

THE RELATIVE EFFECTIVENESS OF SPINAL MANIPULATIVE THERAPY
COMPARED TO DICLOFENAC SODIUM, IN THE MANAGEMENT OF
MECHANICAL LOW BACK PAIN.

BY

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

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DEDICATIONS

It gives me great pleasure to dedicate this dissertation to my family who
has seen me through it all.

Their love, support and assistance were truly appreciated. To my parents,
who gave me the opportunity of a lifetime and allowed me to fulfill my
dream.

They showed me my potential and beyond. They taught me to choose a
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ABSTRACT

Hendler et al. (1995) describes low back pain as the most common, costly and disabling musculoskeletal condition. Giles (1997: 28) supports this, stating that the annual incidence of low back pain in the adult population is between two and five percent, with a lifetime prevalence of well over 50%.

For clinicians to choose the most appropriate therapy for managing this common condition it is essential for research to be carried out to define the most effective treatment. Shekelle (1994) explains that spinal manipulative therapy is an effective treatment for patients with low back pain, while Cherkin et al. (1995) states that there is strong evidence to support the use of nonsteroidal anti-inflammatory drugs in the management of mechanical low back pain. It is therefore the purpose of this investigation to determine the relative effectiveness of spinal manipulative therapy compared to Diclofenac Sodium, in terms of subjective and objective measures, in the management of mechanical low back pain.

This randomized controlled trial consisted of sixty patients between the ages of 18 and 65, complaining of mechanical low back pain. The sixty patients were randomly divided into two treatment groups of thirty each. One group received spinal manipulative therapy and the remaining thirty were administered Diclofenac Sodium. These patients were carefully screened to allow the researcher to diagnose the patient, with Lumbar Facet Syndrome, Sacroiliac Syndrome or Myofascial Pain Syndrome; or any combination of these syndromes. This is in accordance with Kirkaldy-Willis (1992: 105 – 119) classification system. The thorough examination ensured that each patient had no contra-indications to spinal manipulative therapy or Diclofenac Sodium.

Each patient within the spinal manipulative therapy group received four manipulations within a seven to ten day period, while the Diclofenac Sodium group were administered medication over a seven day period.

The statistical data was collected at the initial, second and final consultations. The subjective data was obtained using the Numerical Pain Rating Scale-101 (appendix F) and the Oswestry Low Back Pain Disability Index (appendix G). The objective data was obtained using the algometer and the orthopaedic rating scale. Parametric statistical analysis was used for those sample sizes greater than or equal to 30 patients. The Paired t-test was used to determine the intra-group performance while the Unpaired t-test was used to determine the inter-group performance. The results were all analyzed at a 5% level of significance i.e. $\alpha = 0,05$. Non-parametric statistical analysis was used for those sample sizes less than 30 patients. The Wilcoxin Signed Rank test was used to determine the intra-group performance, while the Mann-Whitney U-test was used to determine the inter-group performance. The results were all analysed at a 5% level of significance i.e. $\alpha = 0,05$.

The intra-group analysis indicated that both treatment groups improved significantly between the initial and final consultations. The inter-group analysis showed no difference between Group 1 and Group 2 by the end of the final consultation.

The overall results lead to the assumption that both treatment groups responded equally and favorably in terms of subjective and objective measures. Therefore within this study spinal manipulative therapy and Diclofenac Sodium were both effective in treating mechanical low back pain.

Although the results of the study indicated that Diclofenac Sodium was effective in the management of mechanical low back pain, the issue of safety and the possible iatrogenic side effects of this medication were important to consider.

The high incidence of dropouts and lack of patient compliance within group 2 was an indication that the patients were not satisfied with the medication. The possible cause of the poor satisfaction is the public's increasing awareness of the high incidence of side effects nonsteroidal anti-inflammatory drugs can cause.

In conclusion, spinal manipulative therapy and Diclofenac Sodium were equally effective in the management of mechanical low back pain. Although Diclofenac Sodium did assist in managing mechanical low back pain, patient dissatisfaction could out weigh the potential benefits of the medication. It is therefore recommended that more research be carried out to gain conclusive results indicating the least complicated and most beneficial treatment protocol.

TABLE OF CONTENTS

Dedication	i
Acknowledgements	ii
Abstract	iii
Table of Contents	vi
List of Tables	xv
List of Photographs	xvii
List of Figures	xvii
List of Abbreviations	xix
Appendices	xix
Definitions	xx

CHAPTER ONE

1.1. Introduction	2
1.2. The Problem and It's Setting	4
1.2.1. The Problem Statement	4
1.2.2. The Objectives	5
1.2.2.1. Objective One	5
1.2.2.2. Objective Two	5
1.2.2.3. Objective Three	5

CHAPTER TWO

2. Review of the Related Literature	
2.1. Introduction	7
2.2. Incidence and Prevalence of Mechanical Low Back Pain (LBP)	7
2.3. The Subluxation Complex	8

2.4.	Relevant Anatomy and Biomechanics	9
2.4.1.	The Anatomy of the Lumbar Zygapophyseal Joint	9
2.4.2.	The Innervation of the Lumbar Zygapophyseal Joint	10
2.4.3.	The Function of the Lumbar Zygapophyseal Joint	10
2.4.4.	The Anatomy of the Sacroiliac Joint	11
2.4.5.	The Innervation of the Sacroiliac Joint	11
2.4.6.	The Function of the Sacroiliac Joint	12
2.4.7.	Consideration of Muscles	12
2.5.	Classification of Mechanical Low Back Pain (LBP)	13
2.6.	Clinical Consideration of Mechanical Low Back Pain (LBP)	16
2.6.1.	The specific clinical lesion categorized within the phase of dysfunction are:	17
2.6.2.	The specific clinical lesion categorized within the phase of instability are:	17
2.6.3.	The specific clinical lesion categorized within the phase of stabilization are:	17
2.6.4.	Posterior Facet Syndrome	18
2.6.5.	Sacroiliac Syndrome	19
2.6.6.	Myofascial Pain Syndrome	20
2.7.	The Effects of Spinal Manipulative Therapy (SMT)	21
2.8.	The Adverse Reactions to Spinal Manipulative Therapy (SMT)	23
2.9.	The Effectiveness of Spinal Manipulative Therapy (SMT)	23
2.10.	The Effects of Diclofenac Sodium	26
2.11.	The Side Effects of Nonsteroidal Anti-inflammatory Drugs (NSAIDs)	26

2.12. The Effectiveness of Nonsteroidal Anti-inflammatory Drugs (NSAIDs)	27
2.13. The comparison of Spinal Manipulative Therapy (SMT) and Diclofenac Sodium in the management of mechanical Low Back Pain (LBP)	29
2.14. The Indications for and Contraindications to Spinal Manipulative Therapy (SMT)	31
2.14.1. Indications of SMT	31
2.14.2. Contraindications of SMT	32
2.15. The Indications for and Contraindications to Diclofenac Sodium	32
2.15.1. Indications for Diclofenac Sodium	32
2.15.2. Contraindications to Diclofenac Sodium	33
2.16. Conclusion	35

CHAPTER THREE

3. Materials and Methods	
3.1. Introduction	37
3.2. The Data	37
3.2.1. The Primary Data	37
3.2.2. The Secondary Data	38
3.3. Criteria Governing Admissibility of the Data	38
3.4. Research Methodology and Materials Used	38
3.4.1. Patients	38
3.4.2. Inclusion and Exclusion Criteria of Patients	39
3.4.3. Intervention	40

3.4.4. Measurements	42
3.4.4.1. Objective measurements	42
3.4.4.2. Subjective measurements	50
3.5. Statistical Procedure	51
3.5.1. Procedure 1: Wilcoxin Signed Rank Test (Intra-group)	51
3.5.2. Procedure 2: Mann-Whitney U-test (Inter-group)	53
3.5.3. Procedure 3: Paired t-test (Intra-group)	53
3.5.4. Procedure 4: Unpaired t-test (Inter-group)	54
3.6. The Specific Treatment of Each Objective	55
3.6.1. Objective One	55
3.6.1.1. The data required	55
3.6.1.2. How the data was secured	55
3.6.2. Objective Two	56
3.6.2.1. The data required	56
3.6.2.2. How the data was secured	56
3.6.3. Objective Three	57
3.6.3.1. The data required	57
3.6.3.2. How the data was secured	57

CHAPTER FOUR

4. The Results	
4.1. Introduction	59
4.1.1. The Use of Non-parametric tests for Statistical Data Analyses	59
4.1.2. The Use of Parametric test for Statistical Data Analyses	60
4.2. Tables of Demographic Data	61
4.2.1. Age distribution within the sample group of 60	61
4.2.2. Gender distribution within the sample group of 60	62
4.2.3. Race distribution within the sample group of 60	62
4.2.4. Patient's excluded from the research	62

4.3.	Incidence of Syndromes	63
4.4.	Parametric Intra-group Analysis for Group 1(SMT)	64
4.4.1.	Analysis of the Subjective Data	64
4.5.	Parametric Intra-group Analysis for Group 2 (NSAID)	66
4.5.1.	Analysis of the Subjective Data	66
4.6.	Parametric Intra-group Analysis for Group 1 (SMT)	68
4.6.1.	Analysis of Objective Data	68
4.7.	Parametric Intra-group Analysis for Group 2 (NSAID)	70
4.7.1.	Analysis of Objective Data	70
4.8.	Parametric Inter-group Analysis	72
4.8.1.	Analysis of the Subjective Data	72
4.8.2.	Analysis of Objective Data	76
4.9.	Non-parametric Intra-group Analysis for Group 1 (SMT)	80
4.9.1.	Analysis of Objective Data from the ORTHOPAEDIC RATING SCALE for:	
	◦ Sacroiliac Syndrome (SIS),	
	◦ Lumbar Facet Syndrome (LFS),	
	◦ Sacroiliac Syndrome with Myofascial Pain Syndrome (SIS & MFPS),	
	◦ Sacroiliac Syndrome with Lumbar Facet Syndrome (SIS & LFS),	
	◦ Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),	
	◦ Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS)	80

4.10. Non-parametric Intra-group Analysis for Group 2 (NSAID)	84
4.10.1. Analysis of the Objective Data from the ORTHOPAEDIC RATING SCALE for:	
◦ Sacroiliac Syndrome (SIS),	
◦ Lumbar Facet Syndrome (LFS),	
◦ Sacroiliac Syndrome with Myofascial Pain Syndrome (SIS & MFPS),	
◦ Sacroiliac Syndrome with Lumbar Facet Syndrome (SIS & LFS),	
◦ Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),	
◦ Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS)	84
4.11. Non-parametric Inter-group Analysis	88
4.11.1. Analysis of the Objective Data from the ORTHOPAEDIC RATING SCALE for:	
◦ Sacroiliac Syndrome (SIS),	
◦ Lumbar Facet Syndrome (LFS),	
◦ Sacroiliac Syndrome with Myofascial Pain Syndrome (SIS & MFPS),	
◦ Sacroiliac Syndrome with Lumbar Facet Syndrome (SIS & LFS),	
◦ Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),	
◦ Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS)	88

CHAPTER FIVE

5. Discussion of Results	
5.1. Redefining the Study Objectives	92
5.2. Parametric Intra-group Analysis for group 1 (SMT) and group 2 (NSAID)	93
5.2.1. The Subjective Data	93
5.2.1.1. Numerical Pain Rating Scale-101 Questionnaire (NRS-101)	93
5.2.1.1. Oswestry Low Back Pain Disability Index Questionnaire (OSWESTRY)	94
5.2.2. The Objective Data	95
5.2.2.1. Algometer Readings	95
5.2.2.2. The Orthopaedic Rating Scale (Percentage Analysis)	95
5.3. Parametric Inter-group Analysis	96
5.3.1. The Subjective Data	96
5.3.1.1. Numerical Pain Rating Scale-101 Questionnaire (NRS-101)	96
5.3.1.2. Oswestry Low Back Pain Disability Index Questionnaire (OSWESTRY)	96
5.3.2. The Objective Data	97
5.3.2.1. Algometer Readings	97
5.3.2.2. The Orthopaedic Rating Scale (Percentage Analysis)	97
5.4. Non-parametric Intra-group Analysis for Group 1 (SMT) and Group 2 (NSAID)	98
5.4.1. The Objective Data	98
5.4.1.1. Discussion of the ORS used within group 1 for:	
◦ Lumbar Facet Syndrome (LFS),	
◦ Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),	

<ul style="list-style-type: none"> ◦ Sacroiliac Syndrome and Myofascial Pain Syndrome (SIS & MFPS), ◦ Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS) 	99
5.4.1.2. Discussion of the ORS used within group 2 for:	
<ul style="list-style-type: none"> ◦ Lumbar Facet Syndrome (LFS), ◦ Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS), ◦ Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS) 	
5.5. Non-parametric Inter-group Analysis	100
5.5.1. The Objective Data	100
5.5.1.1. Discussion of the ORS for:	
<ul style="list-style-type: none"> ◦ Sacroiliac Syndrome (SIS), ◦ Lumbar Facet Syndrome (LFS), ◦ Sacroiliac Syndrome with Myofascial Pain Syndrome (SIS & MFPS), ◦ Sacroiliac Syndrome with Lumbar Facet Syndrome (SIS & LFS), ◦ Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS), ◦ Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS) 	101

CHAPTER SIX

6. Recommendations and Conclusion

6.1. Recommendations 103

6.2. Conclusion 105

REFERENCES 107

LIST OF TABLES

TABLES OF DEMOGRAPHIC DATA.

Table 4.1.	Age Distribution of Patients (n=60)	61
Table 4.2.	Gender Distribution of Patients (n=60)	62
Table 4.3.	Race Distribution of Patients (n=60)	62
Table 4.4.	Patient's excluded from Group 1 (SMT)	62
Table 4.5.	Patient's excluded from Group 2 (NSAID)	63

INCIDENCE OF SYNDROMES.

