTIVITIES? ALL _ MOST _ SOME _
- 4.) DID YOU FEEL THE BRACE RESTRICTS YOU FROM PERFORMING YOUR NORMAL ACTIVITIES PROPERLY? YES _ NO _
- 5.) DID WEARING THE BRACE MAKE YOU FEEL YOU WERE ABLE TO DO MORE ACTIVE MOVEMENTS WITHOUT HURTING YOURSELF? YES _ NO _
- 6.) DO YOU THINK THAT WEARING THE BRACE REMINDED YOU THAT YOU HAVE A BACK PROBLEM AND THAT IT WOULD BE BETTER TO REFRAIN FROM ACTIVITIES THAT MAY STRAIN YOUR BACK? YES _ NO _
- 7.) DO YOU FEEL THAT WEARING THE BRACE RESTRICTS YOU FROM ACTIVITIES WHICH MAY AGGRAVATE YOUR BACK PAIN? YES _ NO _
- 8.) DID YOU FEEL YOU WERE MORE AWARE OF YOUR BACK PROBLEM WHILE WEARING THE BRACE, THAN WITHOUT IT? YES _ NO _
- 9.) DO YOU FEEL THAT YOUR BACK PAIN IS RELIEVED BY THE BRACE? YES _ NO _

APPENDIX - INSTRUCTIONS

You have been selected into the group required to wear a back brace, as an adjunct to the treatment you will receive in the clinic. It is important for research purposes, that you follow the instructions regarding the wearing of the brace. Furthermore if for any reason you are unable to follow these instructions it is important that the researcher is informed and that you are not tempted to keep the information back, in order to please the researcher.

- 1) You will need to wear the brace for the full two weeks of treatment, unless the researcher instructs you to stop before the two weeks is up.
- 2) The brace needs to be worn during all activities, in which your lower back is weight-bearing. This includes any sitting, standing and walking positions.
- 3) The brace should not be worn while sleeping or lying down.
- 4) In your diary please include the approximate number of hours during the day that the brace is worn and the type of activities performed while wearing the brace (eg. Sitting, driving, standing, walking, running, climbing stairs).
- 5) Please also include the type of activities (if any), performed without the brace. Do not include sleeping or lying down, as these positions must not be done with the brace on anyway.

APPENDIX I

APPENDIX - COMPLIANCE DIARY

Please fill in your diary each day and try to be as accurate as possible.

	HOURS/DAY	TYPE OF ACTIVITY WITH BRACE	TYPE OF ACTIVITY WITHOUT BRACE
DAY 1			
DAY 2			
DAY 3			
DAY 4			
DAY 5			
DAY 6			
DAY 7			
DAY 8			
DAY 9			
DAY 10			
DAY 11			
DAY 12			
DAY 13			
DAY 14			

Informed Consent Form
(to be completed in duplicate by patient/subject)

Date:

Title of Research Project:

Name of Patient:

Name of Supervisor:

Name of Research Student:

Please circle the appropriate answer

- | | | |
|--|-----|----|
| 1. Have you read the research information sheet? | Yes | No |
| 2. Have you had the opportunity to ask questions regarding the study? | Yes | No |
| 3. Have you received satisfactory answers to your questions? | Yes | No |
| 4. Have you had the opportunity to discuss this study? | Yes | No |
| 5. Have you received enough information about this study? | Yes | No |
| 6. Whom 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? | | |
| A) at any time | Yes | No |
| B) without giving any reason | Yes | No |
| C) without affecting your future health care | Yes | No |
| 9. Do you agree to voluntarily participate in this study? | Yes | No |

If your answer to any of the questions is No, please seek clarity from the researcher before signing below.

Please print in block letters:

Patient/Subject Name:

Signature:

Parent/Guardian Name:

Signature:

Witness Name:

Signature:

Research Student Name:

Signature: