CHAPTER THREE

3.1 Introduction

This chapter discusses the design, the sample, the clinical procedure, the inclusion and exclusion criteria, and the interventions and measurements utilized. An overview of the methods of statistical analysis is also included.

3.2 Design

This study was a crossover clinical experiment.

3.3 The Sample

3.3.1 Advertising

The public were informed about the research by means of advertisements (appendix B) at the Chiropractic Clinic at Durban Institute of Technology as well as at other public venues. The public were also informed by means of word of mouth and newspaper advertisements.

3.3.2 Sampling method and size

A non-probability, convenience sampling technique was used.

A sample size of 30 male patients and 30 female patients suffering from sacroiliac joint syndrome was used.

3.3.3 Sample allocation / randomization

There were two hats (one for the males, one for the females) each containing 15 A's and 15 B's. The participants were randomly divided into two groups of 30 by means of drawing either A or B from a hat. Each group contained 15 males and 15 females. For the first half of the study group A received treatment by means of a sacroiliac joint manipulation, and group B acted as a control group. A crossover then occurred and group B received treatment and group A acted as a control group for the remaining half of the study.

3.3.4 Telephonic interview

A telephonic interview (appendix A) was conducted with potential participants by the researcher in order to determine whether they could possibly be included in the study.

3.4 Clinical procedure

After meeting the requirements stipulated in the telephonic interview (appendix A), the patients were asked to attend an initial consultation which was performed at the Chiropractic Clinic at Durban Institute of Technology. Prospective patients underwent a full case history (appendix C), a revised physical examination (appendix D), a lumbar regional examination (appendix E), and a hip regional examination (appendix F). This was done to determine whether or not the patient met any of the stipulated inclusion or exclusion criteria, thus deciding acceptance into the study.

3.4.1 Inclusion criteria

- In order to increase group homogeneity patients were required to have a numerical pain rating scale-101 (NRS-101) (appendix I) reading of 50 or more in order to be included.
- Patients between the ages of 25-45 were included. Brandt (2002) found little radiographic evidence of osteoarthritis in patients below the age of 45 years.
- Only English speaking patients were included as English is the researcher's first language and helped to reduce possible linguistic confusion between participants and the researcher.
- Patients had to have sacroiliac joint syndrome. A diagnosis of sacroiliac joint syndrome was made if all of the following were found:
    1. Pain felt over the sacroiliac joint, with possible referral to the groin, trochanter, and buttock (Riggien 2003)
    2. Sacroiliac joint was tender to palpation (McCullach et al. 1997: 180-181)

3. The pain was aggravated by 2 of the following 4 provocation tests: Gaenslen's, Patrick's Faber, Erichson's, and Posterior shear tests (Riggien 2003) (McCullach et al. 1997: 180-181) (The method of doing these tests is described below)
4. Other apparent causes of the patient's sacroiliac joint pain were not present e.g. infection (Riggien 2003 and McCullach et al. 1997: 180-181)

- Patients were only accepted once they had undergone a full case history, revised physical examination, lumbar regional examination, hip regional examination and had read and signed the informed consent form.
- After the initial consultation, patients were required to attend seven follow-up visits.

3.4.2 Exclusion criteria

- If any of the following contra-indications to manipulation were present then the patient was excluded from the study: (Gatterman 1990)

1. Disc herniations with increasing signs and symptoms of neurological deficit
2. Abdominal aortic aneurysm
3. Lumbar spine tumours
4. Lumbar spine infections
5. Lumbar spine traumatic injuries
6. Cauda equina syndrome
7. Spondylolisthesis

- Any patients who began taking medication (e.g. anti-inflammatories or analgesics) for their low back pain (Poul et al. 1993) or began receiving treatment for their low back pain, during the course of the study, were excluded (Haldeman 1992). Patients who had had previous lower back surgery were also excluded.

- Patients suffering from any hip pathologies including instability were excluded. Hip pathologies were ruled out subjectively by a history of groin pain, and objectively by means of a basic hip examination including Quadrant scouring test, Patrick's Faber test, and decreased or painful internal rotation of the hip (Magee, 1992).
- All patients who did not meet the inclusion criteria were replaced.