Table 4.6.	Incidence of Lumbar Facet Syndrome (LFS), Myofascial Pain Syndrome (MFPS) and Sacroiliac Syndrome (SIS)	63
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PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1(SMT):

Table 4.7.	Comparison the subjective data between the initial and second consultations, using the Paired t-test.	64
Table 4.8.	Comparison the subjective data between the initial and final consultations, using the Paired t-test.	64
Table 4.9.	Comparison the subjective data between the second and final consultations, using the Paired t-test.	65

PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 2 (NSAID):

Table 4.10.	Comparison the subjective data, between the initial and second consultations, using the Paired t-test.	66
Table 4.11.	Comparison the subjective data, between the initial and final consultations, using the Paired t-test.	66
Table 4.12.	Comparison the subjective data, between the second and final consultations, using the Paired t-test.	67

PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1 (SMT):

Table 4.13.	Comparison the objective data between the initial and second consultations, using the Paired t-test.	68
Table 4.14.	Comparison the objective data between the initial and final consultations, using the Paired t-test.	68
Table 4.15.	Comparison the objective data between the second and final consultations, using the Paired t-test.	69

PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 2 (NSAID):

Table 4.16.	Comparison the objective data between the initial and second consultations, using the Paired t-test.	70
Table 4.17.	Comparison the objective data between the initial and final consultations, using the Paired t-test.	70
Table 4.18.	Comparison the objective data between the second and final consultations, using the Paired t-test.	71

PARAMETRIC INTER-GROUP ANALYSIS:

Table 4.19.	Comparison of the subjective data for groups 1 and 2 at initial consultation, using the Unpaired t-test.	72
Table 4.20.	Comparison of the subjective data for groups 1 and 2 at second consultation, using the Unpaired t-test.	72
Table 4.21.	Comparison of the subjective data groups 1 and 2 at final consultation, using the Unpaired t-test.	73
Table 4.22.	Comparison of the objective data groups 1 and 2 at initial consultation, using the Unpaired t-test.	76
Table 4.23.	Comparison of the objective data groups 1 and 2 at second consultation, using the Unpaired t-test.	76
Table 4.24.	Comparison of the objective data groups 1 and 2 at final consultation, using the Unpaired t-test.	77

NON-PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1 (SMT):

Table 4.25.	Comparison of the ORS between the initial and second consultations, using the Wilcoxin Signed Rank test.	81
Table 4.26.	Comparison of the ORS between the initial and final consultations, using the Wilcoxin Signed Rank test.	82
Table 4.27.	Comparison of the ORS between the second and final consultations, using the Wilcoxin Signed Rank test.	83

NON-PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 2 (NSAID):

Table 4.28.	Comparison of the ORS between the initial and second consultations, using the Wilcoxin Signed Rank test.	85
Table 4.29.	Comparison of the ORS between the initial and final consultations, using the Wilcoxin Signed Rank test.	86
Table 4.30.	Comparison of the ORS between the second and final consultations, using the Wilcoxin Signed Rank test.	87

NON-PARAMETRIC INTER-GROUP ANALYSIS:

Table 4.31	Comparison of ORS for groups 1 and 2 at initial consultation, using the Mann-Whitney U-test.	88
Table 4.32.	Comparison of ORS for groups 1 and 2 at second consultation, using the Mann-Whitney U-test.	89
Table 4.33.	Comparison of ORS for groups 1 and 2 at final consultation, using the Mann-Whitney U-test.	90

LIST OF PHOTOGRAPHS:

Photograph 3.1.	Demonstration of Kemp's test	43
Photograph 3.2.	Demonstration of Lumbar facet joint challenge	44
Photograph 3.3.	Demonstration of a patient hyperextending in a prone position	45
Photograph 3.4.	Demonstration of Gaenslens test	46
Photograph 3.5.	Demonstration of Yeomans test	47
Photograph 3.6.	Demonstration of Posterior Shear test	48

LIST OF FIGURES:

Figure 4.1.	Mean values of the Numerical Pain Rating Scale-101 at the initial, second and final consultations comparing the SMT and NSAID groups.	74
Figure 4.2.	Mean values of the Oswestry Low Back Pain Disability Index at the initial, second and final consultations comparing the SMT and NSAID groups.	75
Figure 4.3	Mean values of the Algometer Readings at the initial, second and final consultations comparing the SMT and NSAID groups.	78
Figure 4.4.	Mean values of the Orthopaedic Rating Scale (Percentage Analysis) at the initial, second and final consultations comparing the SMT and NSAID groups.	79

LIST OF ABBRVIATIONS

LBP	-	Low Back Pain
LFS	-	Lumbar Facet Syndrome
Me.	-	Median
MFPS	-	Myofascial Pain Syndrome
NRS-101	-	Numerical Pain Rating Scale-101
NSAID	-	Nonsteroidal Anti-inflammatory drug
Oswestry	-	Oswestry Low Back Pain Disability Index
P-value	-	Level of Significance
Sd.	-	Standard Deviation
Se.	-	Standard Error
SIS	-	Sacroiliac Syndrome
SMT	-	Spinal Manipulative Therapy

APPENDICES

Appendix	A	CASE HISTORY.
Appendix	B	PHYSICAL EXAMINATION.
Appendix	C	LOW BACK AND PELVIS REGIONAL EXAMINATION
Appendix	D	NSAID QUESTIONNAIRE.
Appendix	E	INFORMED CONSENT.
Appendix	F	OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE
Appendix	G	NUMERICAL PAIN RATING SCALE-101
Appendix	H	OBJECTIVE CLINICAL FIINDINGS, ALGOMETER READINGS AND ORTHOPAEDIC RATING SCALE READINGS.
Appendix	I	PATIENT INFORMATION LETTER.

DEFINITION OF TERMS

Chiropractic:

Chiropractic is that discipline within the healing arts especially concerned with the aetiology, pathogenesis, diagnostics, therapeutics and prophylaxis of functional disturbances, pathomechanical states, pain syndromes and other neurophysiologic effects related to the statics and dynamics of the neuromusculoskeletal system, particularly those related to the spine and the pelvis (Schafer & Faye 1990).

Manipulation:

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

Adjustment:

A specific form of direct articular manipulation using, in the case of this study, short lever techniques with contacts, characterized by a dynamic thrust of controlled velocity, amplitude, and direction (Gatterman 1990: 405).

Fixation:

The state whereby an articulation has become temporarily immobilized in a position, that it may normally occupy during any phase of physiological movement (Haldeman 1992: 623).

Dysfunction:

The dysfunction implies that one of the three components of the joint is not functioning normally. It refers to any joint where there is decreased or aberrant mobility for which manipulation is indicated (Kirkaldy-Willis and Burton 1992: 105).

Mechanical Low Back Pain:

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

Objective Clinical Findings:

These are defined as those clinical findings ascertained using a full case history, physical examination, orthopaedic and neurological examinations including: pain sensitivity – using an algometer and specific orthopaedic tests – creating an orthopaedic rating scale.

Subjective Clinical Findings:

These are defined as those clinical findings ascertained using the patient's perception of the pain, including: the Oswestry Low Back Pain Disability Questionnaire, and the Numerical Pain Rating Scale – 101.

CHAPTER ONE

CHAPTER ONE

1.1. INTRODUCTION

It is generally understood that low back pain (LBP) is a common entity in our lives. Burton and Cassidy (1992) stated that it is well known that the lifetime prevalence of LBP is between 60% and 90%. Although LBP is a common complaint, the actual causes and development vary. According to Deyo (1996), 95% of people who suffer from LBP have what is categorised as mechanical LBP. This form of LBP can be caused by local inflammation and muscle tension.

Chiropractors commonly treat patients with LBP. In a community-based study involving the use of chiropractic services, it was found that LBP was the most common complaint for which patients sought chiropractic care (Shekelle et al. 1991).

It was discovered by Kirkaldy-Willis (1992: 129) that Posterior Facet Joint Syndrome, Sacroiliac Joint Syndrome and Myofascial Pain Syndrome accounted for 50% of cases of LBP seen at the Royal University Hospital in Saskatoon over a 10-year period.

Due to the various elements involved in mechanical LBP a greater understanding is essential to formulate a logical plan of LBP management. Kirkaldy-Willis (1992: 51) identified the role of muscle pathology and the sequential changes seen in bone, joint and adjacent soft tissue as the initiating causes of mechanical LBP. However, no conclusion was drawn as to whether the muscle pathology is responsible for activating the joint dysfunction, or whether the joint dysfunction is responsible for the patient's symptoms.

Much research has been conducted on the efficacy of medication in the management of mechanical LBP. Kantor (1986) analysed several clinical studies,

and concluded in clinical conditions marked by acute and chronic pain and inflammation, such as LBP, Diclofenac Sodium seemed to be an effective analgesic agent. He also found that oral or intramuscular administration of Diclofenac Sodium, when compared to placebo, provided consistently superior relief of symptoms.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are the worlds most widely used medication (Hirschowitz 1997). They have repeatedly been found to be effective in the treatment of mechanical LBP (Deyo 1996, Koes et al. 1997 and Szapalski et al. 1994). Despite their apparent effectiveness in the management of mechanical LBP, there is still the unfortunate risk of encountering side effects. Goldstein et al. (1997), Goodman et al. (1994) and Hirschowitz (1997) remind us of the potentially life-threatening side effects these drugs can produce, particularly gastro-intestinal complications.

According to Dishman (1988), spinal injury in the lower back region results in the release of leucotrienes, which can lead to the development of trigger points in local muscles. This inflammation spreads throughout the adjacent soft tissue and stimulates the nociceptors producing pain and muscle contraction. The residual effects of the muscle contractions can lead to constrictions, deformities, adhesions and a restricted range of joint movement. Dishman (1988) proposed that these chemical reactions can be inhibited by anti-inflammatory medication and can also be counteracted by repeated spinal manipulative therapy (SMT).

A number of researchers have studied the effectiveness of chiropractic SMT and have discovered its value in the treatment of mechanical LBP (Bronfort 1989, Anderson et al. 1992, Assendelft et al. 1992, McMorland 2000). Haldeman (1992: 420) however commented on the shortcomings of trials studying the effectiveness of SMT in the management of mechanical LBP. These included poor manipulative techniques, the mixing of manipulation with other treatments, poor patient compliance and general lack of control. Due to the limitations of

these various studies, more research needs to be carried out in the area of mechanical LBP, to help determine the most effective treatment protocols for this condition.

Gottlieb (1997) discovered that the conservative approach of chiropractic SMT could have a positive effect on the joint, whereas the administration of NSAIDs is highly controversial in respect to the side effects. The present conservative approach could lead to a better quality of life by reducing the iatrogenic morbidity and mortality associated with NSAID use.

The various side effects of NSAIDs are a concern to health care providers. Should this study provide results that demonstrate that the conservative approach of SMT is more effective, or at least as effective in eliminating mechanical LBP than the use of Diclofenac Sodium, this may reduce the unnecessary use of drugs and thus minimize their side effects.

This randomised controlled trial was designed to determine the relative effectiveness of Diclofenac Sodium alone, versus SMT alone in the management of mechanical LBP. The data gained from this study could contribute to finding a safer and more beneficial treatment for patients suffering from mechanical LBP.

1.2. THE PROBLEM AND IT'S SETTING

1.2.1. THE PROBLEM STATEMENT

The purpose of this investigation is to evaluate the relative effectiveness of spinal manipulative therapy compared to Diclofenac Sodium, in terms of subjective and objective measures, in the management of mechanical LBP.

1.2.2. THE OBJECTIVES:

1.2.2.1. Objective one

The first objective was to evaluate the relative effectiveness of spinal manipulative therapy compared to Diclofenac Sodium, in terms of subjective clinical findings, in the management of mechanical LBP.

1.2.2.2. Objective two

The second objective was to evaluate the relative effectiveness of spinal manipulative therapy compared to Diclofenac Sodium, in terms of objective clinical findings, in the management of mechanical LBP.

1.2.2.3. Objective three

The third objective was to integrate the results of objective one and two in order to determine whether either of the two treatments was more effective in terms of subjective and objective clinical findings.

CHAPTER

TWO

CHAPTER TWO

2. REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

In order to gain a greater understanding of LBP sufferers, it is essential to have a clear knowledge of the complex anatomy, mechanisms and pathologies of the lumbosacral region, and the vast epidemiological influence mechanical LBP has on the population. The purpose of critically evaluating the relevant literature is to compare the effects and the effectiveness of SMT and the use of NSAIDs in the treatment of mechanical LBP.

2.2. INCIDENCE AND PREVALANCE OF LOW BACK PAIN (LBP)

According to Burton and Cassidy (1992: 2), LBP has a lifetime prevalence of between 60% and 90% for any population. Cox (1990: 339) supports this by pointing out that LBP is only marginally less prevalent than the "common cold" amongst the population of the United States.

In a review of clinical management and health care, Waddell (1995) stated that approximately 60% of the population report LBP at some time in their lives. Seventy percent of these LBP sufferers will experience these episodes three or more times in their lives, while 20% will continue experience with some degree of back pain throughout their lives.

According to Cox (1990: 339) the prevalence of LBP rises after the age of 25, to peak in the 55 to 64 year old range. This prevalence decreases again after the age of 65. Shekelle *et al.* (1995) expands on these findings in an epidemiological study on non-elderly Americans (those below the age of 65). Insurance claim forms from a community-based randomised control trial on the use of health services, over a three to five year period were analysed. It was reported that 20% – 25% of non-elderly adult Americans would be treated

for at least one episode of back pain within this three to five year period. These percentages indicate the high prevalence of LBP in non-elderly adults.

According to a review of literature by Walker (1997), LBP is a major health problem throughout the world. It has a point prevalence of between 11% and 33%, a 1-year prevalence between 16% and 64% and several studies show the annual incidence of LBP cases was between 1% and 8%. Costs associated with LBP are significant, with estimates approaching 100 billion dollars per annum in the USA in 1990, and five billion dollars per annum (1,7% of G.N.P.) in the Netherlands.

2.3 THE SUBLUXATION COMPLEX

It is essential to understand the various components involved in mechanical LBP in order to create a logical plan of managing LBP.

According to Gatterman (1995: 11) joint subluxation, also known as motion segment dysfunction, involves a complex interaction of the pathologic changes in nervous, muscular, ligamentous, vascular and connective tissues of the motion segment involved.

The concept of the motion segment, also known as the "three-joint complex", plays an integral part in understanding intervertebral dysfunction. The "three-joint complex" is composed of three joints: i.e. two facet joints and the intervertebral disc. It is a valuable theoretical framework for an approach to diagnosis and treatment of patients with symptomatic conditions of intervertebral dysfunction (Kirkaldy-Willis et al. 1995).

According to Dishman (1988), intervertebral dysfunction refers to a mechanical fault, which is abnormal in both its dynamic and static states. Subluxated vertebrae may be fixated and slightly mal-positioned within one or more axes of rotation, resulting in mechanical changes within the spinal column.

Gatterman (1990: 415) describes the subluxation complex as:

1. The partial or incomplete dislocation of a facet joint.
2. The restriction of motion of a joint in a position exceeding normal physiologic motion, although the anatomical limits have not been exceeded.
3. The unnatural relationship between two adjacent articulations which may have functional or pathological consequences, thus causing alterations in the biomechanical and/ or neurophysiological reflexes of the joint, the structure around the joint and/or the body systems affected by them.

Gatterman (1990: 39) further categorises the subluxation into two parts:

1. Neuropathophysiology – subluxation causes irritation and/or compression of the neural components of motion segments and
2. Kinesiopathology – restriction in movement of motion segments due to muscle hypertonicity, joint stabilization, muscle spindle muscle spasm cycle, joint sprain, muscle spasm and articular locking.

According to Dishman (1988) the mechanical, chemical and histological components of a subluxation cause some of the pain mechanisms, tissue changes and residual effects of acute and chronic intervertebral fixation and the need for repeated spinal manipulations along with prolonged care. It is therefore essential to remove the subluxation or restore normal joint motion to eliminate the pain, inflammation and muscle spasm associated with LBP.

2.4. RELEVANT ANATOMY AND BIOMECHANICS

2.4.1. The Anatomy of the Lumbar Zygapophyseal Joint

Each lumbar spinal motion segment is composed of three joints, two synovial posterior joints and an intervertebral disc i.e. the three-joint complex. Damage to one component of the complex affects both its function and that of the other two components (Kirkaldy-Willis et al. 1995).

The junction between the superior and inferior articular facets of the articular processes on one side of two adjacent vertebrae is known as the zygapophyseal joint. They are diarthrodial synovial joints surrounded by a capsule posterolaterally and the ligamentum flavum anteromedially. A synovial membrane lines the articular capsule, ligamentum flavum and synovial joint folds (Gatterman 1995: 19).

2.4.2. The Innervation of the Lumbar Zygapophyseal Joint

The articulations of the lumbar zygapophyseal joints are innervated by nerves arising from the medial branches of the dorsal primary rami of the spinal nerves. As these nerves pass postero-inferiorly they lie in grooves of the posterior surfaces of the medial parts of the transverse process. Each articular branch supplies the nearby joint, and it may send branches to the subjacent joint as well (Moore 1992: 347).

According to Gatterman (1995: 21) there are three types of sensory receptors that occur within the facet joint capsules, namely:

1. Type I: sensitive static and dynamic mechanoreceptors which fire constantly due to continual joint motion;
2. Type II: less sensitive mechanoreceptors which fire only on joint motion;
3. Type III: slow conducting mechanoreceptors (Gatterman 1995: 21).

2.4.3. The Function of the Lumbar Zygapophyseal Joint

The principle movements exhibited by the lumbar spine and its individual joints are axial compression, axial distraction, flexion, extension, axial rotation and lateral flexion.

Lumbar segmental flexion and extension are the predominant motions in this region of the spine. Axial compression occurs during weight bearing in the upright position. The zygapophyseal joints participate in load bearing. This function is carried out when the surfaces are aligned in a plane other than the coronal plane. The capsule of the zygapophyseal joint is the most significant

element resisting axial distraction. The zygapophyseal joints limit axial rotation in the lumbar spine.

The quality and quantity of motion are determined by many factors, which include the facet orientation, muscular control and degenerative changes (Gatterman 1995:206-207).

2.4.4. The Anatomy of the Sacroiliac Joint

The sacroiliac joint is formed by the articulation between the sacrum and the ilium. The joint is a synovial joint within which the iliac surface is composed of thin fibrocartilage and the articular surface of the sacrum is composed of hyaline cartilage (Kirkaldy-Willis 1992: 71).

The ligaments associated with the sacroiliac joint are, namely the anterior sacroiliac ligaments, posterior sacroiliac ligaments and the interosseous sacroiliac ligaments, contribute to the stability of the sacroiliac joint. The anterior sacroiliac ligament is thin and easily distended by intra-articular swelling. The posterior sacroiliac ligament is strong and thick, which is resistant to trauma (Hendler et al. 1995).

The roughening of the articular surfaces is thought to be a non-pathological adaption to the forces exerted at the sacroiliac joint. Movement in the sacroiliac joint primarily occurs in the sagittal plane, with the axis of rotation centered on the iliac tubercle (Gatterman 1995: 453).

2.4.5. The Innervation of the Sacroiliac Joint

The articular branches of these joints are derived from the superior gluteal nerves, the sacral plexus, and the dorsal rami of S1 and S2 nerves (Moore 1992: 251).

The posterior aspect of the sacroiliac joint is innervated by both posterior rami of L5 – S2 spinal nerves and the anterior aspect is innervated by both posterior branches from the L3 – S2 nerve roots and the superior gluteal nerve L5 – S2 (Schafer and Faye 1990: 244).

2.4.6. The Function of the Sacroiliac Joint

The sacroiliac joints are strong weight bearing synovial joints positioned in an irregular plane. They differ from most synovial joints in that they possess very little mobility. This provides stability and is related to their responsibility for transmitting the weight of most of the body to the hip bones. Because the articular surfaces of the sacrum and ilium are irregular, they fit together securely and are not easily dislocated. Movement of the sacroiliac joints are limited to a slight gliding and rotatory movement. When a considerable force is applied (e.g. jumping), the force is transmitted via the vertebral column to the sacral base, which rotates anteriorly. The interlocking articular surfaces and the strong ligaments counterbalance this rotation. The force is then transmitted to each ilium and lower limb (Moore 1992: 251).

2.4.7. Consideration of muscles

As previously stated in Chapter One, Kirkaldy-Willis (1992: 51) identified the role of muscle and the changes seen sequentially in bone, joint and adjacent soft tissue as being initiating causes of mechanical LBP. It is therefore essential to formulate a logical plan in managing LBP, which addresses all these components. What is surprising to Gatterman (1990: 285) is how little emphasis is placed on the pathophysiology of muscles in both chiropractic and medical curricula.

The amount of pain that originates from muscles is not surprising since collectively, voluntary (skeletal) muscle constitutes the largest single tissue mass in the human body, accounting for 40% or more of body weight (Gray 1960: 405). It therefore seems quite possible that muscle pathology can be a significant factor in mechanical LBP. Levy (1998) supports this fact in stating

that most LBP is caused by a musculoskeletal problem, including muscle strain.

If the cause of pain and decreased spinal mobility is due to acute muscle spasm, Witt (1991: 1623) explains that if left untreated, this muscle spasm will remain symptomatic and may predispose patients to future injury.

2.5. CLASSIFICATION OF MECHANICAL LOW BACK PAIN (LBP)

Classification systems for patients with LBP have become more abundant in literature since the mid – 1980s. Some classification systems are designed to determine the most appropriate treatment; some are designed to follow the progression of mechanical LBP, while others are designed to identify pathology. Riddle (1998) reviewed the Kirkaldy-Willis classification. Due to the following findings, this classification will be used in this study:

- All relevant categories are included in the classification.
- The categories are mutually exclusive.
- The purpose, population and setting are clearly specified.
- The domain of interest and all specific exclusions are specified.
- It is simple to understand and easy to perform.

Kirkaldy-Willis (1992: 105) utilises a three-phase classification of LBP, within which three degenerative processes are described, namely: dysfunction, instability and stabilization.

Stage 1: Dysfunction phase:

The presentation of this phase is a result of rotational or compressive strain, sometimes due to a major but more often due to a minor episode of trauma.

The mechanisms that follow the trauma result in posterior joint and/or annular sprain. Because of the small capsular and/or annular tears, a small degree of joint subluxation takes place. The various pathological changes that occur subsequent to this trauma include injury to the posterior joint synovium resulting in synovitis. The posterior segmental muscles protect the joint by sustained hypertonic contraction. The muscle becomes ischaemic and this causes more pain. Accumulation of metabolites in muscle further aggravates the pain and sustains the hypertonic state of contraction. The posterior joints continue to be splinted and the minor subluxation is maintained. These changes later lead to fibrosis.

Kirkaldy-Willis (1988: 117 - 131) describes the symptoms that are included in this type of pathophysiology as:

- Stimulation of pain sensitive nociceptors by the production of inflammatory metabolites from facet joint inflammation.
- Muscle spasm resulting in ischaemia and pooling of metabolites. The associated chemical irritation may then also stimulate the pain sensitive nerve endings.
- A sclerotogenous pain may be produced which is typically referred or localised.
- The effect of disc pathology, if severe enough, may result in nerve root irritation producing radicular pain characteristics.

Stage 2: Unstable phase:

According to Kirkaldy-Willis (1992: 110) the presentation may be similar to that described in the dysfunction phase, or it may be chronic or insidious without any recorded history of minor trauma.

The mechanisms involved may be two-fold:

Including an episode of trauma or continuing stress.

With either one of these mechanisms, the pathological changes are the same:

- Progressive degenerative changes in the facet joint cartilage.
- Stretching or attenuation of the capsule.
- Laxity of the capsule.

Changes in the disc are:

- Coalescence of tears.
- Loss of nuclear substance with internal disruption.
- Bulging of the annulus around the circumference of the disc.

The healing of these capsular tears of the posterior joint and annular tears of the disc is less complete. As a result, a detectable increase in abnormal movement in the three-joint complex is noted.

Kirkaldy-Willis (1988: 117 -131) describes the symptoms of this phase as:

- Coalescence of radial tears resulting in disc herniation which causes nerve root compression and consequently muscle weakness, reduced tendon reflexes and dermatomal hypaesthesia.
- Inflammation causing muscle spasm and consequent antalgia.
- Excessive movement results in intermittent lateral nerve root entrapments at one level with radicular patterns of pain referral, which are aggravated by flexion, extension and rotational movements.

Stage 3: Stabilization phase:

The presentation of stage three occurs in two ways. In the older patient, there is a long history of LBP. More rarely, in younger patients, the back pain decreases and leg pain is the most pronounced feature.

Three mechanisms are at work:

Stiffness of the posterior joints is increased because of destruction of articular cartilage, fibrosis periarticularly and within the joint, as well as enlargement and locking of the facets. Similar changes occur in the disc, with loss of nuclear material, approximation of vertebral endplates, fibrosis within the disc and osteophyte formation around the periphery of the disc. Occasionally bony ankylosis joins two vertebrae together (Kirkaldy-Willis 1992: 116).

The symptoms in this stage are:

- Fixed lateral canal entrapment due to subluxation, osteophytes and disc fibrosis which results in continuous signs of muscle weakness, reduced tendon reflexes and dermatomal hypoaesthesia, and
- Central canal stenosis due to enlarged inferior articular facets and osteophyte formation.

The symptoms related to this condition are partly due to impaired blood circulation and due to nerve compression. The consequences may include neurogenic claudication and cauda equina syndrome (Kirkaldy-Willis 1988: 117 - 131).

2.6. CLINICAL CONSIDERATION OF MECHANICAL LOW BACK PAIN

There are clinical lesions categorised into three phases. By doing this Kirkaldy-Willis (1992: 121) has placed a framework within which the site and nature of the lesion can be categorised. This allows for a more structured understanding of the mechanical and pathophysiological process of each clinical lesion.

2.6.1. The specific clinical lesions categorized within the phase of dysfunction are:

- Posterior Facet Syndrome
- Sacroiliac Syndrome
- Maigne's Syndrome
- Myofascial Pain Syndrome
 - Gluteus maximus
 - Gluteus medius
 - Gluteus minimus
 - Quadratus lumborum
 - Piriformis
 - Tensor fasciae latae
 - Hamstring
- Disc Herniation

2.6.2. The specific clinical lesions categorized within the phase of instability are:

- Facet and disc degeneration
- Lateral stenosis
- Central stenosis
- Disc herniation

2.6.3. The specific clinical lesions categorized within the phase of stabilization are:

- Lateral stenosis
- Central stenosis
- Multilevel stenosis
- Disc herniation

As explained in Chapter One; Posterior Facet Syndrome, Sacroiliac Syndrome and Myofascial Pain Syndrome accounted for 50% of the lesions seen in cases of LBP at the Royal University Hospital in Saskatoon over a 10-year period. (Kirkaldy-Willis 1992: 129). These three clinical lesions, which fall within the dysfunctional phase, will be assessed within the present study. It is therefore essential to differentiate between each syndrome when confirming a diagnosis.

2.6.4. Posterior Facet Syndrome:

The typical symptoms of Posterior Facet Syndrome present as follows:

Pain is often localized and unilateral. Pain maybe referred to the groin, greater trochanter, and to the posterior thigh as far as the knee (Kirkaldy-Willis 1992: 106).

The associated clinical signs are:

Tenderness to pressure on one side and at one level, and hypertonic muscles at the sight of lesion (Kirkaldy-Willis 1992: 106).

Hyperextension movements of the back increase the pain, whereas flexion reduces it. Activities that may increase the pain include sleeping on the abdomen, sitting in an upright position, lifting a load in front of the body at or above the waistline. When symptoms are acute, sneezing and coughing may accentuate the pain (Gatterman 1995: 162).

The specific clinical tests to identify this clinical lesion include Kemp's test and facet joint challenge test (Schafer and Faye 1990: 217; Magee 1992: 274).

According to Giles et al. (1997: 89), the effect of joint dysfunction on associated soft tissue structure, with possible venous stasis, nerve ischaemia, and soft tissue entrapment has been postulated as a potential mechanism for causing back pain of mechanical origin.

Giles further explains that various soft tissue structures could theoretically be involved in LBP of the mechanical origin. They are:

- The large intra-articular synovial folds of the zygapophysial joints.
- The fibrous tissue within the joint capsules becomes attached by adhesions, to the adjacent hyaline articular cartilage.
- The distorted and tractioned blood vessels within the intervertebral foramen.
- The neural structures which become attached by adhesions to densely fibrotic intra-articular synovial folds.
- Stenosis of the intervertebral foramen due to hypertrophy of the ligamentum flavum with or without adjacent posterolateral intervertebral disc herniation.