If the participant was accepted into the study he was informed about the nature of the study and was given an explanatory letter (appendix G) and an informed consent form (appendix H), both of which had to be read and signed. Questions pertaining to the research may have been asked at any stage.

The patients were randomly assigned to either group A or B, and the intervention was conducted as indicated by the table below.

3.5 Clinical evaluation

This was based on a full case history (appendix C), a revised physical examination (appendix D), a lumbar regional examination (appendix E), and a hip regional examination (appendix F) and included the following in order to include or exclude the patients:

Gaenslen's test:

This is performed with the patient supine. The examiner flexes the patient's left knee and hip towards the chest, while pressing downward over the right thigh to hyperextend the right hip. Pain over the region of the right sacroiliac joint is considered a positive test (Kirkaldy-Willis et al., 1992: 125).

Patrick's Faber test:

This is performed with the patient supine. The examiner positions the patient's test leg so that the foot is on top of the knee of the opposite straight leg. The examiner then slowly lowers the test leg in abduction with hand pressure towards the examining table, while the opposite hand stabilises the pelvis at the anterior superior spine (Magee, 1997:

473). A positive test is when the patient experiences pain in the sacroiliac joint with abduction of the test knee.

Yeomann's test: (also called Erichson's test)
This is performed with the patient prone. The examiner applies a firm pressure over the patient's sacroiliac joint with one hand, whilst the other hand is placed under the thigh above the knee on the same side. The examiner then hyperextends the thigh by lifting the knee off the examining table. If pain is increased in the sacroiliac region, it indicates a positive test (Schafer and Faye, 1990: 271).

Posterior Shear test: (also called Thigh Thrust test)
This is performed with the patient supine and by flexing the hip to 90 degrees and then adducting the femur to the midline before applying axial pressure along the length of the femur. This test uses the femur as a lever to push the ilium posteriorly, thus stressing the posterior structures. A positive test is indicated by pain over the sacroiliac joint (Broadhurst and Bond, 1998: 342).

3.6 Intervention

The evaluations were done by a nominated evaluator, and all treatment was done by the researcher in order to: a) standardize evaluation and treatment
b) ensure that there was a blinding process to exclude experimental bias
(Mouton, 1996: 141-160)

Treatment A included:

- Motion palpation of the sacroiliac joints, and a sacroiliac joint manipulation.

Treatment B included:

- Motion palpation of the sacroiliac joints.

Only one side was chosen to be evaluated and treated. This was decided by taking the following into consideration:

- The side that was symptomatic for the patient
- The side on which the provocation tests for sacroiliac syndrome were positive
- The side on which the sacroiliac joint was restricted

Week	Visit	Group A	Group B
1	1	Case history, Physical, Lumbar regional, Clinical evaluation and Treatment A	Case history, Physical, Lumbar regional, Clinical evaluation and Treatment B
	2	Inclinometer (including JPS) and algometer readings and Treatment A	Inclinometer (including JPS) and algometer readings and Treatment B
2	3	Treatment A	Treatment B
	4	Clinical evaluation **CROSSOVER** Treatment B	Clinical evaluation Treatment A
3	5	Inclinometer (including JPS) and algometer readings and Treatment B	Inclinometer (including JPS) and algometer readings and Treatment A
	6	Treatment B	Treatment A
4	7	Clinical evaluation	Clinical evaluation

<u>A clinical evaluation included:</u>

- Completing the numerical pain rating scale-101 (NRS-101) (appendix I) in order to measure pain intensity.
- Undergoing active hip range of motion testing using an Inclinometer. This was done pre- and post- treatment.

- Measuring pressure threshold over the Piriformis muscle using an Algometer. This was done pre- and post- treatment.
- Completing the Oswestry Low Back Pain Disability Index questionnaire (appendix J) in order to indicate the effect of low back pain on your ability to manage everyday life.
- Undergoing hip rotation range of motion testing using an Inclinometer in order to measure joint position sense (JPS) and thus proprioception of the hip joint. This was done pre- and post- treatment.

3.7 Measurements

3.7.1 Subjective Measurements

Subjective measurements were obtained via the following in order to assess low back pain intensity:

- Numerical Pain Rating Scale-101 (NRS-101) (appendix I) to measure pain intensity. The results of a study conducted by Jensen et al. (1986) indicated that it was superior to other measures due to its simple and practical method of administering and scoring.
- Oswestry Low Back Pain Disability Index questionnaire (appendix J) to indicate the effect of low back pain on the patient's ability to manage everyday life. Fairbank et al. (1980) confirmed that the questionnaire was both valid and reliable.