2.6.5. Sacroiliac Syndrome:

The typical symptoms of Sacroiliac Syndrome include:

Pain over the posterior aspect of the sacroiliac joint that varies in its degree of severity; referred pain in the groin, over the greater trochanter, down the back of the thigh to the knee, and occasionally down the lateral or posterior calf to the ankle, foot, and toes (Kirkaldy-Willis 1992: 124).

The associated clinical signs include:

Tenderness over the posterior superior iliac spine in the region of the sacroiliac joint. Movement of the joint is restricted. The diagnosis of the Sacroiliac Syndrome is confirmed by positive Faber Patrick test, Gaenslen's test and Extension test (Yeomans test) (Kirkaldy-Willis 1992: 124).

According to Aprill (1992), sacroiliac joint dysfunction appears to be an overlooked condition, which is not even considered a possibility by many clinicians involved in the diagnosis and treatment of patients with mechanical

LBP. A survey by Aprill (1992) revealed that 25% - 30% of non-specific back pain patients have symptomatic sacroiliac dysfunction in conjunction with other defined lesions (symptomatic annular fissure and symptomatic zygapophysial joint dysfunction).

2.6.6. Myofascial Pain Syndrome:

Kirkaldy-Willis (1992: 126), describes six different myofascial syndromes associated with LBP. These include:

- The gluteus maximus muscle. This is associated with local pain and tenderness over the buttocks region referring into the posterior thigh. This lesion is often associated with Sacroiliac Syndrome.
- The gluteus medius muscle. This is associated with local pain and tenderness along the iliac crest with referred pain down the back of the thigh and calf almost to the ankle or down the lateral thigh and calf.
- The quadratus lumborum muscle. This is associated with local pain and tenderness lateral to the lumbar spine with referred pain into the buttock, groin and anterior thigh region.
- The piriformis muscle. This is often injured with a twisting injury of one leg while the patient is lifting or carrying in an awkward position. The pain is often deep seated in the rectum or vagina and may incapacitate the patient. The referred pain is down the back of the thigh to the knee and sometimes to the ankle.
- The tensae fascia lata muscle refers pain down the lateral aspect of the thigh, knee and calf.
- The hamstring muscle. This is associated with local tenderness originating from the ischial tuberosity to over the hamstring body.

According to Travell and Simons (1989: 18) when diagnosing a patient with Myofascial Pain Syndrome the following signs and symptoms are identified:

- Characteristic referral patterns of pain specific to each muscle.
- Weakness and restriction in the stretch range of motion of the affected muscle.
- A taut palpable band in the affected muscle.
- Exquisite focal tenderness to digital pressure.
- A local twitch response elicited through snapping palpation or needling of the tender spot.
- Reproduction of the patients pain complaint by pressure.
- Elimination of symptoms by therapy directed specifically to the affected muscle.

2.7. THE EFFECTS OF SPINAL MANIPULATIVE THERAPY (SMT)

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

- A facet joint is immobilized by an acute synovial reaction and adherence of the joint surfaces of the facets takes place. A passive movement, which involves the mobilization of the spinal motion segment back and forth through its passive range of motion, separates these surfaces.
- The mechano-receptors of the joint are desensitised by the abrupt movement of the joint (manipulation), and reflex protective spasm is eliminated allowing the joint to move again.
- The manipulation allows an entrapped meniscus to exit the facet joint in which it became entrapped.
- The capsule of the facet joint becomes lodged between two adjacent articular surfaces and the manipulative process allows this capsule to be freed.

- The spindle systems of the adjacent muscles are reflexly stimulated by the dynamic thrust of the manipulation and reciprocally relax the extrafusal muscle fibres.
- The mal-aligned spinal segments are aligned to conform to the centre of gravity.

Mierau et al. (1988) recalls the use of manipulation dating back to Hippocrates and the ancient Chinese. The term "manipulation" is described by Mierau et al. (1988) as any passive physical manoeuvre applied to the spine to increase either regional or segmental range of motion.

Shekelle (1994) explains that SMT is a form of manual therapy. It involves the movement of a joint through its normal physiological range, past its usual end range of motion, however not past its anatomical range, into an area that has been termed the 'paraphysiological zone'. The physiological range of motion includes the active and passive ranges of the joint.

Herzog (1995) stated that SMT consists of a thrusting, impulse-like force of specified intensity (measured in Newtons), direction and time, applied to target vertebrae. Herzog (1995) reviewed the data gathered on the mechanical and physiological responses produced by SMT. The forces exerted cause reflex responses in the muscle spindle proprioceptors and in the mechano-receptors located in the capsule and articular facet joints. These responses lead to reflex inhibition of spastic muscles in the treatment area. However the study did have limitations. Due to this, it was suggested that further trials be carried out to understand more about the internal forces of SMT and the assessment of EMG reflex responses must involve patients with muscle spasm rather than asymptomatic patients.

2.8. THE ADVERSE REACTIONS TO SPINAL MANIPULATIVE THERAPY (SMT)

Leboeuf-Yde et al. (1997) carried out a prospective interview survey on 625 patients assessing adverse reactions to SMT. Using a standardised questionnaire, the adverse reactions to SMT were identified and categorized into common and uncommon reactions.

The common reactions included:

- Local discomfort in the area of treatment, which made up two thirds of the reactions experienced. This reaction appeared soon after treatment, it was mild and only lasted a day in most cases.
- 10% of the reactions experienced included pain and fatigue outside the area of treatment.

The uncommon reactions included:

- Nausea and dizziness, which made up less than 5% of the reactions experienced.

No mention was made of any fatalities within the group of 625 patients following SMT. Leboeuf-Yde et al. (1997) explained that these common and uncommon reactions to SMT are to a large degree foreseeable or predictable and were predominantly physiological in nature.

2.9. THE EFFECTIVENESS OF SPINAL MANIPULATIVE THERAPY (SMT)

Waagen et al. (1986) conducted a double-blinded study on the efficacy of SMT delivered by chiropractors. The trial was designed and implemented at the clinic of a chiropractic college. Nineteen patients (n=19) with LBP completed a two-week period of treatment. It was concluded that both

subjectively and objectively, chiropractic SMT was more effective at relieving LBP than a manual placebo treatment. The various authors stated that prior to this trial, no controlled study on the effectiveness of chiropractic therapy had been conducted. The previous studies on SMT were performed using medical practitioners, osteopaths or physiotherapists trained in the art of manipulation. However, because chiropractors specialise in the delivery of specific spinal adjustments and receive a longer period of formal training than other manipulators, the authors of this study believed that it was not possible to extrapolate the results of previous trials in manipulative therapy directly to chiropractic research.

Di Fabio (1992) and Manga et al. (1993) extensively studied manual therapy for LBP. Both researchers reviewed a number of clinical trials comparing SMT to several alternative treatments for LBP. The analysis provided evidence that SMT applied by chiropractors is more effective than any other alternative treatment for LBP. In reviewing these case-control, clinical trial, meta-analysis and descriptive studies, it was noted that better methodology, a uniform screening procedure and appropriate follow-up intervals for reassessment were needed. These are points that future researchers need to consider.

Meade et al. (1990) stated that the high incidence of back pain, its chronic and recurrent nature, and its contribution to work absence are all well known, however no general consensus exists regarding which treatment is most effective for managing mechanical LBP. Meade et al. (1990) conducted a randomised clinical trial comparing chiropractic and hospital outpatient management of LBP. The trial indicated that within the 741 LBP patients between the age of 18 and 65 who had no contraindications to SMT, chiropractic treatment was more effective than hospital outpatient management for LBP. A benefit of about 7% on the Oswestry scale was seen at two-years, however the benefit was more evident within the three-year follow-up period. Further trials need to be undertaken with more structured treatment protocols. The results of the trial could have been altered by the fact that both treatment protocols had differing time periods within which the

patients were treated. It was suggested that more trials are needed to identify the specific components involved in SMT resulting in its effectiveness.

Anderson et al. (1992) conducted a meta-analysis of 23 randomised controlled clinical trials to assess the efficacy of SMT in the treatment of LBP. SMT proved to be consistently more effective than an array of other treatments. The tendency for SMT to produce better results than any form of treatment to which it was compared was consistent and strong. However, to fulfil the potential of the future meta-analysis in the clinical arena, it is suggested that researchers strive for more consistent measures in terms of explicit descriptions of the nature of SMT.

To assess the effectiveness of chiropractic SMT in patients with LBP, Assendelft et al. (1992) and Shekelle (1994) reviewed between 25 and 30 clinical trials. It was concluded that even though there were relatively few chiropractic trials on LBP, SMT seemed to be an effective treatment for LBP. The data that exists is sufficient to conclude that SMT is more effective than a sham manipulation and more effective than medical therapies (including NSAIDs) in reducing the patients LBP symptoms. However, it was stated that more studies with better research methodology were still needed.

Mc Morland et al. (2000) suggests there is evidence that SMT is an effective treatment for mechanical LBP. A retrospective, outcome-based analysis was conducted on 58 new patients attending a private chiropractic clinic for treatment of uncomplicated mechanical LBP. The analysis revealed statistically significant reductions in the patients' disability and pain scores after treatment. An average reduction of 52,5% and 52,9% in pain and disability was achieved in this LBP group. These results indicated that chiropractic manipulation is beneficial for the treatment of mechanical LBP.

2.10. THE EFFECTS OF DICLOFENAC SODIUM

According to Kantor (1986) Diclofenac has been established as a leading NSAID in worldwide studies during the past 12 years. Diclofenac has been used successfully for acute as well as chronic relapsing syndromes marked by pain and inflammation. Several studies have been conducted into the mechanism of action of these drugs.

Arky (1997: 833) explains that Diclofenac Sodium has shown anti-inflammatory, analgesic and antipyretic activity. As with other NSAIDs, this has the ability to inhibit prostaglandin synthesis, resulting in anti-inflammatory activity, as well as contributing to relieving pain-related inflammation. Kantor (1986) expands on this information stating that inflammation is commonly associated with pain and that prostaglandins act as a mediator of inflammation. The interaction between prostaglandins and bradykinin or histamine in subcutaneous and muscle tissue is immediate pain and inflammation.

Cashman (1996) explains the action of NSAIDs in detail. It was previously believed that tissue damage is associated with the release of prostaglandins, causing hyperalgesia by sensitising nociceptive afferents to the effects of various other mediators. This statement is now considered to be an oversimplification. It is likely that NSAIDs exert their analgesic effect not only through peripheral inhibition of prostaglandin synthesis but also through a variety of other peripheral and central mechanisms, which may include interference with the formation of prostaglandins within the central nervous system.

2.11. THE SIDE EFFECTS OF NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

Although the incidence of NSAIDs side effects is low, the widespread use of these drugs and the fact that some people are seriously affected by the

medication means that the possibility of these side effects must be taken seriously (Goodman et al. 1994).

The use of NSAIDs is associated with a 2% to 4% annual incidence of serious gastrointestinal complications. In a day-to-day clinical practice, a physician is regularly confronted with having to balance the control of symptoms, pain, and functional status against the risk of gastrointestinal complications associated with NSAID use. Clinicians would agree that for those patients at risk, it is of great importance to select a treatment that is safe (Goldstein et al. 1997).

According to Dabbs (1995) and Deyo (1996), despite the widespread use and perceived safety, NSAIDs have a significant risk of serious complications. The most common side effects of NSAIDs are gastrointestinal irritation and bleeding, which increase in frequency and severity in older patients. Another important side effect is deterioration of renal function, usually attributed to inhibition of renal prostaglandin synthesis. In most patients, this problem is reversible, but other forms of more permanent renal injury also have been described.

2.12. THE EFFECTIVENESS OF NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

According to Hirschowitz (1997), NSAIDs are among the most widely used drugs. A third or more of our population takes prescription and over-the-counter preparations for their anti-inflammatory, analgesic, and even anti-thrombotic effects.

As previously explained, Diclofenac Sodium has been established as a leading NSAID in worldwide studies during the past twelve years. When compared with placebo, Diclofenac provided consistent relief of various symptomatic systems within the body. In comparison with other NSAIDs or with opioids, such as pentaocine or spasmofen, the symptomatic relief received from Diclofenac was either comparable to or better than that obtained with these other agents (Kantor 1986).

Koes et al. (1997) and Van Tulder et al. (1997) carried out systematic reviews of several randomised control trials evaluating the use of NSAIDs in managing LBP. Within the 26 randomised clinical trials reviewed by Koes et al. (1997), including placebo control studies, it was evident that the trials suggested that NSAIDs are effective for symptomatic short-term relief in patients with uncomplicated LBP. Van Tulder et al. (1997) discovered strong evidence supporting the effectiveness of NSAIDs in the treatment of non-specific LBP. It was therefore concluded that within the 19 trials identified, the patients with acute LBP gained symptomatic relief from the NSAIDs. Both studies had limitations to the methods used in gathering the literature. Relevant trials could have been missed as they were published in non-index journals. Only English journals were reviewed allowing for language bias. Unpublished trials were not included in these reviews, as it was feared that negative results were present within these trials. The selective nature of these two reviews appears to have allowed the researchers to be biased. Adequate indexing and registration of published trials, and assistance in converting trials published in other languages to English should be aimed for, to reduce the possibility of bias.

In a pharmacy-based survey (n=82) of Diclofenac, it was found that the majority of purchases were for musculoskeletal conditions. Over two-thirds of the respondents (71%) indicated receiving either moderate or complete relief of their symptoms after taking Diclofenac. Sixteen percent of the respondents claimed to have experienced adverse reactions to Diclofenac usage, however none of these reactions were severe enough to prompt the user to notify his or her pharmacist or doctor. Eighty-three percent of the respondents indicated their willingness to use Diclofenac again in the future. When using post marketing surveillance research methods it would seem that larger sample sizes would be required, in order to accurately determine the information portrayed in this survey. Other factors influencing the outcome of surveys like this would depend on the quality of data obtained and the efficiency of administration (Emmerton et al. 1995).

In a study analysing the anti-nociceptive effect of Diclofenac in the rat, it was found that acetaminophen and ketorolac exhibited a faster onset and it was possible to relate it to the circulating drug concentration. The reason that Diclofenac has a prolonged antinociceptive effect when compared to other NSAIDs is that this agent is transferred across the synovial membrane to the synovial fluid, from which it is eliminated more gradually than from plasma. It has been suggested that the clearance of Diclofenac from synovial fluid to blood occurs slowly because the drug binds with high affinity to the albumin that is expropriated into the synovial space in joint disease. Thus, the prolonged effect of Diclofenac can be attributed to the notion that it is retained by the albumin-enriched synovial fluid (Torres-Lopez *et al.* 1997).

According to Deyo (1996), several NSAIDs have been tested in clinical trials for LBP. Generally these show superiority of NSAIDs over placebo therapy. There was also strong evidence indicating the efficacy of NSAIDs in treating uncomplicated acute back pain, and moderate evidence for their efficacy in treating chronic back pain.

2.13. THE COMPARISON OF SPINAL MANIPULATIVE THERAPY (SMT) AND DICLOFENAC SODIUM IN THE MANAGEMENT OF MECHANICAL LOW BACK PAIN (LBP).

Brontfort (1989) conducted a small-scale randomised clinical trial to compare the effectiveness of chiropractic versus general medical treatment of LBP. Medical treatment consisted mostly of analgesics, anaesthetic injections, bed rest and physiotherapy, whereas chiropractic treatment consisted of manipulative procedures. The chiropractic treatment group reported greater subjective improvement than the general medical treatment group. The small number of patients ($n = 19$) allocated to this study makes it difficult to draw strong conclusions regarding the effectiveness of the chiropractic SMT compared to the medical treatment for LBP.

According to Deyo (1996), drug therapy and SMT are only two of many commonly used treatments for patients with LBP, which Deyo suggests

makes it difficult to identify the most effective approach. The multitude of causes of LBP may be related to the fact that a variety of drugs are used to manage LBP. There is no uniquely successful form of drug therapy. Drug therapy generally does not alter anatomy or organ function, although it may have important physiologic effects on inflammation, muscle relaxation, neurotransmitter balance (in depression), or central pain perception. However this physiological thinking is often speculative and poorly supported by firm scientific evidence. Further research therefore needs to be carried out to gain a clearer understanding of the pathoanatomy and pathophysiology of this LBP problem.

According to Manga et al. (1993), LBP is a common and economically costly problem. Chiropractic management of back pain has undergone a transition and is now a more respected and understood alternative to conservative medical care. In this paper, the evidence on the effectiveness of different alternatives for treating and managing LBP were reviewed. The evidence suggested that many traditional medical therapies for LBP have questionable effectiveness, sometimes resulting in severe iatrogenic complications for the patient. The literature suggests that chiropractic manipulation is (at least) as safe, and probably safer than the medical treatment for LBP. There is however a need for more clinical evidence to support the validity of alternative therapies including medical and chiropractic management of LBP.

Giles et al. (1999) conducted a clinical pilot trial comparing acupuncture, a NSAID, and SMT. There was evidence that in patients with chronic spinal pain syndromes SMT, if not contraindicated, resulted in greater improvement than acupuncture and medicine. This trial supports the use of SMT in the management of mechanical LBP, above the use of prescription medication.

When comparing the trials within this literature review one fact remained unchanged and that was that when using NSAIDs the risk of side effects are more common than when receiving SMT. According to Deyo (1996), Koes et al. (1997) and Goldstein et al. (1997) complications or side effects of NSAIDs were reported in most of the trials using these drugs. According to Shekelle

(1994) there are no systematic reports on the complications or risks of SMT. All that is known comes from case reports. Assendelft et al. (1992), Anderson et al. (1992) and Di Fabio (1992) reviewed several clinical trials within which no mention was made of side effects to SMT in the lower back region.

Manga (2000) explains that the role and position of chiropractic care in the health care system must be transformed from being alternative and separate to alternative and mainstream. This transformation requires that chiropractic services become integrated in the many health care organizations that constitute the health system. Professionals have discovered impressive economic benefits when using this approach to managing neuromusculoskeletal conditions. It is also safer and as indicated by the high patient retention rates the public use this approach more often. The use of chiropractic care in the health care system should serve to improve health outcomes.

2.14. THE INDICATIONS FOR AND CONTRAINDICATIONS TO SPINAL MANIPULATIVE THERAPY (SMT)

The benefits of SMT far outweigh the risks of complications. By carrying out a careful diagnostic procedure and by employing skilled and precise manipulative techniques, complications can be avoided (Gatterman 1990: 55).

2.14.1. Indications for SMT:

Essentially the indications for SMT can be a diagnosis of mechanical LBP and can include the following:

- Posterior and sacroiliac joint dysfunction
- Paraspinal muscle syndrome
- Disc herniation
- Joint dysfunction in lateral and central stenosis
- Joint dysfunction in spondylolisthesis
- Sacroiliac Syndrome in postoperative LBP (Kirkaldy-Willis 1992: 291).

2.14.2.Contraindications to SMT:

Kirkaldy-Willis (1992: 291) divides contraindications into two main categories - relative and absolute contraindications:

Relative contraindications may merely call for a modification of technique and are very case dependent. They include:

- Osteopenia
- Spondyloarthropathies
- Patients on anticoagulant medication
- Bleeding disorders
- Psychological overlay.

In the presence of absolute contraindications, no manipulative therapy should be employed under any circumstances. These include:

- Destructive lesions of the spine, ribs and pelvis
- Healing fractures or dislocations
- Gross instability
- Cauda Equina Syndrome
- Large abdominal aneurysms
- Visceral referred pain.

2.15. THE INDICATIONS FOR AND CONTRAINDICATIONS TO DICLOFENAC SODIUM

2.15.1. Indications for Diclofenac Sodium

According to Arky (1997: 834), the administration of Diclofenac Sodium is indicated for the following conditions:

- Osteoarthritis
- Rheumatoid Arthritis
- Ankylosing Spondilitis
- Management of pain
- Primary dysmenorrhea

Kantor (1986) states that within clinical conditions marked by acute or chronic pain and inflammation, Diclofenac Sodium, with its potent prostaglandin synthetase inhibition has shown to be an effective analgesic agent in conditions such as:

- Oral surgery
- Dysmenorrhea
- LBP
- Renal Colic
- Biliary Colic
- Post-traumatic conditions
- Postoperative conditions

The inhibition of prostaglandin synthesis by NSAIDs alleviates the pain and inflammation associated with a variety of the above disorders. In the treatment of non-rheumatic conditions as well as in the treatment of rheumatic diseases, NSAIDs have been used and studied more extensively (Kantor 1986).

Goodman (1994) explains that NSAIDs are prescribed extensively for their anti-inflammatory, analgesic and antipyretic properties.

Emmerton *et al.* (1995) conducted a pharmacy-based surveillance, which identified that Cataflam was most commonly purchased for muscular or skeletal conditions and headaches.

2.15.2. Contraindications to Diclofenac Sodium

Arky (1997: 834) lists the various contraindications to Diclofenac Sodium as:

- Sensitivity to Diclofenac products and
- Patients suffering from asthma, urticaria or other allergic reactions after taking aspirin or other NSAIDs.
- Gastrointestinal effects – peptic ulceration and gastrointestinal bleeding has been reported in patients receiving Diclofenac. Elderly and debilitated patients have a problem tolerating ulceration or bleeding. These patients should remain alert to this spontaneous bleeding.
- Advanced kidney disease – treatment with Diclofenac, should only be initiated with close monitoring of the patients kidney function.
- Late pregnancy - Diclofenac should, as with other NSAIDs be avoided because it could cause premature closure of the ductus arteriosus.
- Those patients who are predisposed to anaphylactic reaction. This includes asthmatic patients who exhibit severe potentially fatal bronchospasm after taking aspirin or other NSAIDs.

Arky (1997: 835) explains that patients should be warned of the various drug interactions that may occur when certain drugs are administered in conjunction with Diclofenac. These drugs include: aspirin, anticoagulants, digoxin, methotrexate, cyclosporin, lithium, diuretics and phenobarbital.

Although Goodman (1994) mentioned that the incidence of significant adverse reactions to NSAIDs is low, the widespread use of these drugs make it essential for clinicians to recognise patients at highest risk and take steps to minimise side effects.

2.16. CONCLUSION

There is an overwhelming amount of evidence suggesting that mechanical LBP is a recurrent, chronic, costly and a widespread phenomenon throughout the world's population, resulting in significant medical, social and economic implications. According to Manga et al. (1993) the approaches for dealing with LBP have been mainly medical, chiropractic and physiotherapeutic. Therefore in this review the evidence on the relative effectiveness of chiropractic and medical protocols for treating and managing LBP have been discussed.

As previously stated by Hirschowitz (1997) and Koes et al. (1992), NSAIDs are among the most widely used drugs. This form of medical management can be a lot more complex and risky, whereas the hands-on therapy approach by chiropractors is far safer. When managing patients on chronic NSAID therapy, clinicians must weigh the therapeutic benefits of their intervention against the potential risk for the development of NSAID-induced complications. Management approaches vary considerably; therefore clinicians dealing with patients at risk, have to select a treatment that is both safe and cost-effective (Goldstein 1997).

The above literature review seems to suggest that chiropractic SMT, has less potential side effects, and is associated with greater patient satisfaction, when compared to the use of NSAIDs, particularly Diclofenac Sodium; however no conclusive comparative studies have been done. Deyo (1996) stated that a variety of drugs are used but there is no uniquely successful form of drug therapy. The reason for this statement is that there is a limited amount of quality clinical trials involving research of NSAIDs in managing mechanical LBP. The trials that exist have inadequate description of patients and unreliable results. It is essential to conduct further research into areas where the use of medications and physical therapy are evaluated.

CHAPTER THREE

CHAPTER THREE

3. MATERIALS AND METHODS

3.1 INTRODUCTION

This chapter deals with the methods employed in data collection, as well as the statistical methods used for the interpretation of the data.

3.2 THE DATA

The data used in this study was of two kinds: primary and secondary data. The nature of each of these two types of data shall be discussed below.

3.2.1. The Primary Data

The primary data was obtained directly from the patients and it consisted of the following:

- Information gathered from the case history (appendix A), physical examination (appendix B), regional low back and pelvis examination (appendix C).
- The patient's pain sensitivity, as determined by an algometer.
- Specific diagnosis and evaluation of the three syndromes involved, namely Sacroiliac Syndrome, Lumbar Facet Syndrome and Myofascial Pain Syndrome, by use of an Orthopaedic Rating Scale (appendix H).
- The patient's disability as determined by the Oswestry Low Back Disability Index (appendix F) (Fairbank et al. 1980).
- The patient's pain perception, as determined by the Numerical Pain Rating Scale – 101 (appendix G) (Jenson et al. 1986).

3.2.2. The Secondary Data

The secondary data was obtained from a search of related literature. This included journals articles, published reports and textbooks, containing information relevant to the research being conducted.

3.3. **CRITERIA GOVERNING ADMISSIBILITY OF THE DATA**

The only subjective data that was admitted came from the Numerical Pain Rating Scale-101 (appendix G), Oswestry Back Disability Index (appendix F), which was used to assess the patient's subjective response to treatment. The patient's objective response to treatment was clinically obtained from the algometer (appendix H), and the Orthopaedic Scale Ratings (appendix H). All these findings were completed and documented under supervision of the researcher.

3.4. **RESEARCH METHODOLOGY AND MATERIALS USED**

3.4.1 Patients

The objective of this investigation was to evaluate the relative effectiveness of Spinal Manipulative Therapy (SMT) compared to Diclofenac Sodium, using subjective and objective measures, in the management of mechanical low back pain (LBP).

A sample size of 60 patients was utilized in the study. These patients presented to the Chiropractic Clinic at Technikon Natal suffering with mechanical LBP. There were 30 patients randomly assigned to Group 1, the SMT group; and 30 to group 2, the Diclofenac Sodium group. Five additional patients per group were included, to make up for a percentage drop out or non-compliance.

Patients were recruited by placing advertisements in the Natal Mercury, Berea Mail, local gyms, sports clubs and the local radio station - East Coast Radio. It

was advertised that free treatment would be administered to any patients suffering from LBP, aged between 18 and 65 years. Potential patients had the research protocol explained to them and an initial consultation was scheduled for patients who met the following criteria:

3.4.2. Inclusion and Exclusion Criteria of Patients:

The inclusion criteria for the study are:

- Patients had to be between the ages of 18 and 65 years.
- Patients receiving treatment or medication for their current LBP underwent a 48-hour wash out period before entering the study.
- Patients suffering from mechanical LBP including Myofascial Pain Syndrome, Sacroiliac Syndrome and Lumbar Facet Syndrome were included (Kirkaldy-Willis 1992: 291).

Patients were excluded from the study according to the following contraindications to SMT (Kirkaldy-Willis 1992: 291):

- Osteopenia
- Spondyloarthropathies
- Patients on anticoagulant medication
- Bleeding disorders
- Psychological overlay
- Destructive lesions of the spine, ribs and pelvis
- Healing fractures or dislocation
- Gross instability
- Cauda equina syndrome
- Large abdominal aneurysms
- Visceral referred pain

Patients with the following contra-indications to Diclofenac Sodium administration (Arky 1997: 834) were excluded from the study:

- Sensitivity to Diclofenac products
- Patients suffering from asthma, urticaria or allergic reactions after taking aspirin or other nonsteroidal anti-inflammatory drugs.
- Patients suffering for gastrointestinal disorders, such as peptic ulcers and gastric bleeding.
- Advanced kidney diseases
- Late pregnancy (the third trimester)
- Patients predisposed to anaphalactic reaction
- Patients taking these drugs: aspirin, anticoagulants, digoxin, methotrexate, cyclosporin, lithium, diuretics and Phenobarbital were excluded due to potential adverse drug reactions with Diclofenac Sodium.

3.4.3. Intervention

At the initial consultation, all potential candidates for the study underwent a full case history (appendix A), a physical examination (appendix B) and a regional low back and pelvis examination (appendix C). Patients were screened (appendix D) for contraindications to Diclofenac Sodium and SMT. Those with contraindications were excluded from the trial. Informed Consent (appendix E) was obtained from all patients before inclusion into the study.

A method of simple consecutive randomised allocation of each patient to either the SMT (group 1) or the Diclofenac Sodium group (group 2) occurred at the initial consultation. The method that was used was the "goldfish bowl technique" (Willemmse 1990: 14). As the patients were accepted into the study, they were asked to draw a number with their eyes closed. As the total size of the group was 60, all the odd numbers from 1 – 60 were designated to the SMT group whilst all the even numbers from 1 – 60 were designated to the Diclofenac Sodium group. The number chosen by the patient was

discarded and the process was repeated until the final patient was automatically allocated the remaining number. The result was two groups of 30 patients each.