3.7.2 Objective Measurements

Objective measurements were obtained via an Inclinometer and an Algometer.

An **Inclinometer** measures range of motion of a joint. The normal active range of motion of the hip joint is:

Flexion = 110-120 degrees
Extension = 10-15 degrees
Abduction = 30-50 degrees
Adduction = 30 degrees

Internal rotation = 30-40 degrees
External rotation = 40-60 degrees
(Magee, 1992:335).

The Inclinometer used in this study was the DUALER system of inclinometry (JTech Medical Industries 4314 ZEVEX Park Lane, Salt Lake City, UT 84123 USA, tel 801/264-1001). As a result of inclinometer insensitivity to placement, inclinometers are more accurate than goniometers for measuring range of motion of the large extremities (Livingston, 1992:3). See appendix K for the measurement procedure.

Hip joint proprioception was assessed by means of measuring joint position sense of the hip joint pre- and post- treatment using an Inclinometer. In a study conducted by Deshpande et al. (2003) to determine the reliability and validity of ankle proprioceptive measures, results showed that joint position sense was a reliable tool for measuring proprioception, and that active movement was a reliable method for measuring joint position sense. See appendix L for the measurement procedure.

An **Algometer** is a device for measuring pressure threshold which Fischer (1987: 207) described as the minimum pressure or force that induces pain or discomfort. In a study conducted by Fischer (1986) he found that the reproducibility and validity of pressure threshold measurements were consistently good thus indicating that the records of pain intensity are reliable. Further he confirmed that algometer measurements were useful in evaluating manipulative intervention, and could be used to quantify the patient's response to manipulation. The most frequent cause of error is failure to find the exact point of maximum tenderness, and often results in false readings mounting to several kg/cm² if missed by a few millimeters (Fischer, 1987: 209). Fischer (1987: 212) added that caution should be taken in the clinical use of the algometer because of the very complicated problem of how pain perception varies in different individuals, as well as in the same person under various conditions e.g. psychological tension, change in the weather.

The Algometer used in this study was the Wagner FDK20 Force Dial (Wagner Instuments, P.O. Box 1217, Greenwich, CT, 06836, U.S.A.), and was applied to the Piriformis muscle on the side chosen to be tested. This gave an indication of the myofascial dysfunction status of the Piriformis muscle, and the possible effect which sacroiliac joint manipulation had on this status. See appendix M for the measurement procedure.

With this information one could draw conclusions regarding the effect of sacroiliac joint manipulation on hip functional ability by means of comparing the results of the various measurement tools at various stages of the study.

3.8 Statistical Analysis

Data analysis was done in SAS version 9.1 (SAS Institute Inc., Cary, NC). Baseline comparisons between the categorical baseline variables and the group to which the participant was assigned were done using Fisher's exact test. Continuous baseline variables that were not normally distributed were compared between groups using a non-parametric Wilcoxon Mann-Whitney test. Continuous normally distributed baseline data were compared using the two sample t-test.

The follow-up measures were summarised according to the treatment received. The baseline measurement is the measurement for both groups of symptomatic patients at Visit 1 before they received any manipulation. The measurement immediately before and after the manipulation and control is summarised, as well as the measurement at the beginning of the following phase. This measurement is regarded as an indication of the long-term effect of the previous treatment.

The immediate treatment effect was evaluated by getting the difference between the pre- and post-treatment values. The differences obtained in each of the periods of the cross-over design are then analysed using a repeated measures analysis of variance (ANOVA). There are three main

issues to consider in a crossover trial, namely period, treatment, and group or carryover effects.

To determine whether the adjustment had a long term effect in patients treated with the adjustment first (Group A), the readings were summarised for Group A only at pre-adjustment Visit 1 and at Visit 7. No statistical analysis was done on this, since the same data points did not exist for the control group.

To determine the effect of certain baseline variables on the treatment, a repeated measures ANOVA was done with the baseline variables included as covariates (side treated, cavitation present or absent, bilateral syndrome).