The symptomatic joints were identified by motion palpation of the Lumbar spine and the Sacroiliac joints (Schafer and Faye 1990: 211 - 217). Motion palpation was used to identify segments of the lumbar spine and sacroiliac joints with restricted and/or abnormal motion. Motion palpation was also used to identify in which plane an adjustive technique should be given, thus allowing the subject to have the least amount of discomfort and to restore maximum joint play to their spine (Schafer and Faye 1989: 211-216, 256-259).

Those patients assigned to group 1 received SMT in accordance with the treatment protocol of Kirkaldy-Willis (1988: 249). This involved receiving four treatments over a period of seven to ten days. If the LBP resolved completely before the four treatments were completed, the SMT was discontinued but the patients were monitored throughout the remaining consultations. If the same condition did recur within the monitored period, the treatment was continued until the fourth consultation.

Patients within group 2 took one 50mg Diclofenac Sodium tablet three times per day after meals, for a course of seven days. If the patients LBP resolved completely before the final treatment and was maintained for 48 hours, they stopped taking the medication, but were assessed in the subsequent consultations.

The diversified adjusting technique, as described by Szaraz (1990:137-160), was used in treating the low back. The manipulations for the lumbar spine included the lumbar roll (pisiform-mamillary), sitting lumbar and spinous push or hook technique. The techniques that were used to manipulate the sacroiliac joints included the upper sacroiliac, lower sacroiliac and prone sacroiliac techniques.

3.4.4. Measurements

The severity of the patients mechanical LBP was measured at the initial, second and final consultations. Before each consultation the subjective and objective readings were obtained and recorded.

3.4.4.1. Objective measurements

The force dial algometer was used as an objective reading that measured spinal tenderness. A higher reading indicated a greater pain tolerance of the patient at the symptomatic point. These measurements were taken by placing the rubber tip of the algometer over the symptomatic facet joint of the lumbar vertebrae, or the sacroiliac joint, or the active myofascial trigger point. Pressure was applied to the patient's tolerance. The force readings were measured in kilograms per square centimetre (kg/cm²). The use of the algometer to measure sensitivity is widespread. Fischer (1986) states that the algometers ability to measure pressure sensitivity and to identify aberrant tender areas provides a means of quantifying treatment, so as to identify patient improvement.

Further objective findings were carried out through the creation of an Orthopaedic Rating Scale (appendix H). During the orthopaedic low back and pelvis regional examination (appendix C), specific tests were performed to diagnose mechanical LBP. These specific tests were used to identify the clinical lesions of Lumbar Facet Syndrome, Sacroiliac Syndrome, and Myofascial Pain Syndrome of the following muscles: Gluteus Maximus and Medius, Quadratus Lumborum, Piriformis, Tensae Fascia Lata and the Hamstring.

The specific orthopaedic tests included:

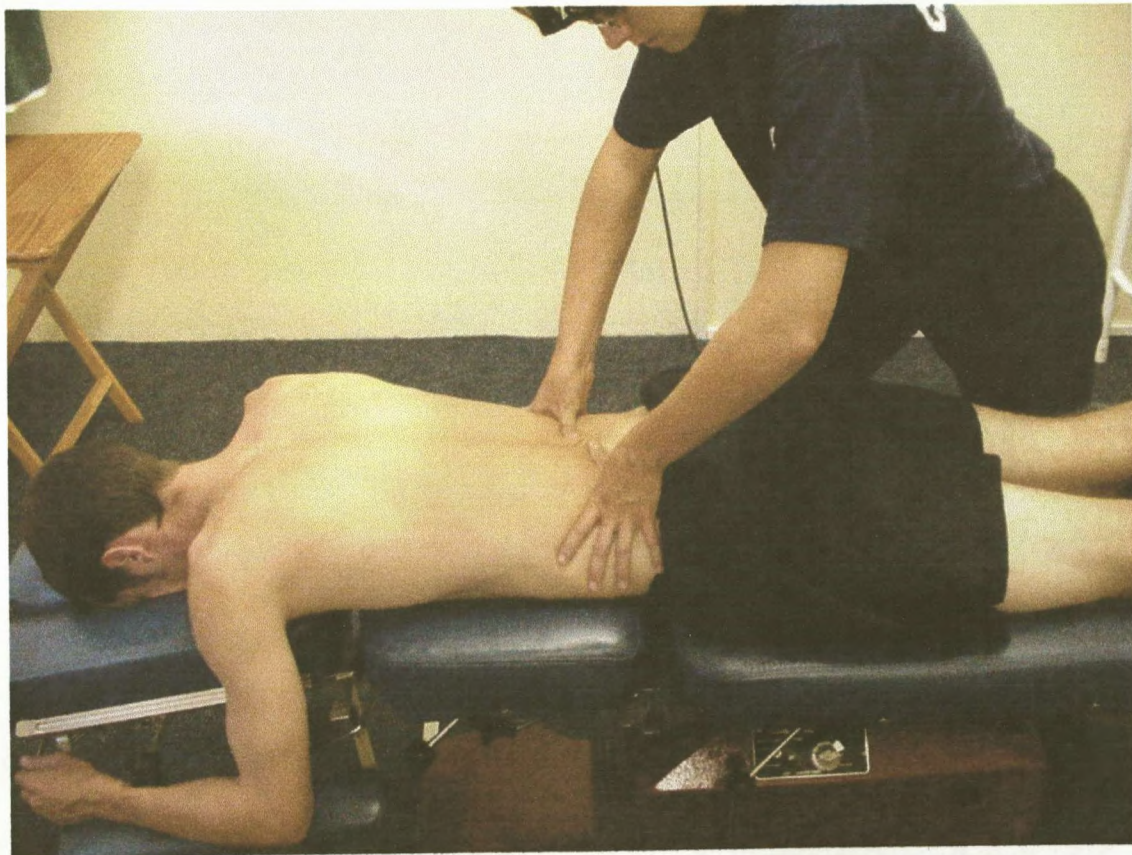
Kemps test, Facet Joint Challenge test and hyperextension in a prone position, for Lumbar Facet Syndrome. Gaenslen's, Patrick Faber, Yeoman's and a Posterior Shear or "Thigh Thrust Test", for Sacroiliac Syndrome. Eliciting a pattern of referred pain, a local twitch response, a taut palpable band and exquisite focal tenderness to digital pressure indicated Myofascial Pain Syndrome.

Kemp's test as described by Giles (1997: 346), includes a combination of extension and lateral bending over the facet joints. This was carried out with the patient in a seated position. The examiner reaches around the patient's shoulders from behind laterally bends, rotates and extends the patient maximally to the right then the left. Axial compression is then applied with the patient in this position. Pain in the lumbar region is indicative of a positive test (Gatterman 1990: 141).



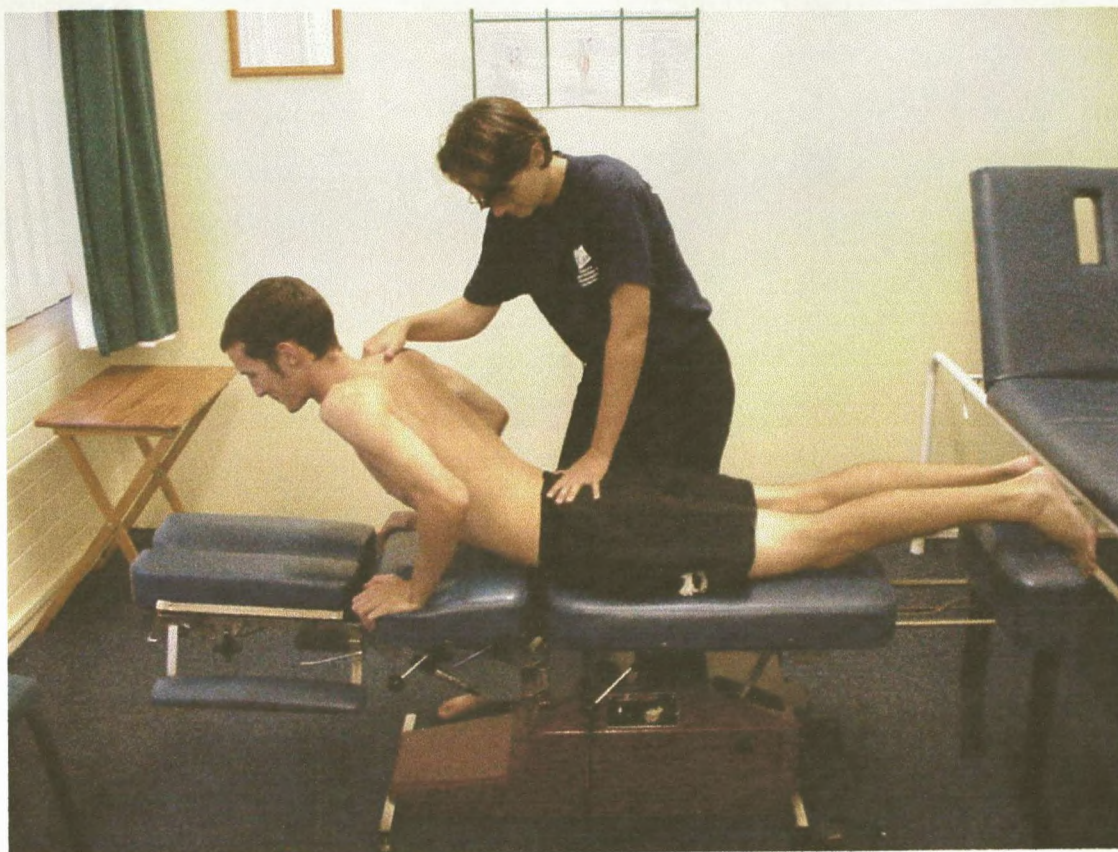
Photograph 3.1. Demonstration of Kemp's test.

Lumbar facet joint challenge is performed with the patient prone. "Springing" the spinous process discerns the status of the facet joints. The examiner places one thumb on the spinous process above and one on the spinous process below. The force is applied in opposite direction, pushing in a horizontal plane. If there is no pain response to gentle pressure the examiner might bounce the joint with a little more force. It is this "springiness" or joint-play that one palpates for when performing facet joint challenge (Gatterman 1990: 84).



Photograph 3.2. Demonstration of Lumbar facet joint challenge.

Gatterman (1990: 162) describes that pain is increased in spine hyperextension, in a prone position for Lumbar Facet Syndrome.

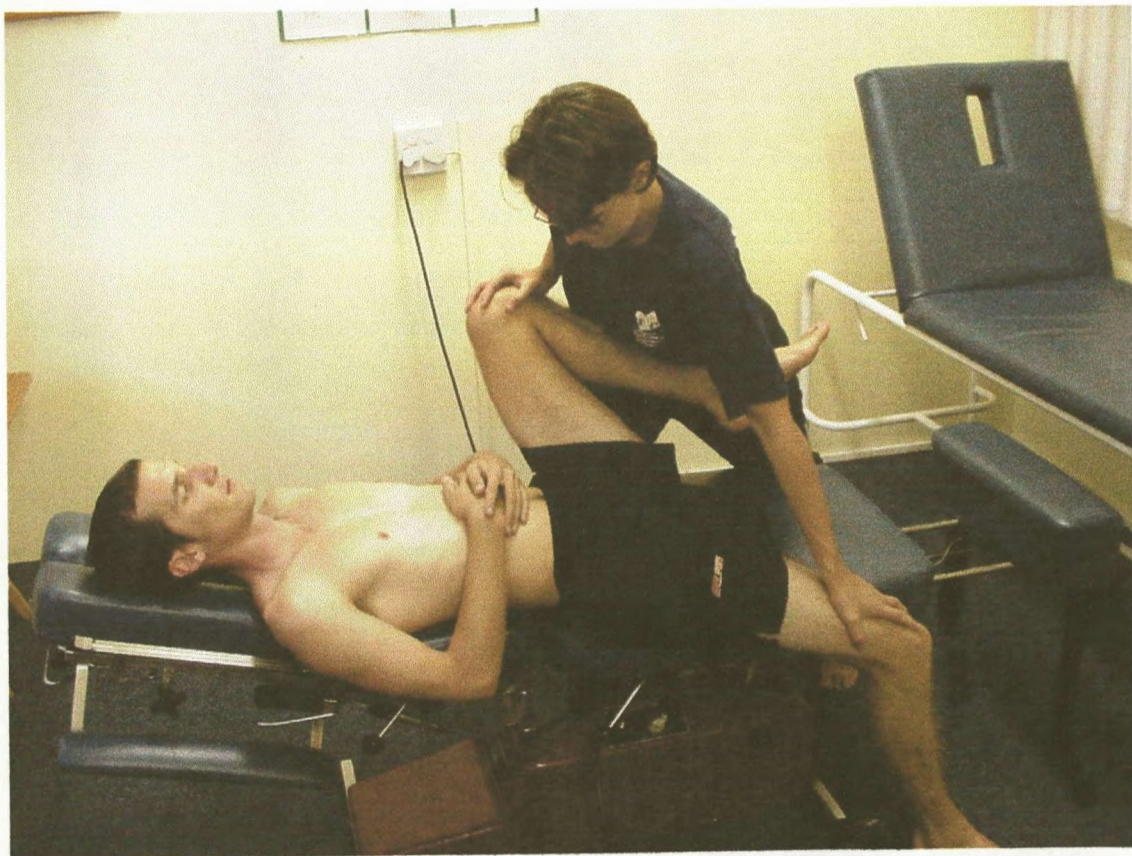


Photograph 3.3. Demonstration of a patient hyperextending in a prone position.

Magee (1997: 473) describes the Patrick Faber test, with the patient lying supine. The examiner places the patient's test leg so that the foot of the test leg is on top of the knee of the opposite straight leg. The examiner then slowly lowers the test leg in abduction toward the examining table, while the opposite hand stabilises the pelvis at the Anterior Superior Iliac Spine. A negative test is indicated by the test leg falling to the table or at least being parallel with the opposite leg. A true positive test results in the leg remaining above the opposite straight leg. If positive, pain is located over the sacroiliac joint thus

indicating sacroiliac dysfunction. A false positive indicated possible hip joint or thigh adductor pathologies.

Gaenslen's test is described by Magee (1997: 446), with the patient lying supine. The test hip extends beyond the edge of the table. The patient draws both legs up onto the chest and then slowly lowers the test leg into extension with the assistance of the examiner. The examiner applies a shearing pressure in opposite direction. The other leg is tested in a similar fashion for comparison. Pain in the sacroiliac joints is indicative of a positive test.



Photograph 3.4. Demonstration of Gaenslen's test.

Yeoman's test is described by Schafer and Faye (1990: 271), with the patient placed prone. One hand applies a firm pressure over the involved sacroiliac joint, with the other hand, extending the patient's hip on the affected side to the limit. The patient's thigh is hyperextended by lifting the patient's knee off the examining table. If pain is increased in the sacroiliac area, it indicates a sacroiliac dysfunction.



Photograph 3.5. Demonstration of Yeoman's test.

Laslett and Williams (1994) describe the Posterior Shear Test, with the patient supine. The hip is flexed and adducted while the examiner applies a force by pushing posteriorly along the line of the femur, thus stressing the sacroiliac joint. The test is positive when there is an increase in pain over the sacroiliac joint or a reproduction of the patient's symptoms.



Photograph 3.6. Demonstration of Posterior Shear test.

Upon creation of the Orthopaedic rating scale (appendix H) each of the above tests were allocated a score on production of a positive result.

To determine the prescence of Lumbar Facet Syndrome:

Kemp's test and Lumbar Facet Challenge each received a score of four when positive. The reason for the higher rating was according to Laboeuf (1990), who stated that these two tests are the most commonly used tests in chiropractic and orthopaedic low back examinations. Schafer and Faye (1990: 217), Magee (1997: 399), and Gatterman (1990: 162) were authors who described these two tests in their diagnoses of Lumbar Facet Syndrome. The prone hyperextension test described by Gatterman (1990: 162) received a score of two when positive.

To determine the prescence of Sacroiliac Syndrome:

The Posterior Shear test was the most sensitive test according to Laslett and Williams (1994). A score of four was allocated when positive. When Gaenslen's, Patrick Faber and Yeoman's test were positive they were each allocated a score of two.

To determine the prescence of Myofascial Pain Syndrome:

Travell and Simons (1983: 18 –21) analysed various research and discovered that the referral of pain was the most important indicator of this syndrome. Therefore a score of four was allocated when the Myofascial Trigger point refered pain on digital pressure. A local twitch response, a taut palpable band and exquisite focal tenderness were all of equal importance and received a score of two when positive.

The Orthopaedic Rating Scale for each syndrome was out of 10. Only patients with a rating of 6 out of 10 or higher; or a combined involvement of two syndromes rating 12 out of 20 or higher; or the involvement of all three syndromes rating 18 out of 30 or higher were diagnostically acceptable and were included into the study. This assessment was carried out before the treatments at the initial consultation, the second consultation as well as after the treatment at the final consultation. The consulting clinician gave the patient a rating independently to that of the researcher and the mean rating was determined and recorded by the researcher. A change in score gave an indication as to whether there was a change in the patient's condition. The

Orthopaedic Rating Scale was statistically analysed as a percentage of mechanical LBP for each patient. This allowed for all 60 subjects to be analysed. Additional analysis was carried out on the specific syndromes and the combination of syndromes. This was dependent on how many patients were selected for each syndrome or combination of syndromes. If the sample size was too small the appropriate statistical tests could not be run.

3.4.4.2. Subjective measurements

According to Triano et al. (1993), both the Oswestry Low Back Pain Disability Questionnaire (appendix F) and the Numerical Pain Rating Scale - 101 (appendix G) are accepted as valid and reliable measurement criteria. Furthermore Jenson et al. (1986) found the Numerical Pain Rating Scale - 101 to be the most practical index when compared to six other methods of measuring clinical pain intensity.

The Oswestry Low Back Pain Disability Questionnaire (appendix F) consists of ten sections of six questions each. For each section, the total possible score is five points, with the point distribution ranging from zero (if the first statement of the respective section was marked) to five (if the sixth statement was chosen). Upon completion of the questionnaire, the points for each section were added, with the maximum possible score being fifty. The final score was then converted to a percentage for each patient, for that particular consultation. In the event that one section was not completed, the highest possible score became 45 and the total score was then calculated out of 45, and was then converted to a percentage. Similarly, if more than one section was not answered, the total score was then divided by five less points per section unanswered before converting to a percentage (Fairbank et al. 1980). These scores were calculated and recorded on the patient's files at the time of data collection.

The Numerical Pain Rating Scale - 101 (appendix G), a numerical pain intensity scale, was designed to ascertain the pain intensity that the subjects experience. The questionnaire instructed the subject to rate their pain when it

was at its worst and when it was at its least. A numerical scale from zero to one hundred was used, where zero indicated "no pain at all" and one hundred indicated "pain as bad as it could be". An accurate assessment of the pain intensity was then obtained by taking the average of the two scores (Jenson et al. 1986).

An average of the amount of pain experienced by each patient at the initial, second and final consultations was then utilised for statistical analysis.

Jenson et al. (1986) suggests that the Numerical Pain Rating Scale is a reliable method of measurement and should be used as a questionnaire of choice.

3.5. STATISTICAL PROCEDURE

The data was analysed using the computer statistical package SPSS version 9.0.

Both parametric and non-parametric tests were used in order to analyse the data obtained. Parametric tests were used to analyse the algometer, Orthopaedic Rating Scale (Percentage analysis), the results of the Numerical Pain Rating scale-101 and the Oswestry Low Back Pain Disability Questionnaire readings. While non-parametric tests were used for those variables where the sample sizes were less than ($n < 30$). This is specific to syndromes or combination of syndromes within the Orthopaedic Rating Scale. Non-parametric tests included, the Wilcoxin Signed Rank test and the Mann-Whitney U-test. Parametric tests included the unpaired t-test and the paired t-test.

3.5.1. Procedure 1: Wilcoxin Signed Rank Test (Intra-group)

The Wilcoxin Signed Rank test was used at the 5% level of significance. It was used to determine whether any statistically significant improvement occurred within group 1, and group 2 between the initial and the second

consultation; between the initial and final consultation; and between the second and final consultation.

The null hypothesis (H_0) stated that there would be no significant improvement between each of these consultations. Therefore the null hypothesis is either rejected or accepted depending on the p-value being greater than or less than α .

The alternative hypothesis (H_1) stated that there was significant improvement between each consultation (Fisher and Van Belle 1993: 315 – 319).

One-tailed test.

H_0 : There is no improvement between the consultations.

H_1 : There is an improvement between the consultations.

$\alpha = 0,05$

Decision rule:

If $p < \alpha$, reject H_0 .

If $p \geq \alpha$, accept H_0 .

$$(i) \quad p = \frac{\text{reported p-value}}{2} \quad \begin{array}{l} \text{If } H_a \text{ is of form } > \text{ and } z \text{ is positive} \\ \text{If } H_a \text{ is of form } < \text{ and } z \text{ is negative} \end{array}$$

$$(ii) \quad p = 1 - \left(\frac{\text{reported p-value}}{2} \right) \quad \begin{array}{l} \text{If } H_a \text{ is of form } > \text{ and } z \text{ is negative} \\ \text{If } H_a \text{ is of form } < \text{ and } z \text{ is positive} \end{array}$$

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

3.5.2. Procedure 2: Mann-Whitney U-test (Inter-group)

The Mann-Whitney U-test was used at the 5% level of significance. It was used to determine whether any significant difference existed between group 1 and group 2 at the time of the initial, second and final consultations.

The null hypothesis (H_0) stated that there would be no significant difference between each group. Therefore the null hypothesis is either rejected or accepted depending on the p-value being greater than or less than α .

The alternative hypothesis (H_i) stated that there was significant difference between each group (Fisher and Van Belle 1993: 315 – 319).

H_0 : There is no difference between the two groups.

H_i : There is a difference between the two groups.

$$\alpha = 0,05$$

Decision rule:

If $p < \alpha$, reject H_0 .

If $p \geq \alpha$, accept H_0 .

Where p is the reported p-value.

3.5.3. Procedure 3: Paired t-test (Intra-group)

Paired t-test (one sample analysis) was used at the 5% level of significance. It was used to determine whether any significant improvement occurred within group 1 and group 2 between the initial and the second consultation; between the initial and final consultation; and between the second and final consultation. This parametric test was used, as the sample size was greater than or equal to 30 ($n \geq 30$).

The null hypothesis (H_0) stated that there would be no significant improvement between each of these consultations. Therefore the null

hypothesis is either rejected or accepted, depending on whether the p-value was greater than or less than α .

The alternative hypothesis (H_i) stated that there was significant improvement between each consultation (Fisher and Van Belle 1993: 315 – 319).

One-tailed test.

H_o : There is no improvement between the consultations.

H_i : There is an improvement between the consultations.

$\alpha = 0,05$

Decision rule:

If $p < \alpha$, reject H_o .

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

$$(i) \quad p = \frac{\text{reported p-value}}{2} \quad \begin{array}{l} \text{If } H_a \text{ is of form } > \text{ and } z \text{ is positive} \\ \text{If } H_a \text{ is of form } < \text{ and } z \text{ is negative} \end{array}$$

$$(ii) \quad p = 1 - \left(\frac{\text{reported p-value}}{2} \right) \quad \begin{array}{l} \text{If } H_a \text{ is of form } > \text{ and } z \text{ is negative} \\ \text{If } H_a \text{ is of form } < \text{ and } z \text{ is positive} \end{array}$$

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

3.5.4. Procedure 4: Unpaired t-test (Inter-group)

Unpaired t-test (two sample analysis) was used at the 5% level of significance. It was used to determine whether there was any significant difference between the two groups at the time of the initial, second and final consultations. This parametric test was used as the sample size was greater than or equal to 30 ($n \geq 30$).

The null hypothesis (H_o) stated that there would be no significant difference between each group. Therefore the null hypothesis is either rejected or accepted depending on the p-value being greater than or less than α .

The alternative hypothesis (H_i) stated that there was significant difference between each group (Fisher and Van Belle 1993: 315 – 319).

H_o : There is no difference between the two groups.

H_i : There is a difference between the two groups.

$$\alpha = 0,05$$

Decision rule:

If $p < \alpha$, reject H_o .

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

Where p is the reported p-value.

3.6. THE SPECIFIC TREATMENT OF EACH OBJECTIVE

3.6.1. Objective One

The first objective was to evaluate the relative effectiveness of Spinal Manipulative Therapy, compared to Diclofenac Sodium in terms of subjective clinical findings, in the management of mechanical LBP.

3.6.1.1. The data required

The data required for the first objective was the response of the patients in both the groups to the Oswestry Low Back Pain Disability Questionnaire (appendix F) and the Numerical Pain Rating Scale-101 (appendix G).

3.6.1.2. How the data was secured

All data was collected from the participating patients treated at Technikon Natal's Chiropractic Day Clinic.

This data was recorded in each patient's file at the aforementioned times of data collection.

Under the researcher's supervision, all questionnaires were completed at the appointed consultations, as explained in the methodology.

3.6.2. Objective Two

The second objective was to evaluate the relative effectiveness of Spinal Manipulative Therapy compared to Diclofenac Sodium, in terms of objective clinical findings, in the management of mechanical LBP.

3.6.2.1. The data required

The data required for the second objective were the findings collected from the patients in both groups using the algometer and the Orthopaedic Rating Scale (appendix H).

3.6.2.2. How the data was secured

All data was collected from the participating patients treated at Technikon Natal's Chiropractic Day Clinic.

This data was recorded in each patient's file at the aforementioned times of data collection.

The objective clinical findings and readings were observed and noted by the researcher at the appointed consultation in the relevant documents (appendix H).

3.6.3. Objective Three

The third objective was to integrate the results of objective one and objective two in order to determine whether either of the treatments was more effective in the management of mechanical LBP, in terms of subjective and objective clinical findings.

3.6.3.1. The data required

The data required for the third objective was the response of the patients in both the groups to the Oswestry Low Back Pain Disability Questionnaire (appendix F), the Numerical Pain Rating Scale-101 (appendix G), the algometer readings (appendix H) and the Orthopaedic Rating Scale (appendix H).

3.6.2.2. How the data was secured

The data required was recorded in the files of all participating patients during the process of securing data for objective one and two.

CHAPTER

FOUR

CHAPTER FOUR

4. THE RESULTS

4.1. INTRODUCTION

This chapter deals with the results obtained after statistically analysing the data from the measurement criteria utilized, that is:

- The Algometer.
- The Orthopaedic Rating Scale (ORS).
- The Numerical Pain Rating Scale-101 (NRS-101).
- The Oswestry Low Back Pain Disability Questionnaire (OSWESTRY).
- The age, race and gender distribution tabulated.
- The incidence of syndromes and the patient's excluded from the research.

This study included a total of 60 patients, with 30 patients in group 1 and 30 in group 2. Using the ORS, each patient was analysed for SIS, LFS and MFPS, including any combination of these syndromes. This resulted in variations in the sizes of the samples being analysed, which necessitated the use of both Parametric and Non-parametric tests. The data was statistically analysed in order to accept or reject the null hypothesis. The results obtained from the inter-group and intra-group data analysis are tabulated. The tables for statistical results include the mean (Me), the standard deviation (Sd), the standard error (Se) and the level of significance (p-value).

4.1.1. The Use of Non-parametric tests for Statistical Data Analyses

If the sample size was less than 30 ($n < 30$), the Wilcoxin Signed Rank test and Mann-Whitney U-test were the two tests utilized. The level of significance for these two tests was set at $\alpha = 0,05$ (5%).

The Wilcoxin Signed Rank test was used as an intra-group comparison. Each group was analysed individually to determine if there was any significant improvement within the group between the following consultations:

- The initial and the second consultation.
- The initial and final consultation.
- The second and the final consultation.

The Mann-Whitney U-test was used as an inter-group comparison. The test was used to determine whether any significant difference existed between group 1 and group 2 at each of the following consultations:

- The initial consultation.
- The second consultation.
- The final consultation.

4.1.2. The Use of Parametric tests for Statistical Data Analyses

If the sample size was more than 30 ($n > 30$), the Unpaired and Paired t-tests were used. The level of significance for these two tests was set at $\alpha = 0,05$ (5%).

The Two Sample Paired t-test was used as an intra-group comparison, to determine whether any change occurred within the group between:

- The initial and the second consultation.
- The initial and final consultation.
- The second and the final consultation.

The Two-Sample Unpaired t-test was used as an inter-group comparison, to determine whether any differences occurred between group 1 and group 2 at the following consultations:

- The initial consultation.
- The second consultation.
- The final consultation.

4.2. TABLES OF DEMOGRAPHIC DATA

The demographic data was recorded for all patients accepted into the trial. It included age, gender and race distribution, as well as the number of patients excluded from the research.

4.2.1. Age distribution within the sample group of 60.

Table 4.1. Age Distribution of Patients (n=60):

<u>AGE</u>	NUMBER OF PATIENTS	TOTAL % OF PATIENTS
11-20	5	8.3%
21-30	29	48.3%
31-40	16	26.7%
41-50	8	13.3%
51-60	2	3.3%
TOTAL	60	100%

The ages of the patients within this study ranged from 18 to 55. The mean age was 26.

4.2.2. Gender distribution within the sample group of 60.

Table 4.2. Gender Distribution of Patients (n=60):

GENDER	NUMBER OF PATIENTS	TOTAL PERCENTAGE
Male	29	48.3%
Female	31	51.7%
TOTAL	60	100%

4.2.3. Race distribution within the sample group of 60

Table 4.3. Race Distribution of Patients (n=60):

RACE	NUMBER OF PATIENTS	TOTAL PERCENTAGE
White	39	65%
Black	14	23.3%
Indian	7	11.7%
TOTAL	60	100%

4.2.4. Patient's excluded from the research

Table 4.4. Patient's excluded from Group 1 (SMT):

REASON FOR EXCLUSION	NUMBER OF PATIENTS EXCLUDED
Lack of transport	2
Poor compliance	1
Patient suffering from Sacroilitis.	1
TOTAL	4

Table 4.5. Patient's excluded from Group 2 (NSAID):

REASON FOR EXCLUSION	NUMBER OF PATIENTS EXCLUDED
Telephonically excluded as suffer from Peptic Ulcer.	5
Excluded from the study following Dr Moodley's request as they had a history of an endoscope examination.	4
Lack of transport.	2
Patient suffers from recurrent heartburn associated with meals.	1
Medication caused heartburn.	1
Medication caused abdominal discomfort.	1
Medication caused nausea and heartburn.	1
TOTAL	15

4.3. INCIDENCE OF SYNDROMES

Table 4.6. Incidence of Lumbar Facet Syndrome (LFS), Myofascial Pain Syndrome (MFPS) and Sacroiliac Syndrome (SIS):

<u>SYNDROME:</u>	<u>NUMBER OF PATIENTS:</u>
SIS.	2
LFS.	14
MFPS.	0
SIS & MFPS.	2
SIS & LFS.	3
LFS & MFPS.	22
SIS, LFS & MFPS.	17
Mechanical LBP (Total)	60

4.4. PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1 (SMT):

4.4.1. Analysis of the Subjective Data.

Table 4.7. Comparison of the subjective data between the initial and second consultations, using the Paired t-test.

	TREATMENT GROUP 1: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 1 SECOND CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	39.67	13.51	2.47	0.000	29.92	14.96	2.73
OSWESRTY	16.33	9.87	1.80	0.000	12.67	9.28	1.69

The null hypothesis is rejected for both the NRS-101 and the OSWESTRY questionnaires, which indicates that a statistically significant improvement took place between the initial and the second consultations within group 1.

Table 4.8. Comparison of the subjective data between the initial and final consultations, using the Paired t-test.

	TREATMENT GROUP 1: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 1 FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	39.67	13.51	2.47	0.000	21.45	16.75	3.06
OSWESRTY	16.33	9.87	1.8	0.000	8.77	7.47	1.36

The null hypothesis is rejected for both the NRS-101 and the OSWESTRY questionnaires, which indicates that a statistically significant improvement took place between the initial and the final consultations within group 1.

Table 4.9. Comparison of the subjective data between the second and final consultations, using the Paired t-test.

	TREATMENT GROUP 1: SECOND CONSULTATION			P-VALUE	TREATMENT GROUP 1 FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	29.92	14.96	2.73	0.000	21.45	16.74	3.06
OSWESRTY	12.67	9.28	1.69	0.001	8.77	7.47	1.36

The null hypothesis is rejected for both the NRS-101 and the OSWESTRY questionnaires, which indicates that a statistically significant improvement took place between the second and the final consultations within group 1.

4.5. PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 2 (NSAID):

4.5.1. Analysis of the Subjective Data.

Table 4.10. Comparison of the subjective data, between the initial and second consultations, to using the Paired t-test.

	TREATMENT GROUP 2: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 2: SECOND CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	40.45	10.36	1.89	0.000	29.88	13.71	2.5
OSWESRTY	16.8	6.74	1.23	0.000	10.2	5.97	1.09

The null hypothesis is rejected for both the NRS-101 and the OSWESTRY questionnaires, which indicates that a statistically significant improvement took place between the initial and the second consultations within group 2.

Table 4.11. Comparison of the subjective data between the initial and final consultations, using the Paired t-test.

	TREATMENT GROUP 2: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 2: FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	40.45	10.36	1.89	0.000	20.47	17.11	3.12
OSWESRTY	16.8	6.74	1.23	0.000	5.53	5.24	0.96

The null hypothesis is rejected for both the NRS-101 and the OSWESTRY questionnaires, which indicates that a statistically significant improvement took place between the initial and the final consultations within group 2.

Table 4.12. Comparison of the subjective data between the second and final consultations, using the Paired t-test.

	TREATMENT GROUP 2: SECOND CONSULTATION			P-VALUE	TREATMENT GROUP 2: FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	29.88	13.71	2.5	0.003	20.47	17.11	3.12
OSWESRTY	10.2	5.97	1.09	0.001	5.53	5.24	0.96

The null hypothesis is rejected for both the NRS-101 and the OSWESTRY questionnaires, which indicates that a statistically significant improvement took place between the second and the final consultations within group 2.

4.6. PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1 (SMT):

4.6.1. Analysis of the Objective Data.

Table 4.13. Comparison of the objective data between the initial and second consultations, using the Paired t-test.

	TREATMENT GROUP 1: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 1: SECONDCONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	4.08	1.45	0.26	0.000	4.9	1.37	0.25
ORS (%)	78.53	10.76	1.97	0.007	67.60	19.12	3.49

The null hypothesis is rejected for the ALGOMETER READINGS and the ORS (percentage analysis). This indicates that a statistically significant improvement took place between the initial and second consultations within group 1.

Table 4.14. Comparison of the objective data between the initial and final consultations, using the Paired t-test.

	TREATMENT GROUP 1: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 1: FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	4.08	1.45	0.26	.0.000	5.98	2.17	0.4
ORS (%)	78.53	10.76	1.97	0.000	39.67	21.51	3.93

The null hypothesis is rejected for the ALGOMETER READINGS and the ORS (percentage analysis). This indicates that a statistically significant improvement took place between the initial and final consultations within group 1.

Table 4.15. Comparison of the objective data between the second and final consultations, using the Paired t-test.

	TREATMENT GROUP 1: SECONDCONSULTATION			P-VALUE	TREATMENT GROUP 1: FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	4.9	1.37	0.25	0.004	5.98	2.17	0.4
ORS (%)	67.60	19.12	3.49	0.000	39.67	21.51	3.93

The null hypothesis is rejected for the ALGOMETER READINGS and the ORS (percentage analysis). This indicates that a statistically significant improvement took place between the second and final consultations within group 1.

4.7. PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 2 (NSAID):

4.7.1. Analysis of the Objective Data.

Table 4.16. Comparison of the objective data between the initial and second consultations, using the Paired t-test.

	TREATMENT GROUP 2: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 2: SECOND CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	3.64	1.23	0.23	0.042	4.08	1.23	0.23
ORS (%)	85.83	11.75	2.15	0.000	69.27	23.15	4.23

The null hypothesis is rejected for the ALGOMETER READINGS and the ORS (percentage analysis). This indicates that a statistically significant improvement took place between the initial and the second consultations within group 2.

Table 4.17. Comparison of the objective data between the initial and final consultations, using the Paired t-test.

	TREATMENT GROUP 2: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 2: FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	3.64	1.23	0.23	0.000	5.42	1.79	0.33
ORS (%)	85.83	11.75	2.15	0.000	44.43	30.22	5.52

The null hypothesis is rejected for the ALGOMETER READINGS and the ORS (percentage analysis). This indicates that a statistically significant improvement took place between the initial and the final consultations within group 2.

Table 4.18. Comparison of the objective data between the second and final consultations, using the Paired t-test.

	TREATMENT GROUP 2: SECONDCONSULTATION			P-VALUE	TREATMENT GROUP 2: FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	4.08	1.23	0.22	0.000	5.42	1.79	0.33
ORS (%)	69.27	23.15	4.23	0.000	44.43	30.22	5.52

The null hypothesis is rejected for the ALGOMETER READINGS and the ORS (percentage analysis). This indicates that a statistically significant improvement took place between the second and the final consultations within group 2.

4.8. PARAMETRIC INTER-GROUP ANALYSIS:

4.8.1. Analysis of the Subjective Data.

Table 4.19. Comparison of the subjective data for groups 1 and 2 at the initial consultation, using the Unpaired t-test.

	TREATMENT GROUP 1 (SMT) INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 2 (NSAIDS) INITIAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	39.67	13.51	2.47	0.803	40.45	10.36	1.89
OSWESTRY	16.33	9.87	1.8	0.831	16.8	6.74	1.23

The null hypothesis is accepted for the NRS-101 and the OSWESTRY questionnaires, indicating that no statistically significant difference existed between group 1 and group 2 at the initial consultation. This suggests that each group was similarly matched regarding the severity of their LBP at the onset of the study.

Table 4.20. Comparison of the subjective data for groups 1 and 2 at the second consultation using the Unpaired t-test.

	TREATMENT GROUP 1 (SMT) SECOND CONSULTATION			P-VALUE	TREATMENT GROUP 2 (NSAIDS) SECOND CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	29.92	14.96	2.73	0.993	29.88	13.71	2.5
OSWESTRY	12.67	9.28	1.69	0.226	10.2	5.97	1.09

The null hypothesis is accepted for the NRS-101 and the OSWESTRY questionnaires, indicating that no statistically significant difference existed between group 1 and group 2 at the second consultation.

Table 4.21. Comparison of the subjective data for groups 1 and 2 at the final consultation using the Unpaired t-test.

	TREATMENT GROUP 1 (SMT) FINAL CONSULTATION			P-VALUE	TREATMENT GROUP 2 (NSAIDS) FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
NRS-101	21.45	16.75	3.06	0.823	20.47	17.11	3.12
OSWESTRY	8.77	7.47	1.36	0.057	5.53	5.24	0.96

The null hypothesis is accepted for the NRS-101 and the OSWESTRY questionnaires, indicating that no statistically significant difference existed between group 1 and group 2 at the final consultation.

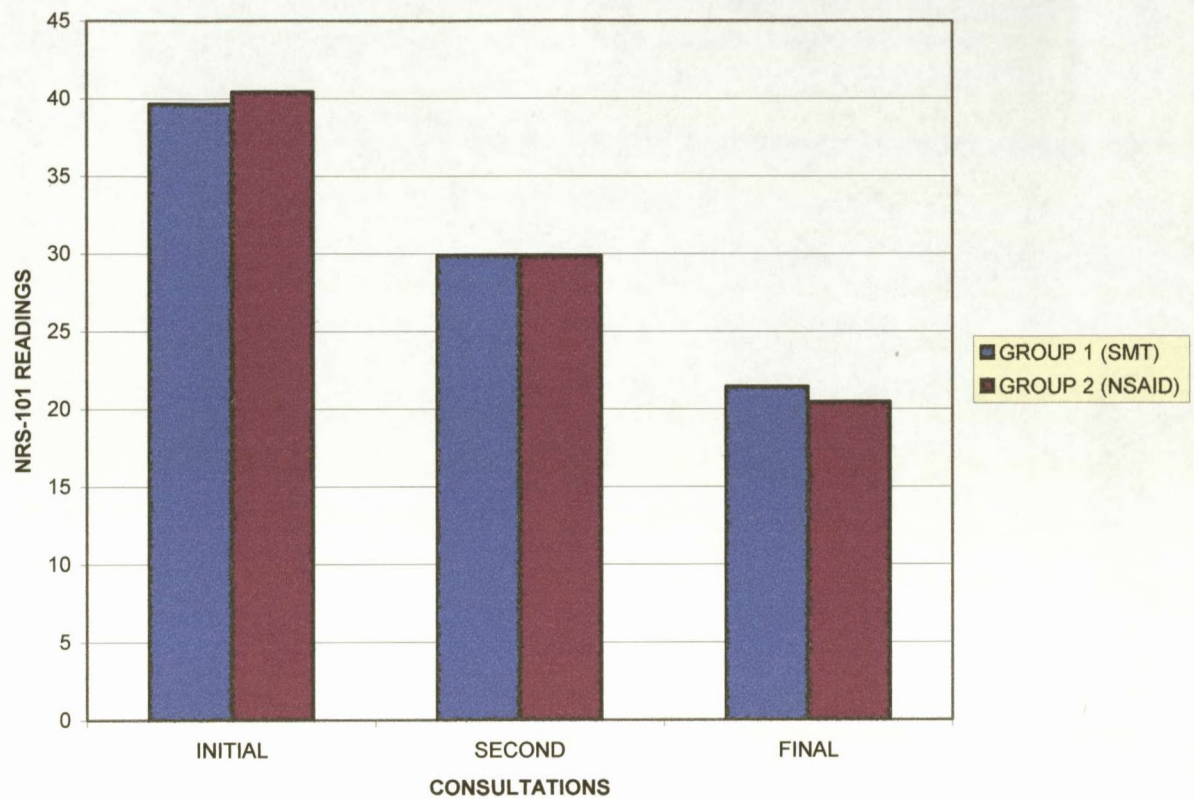


FIGURE 4.1. Mean values of the Numerical Pain Rating Scale-101 at the initial, second and final consultations comparing the SMT and NSAID groups.

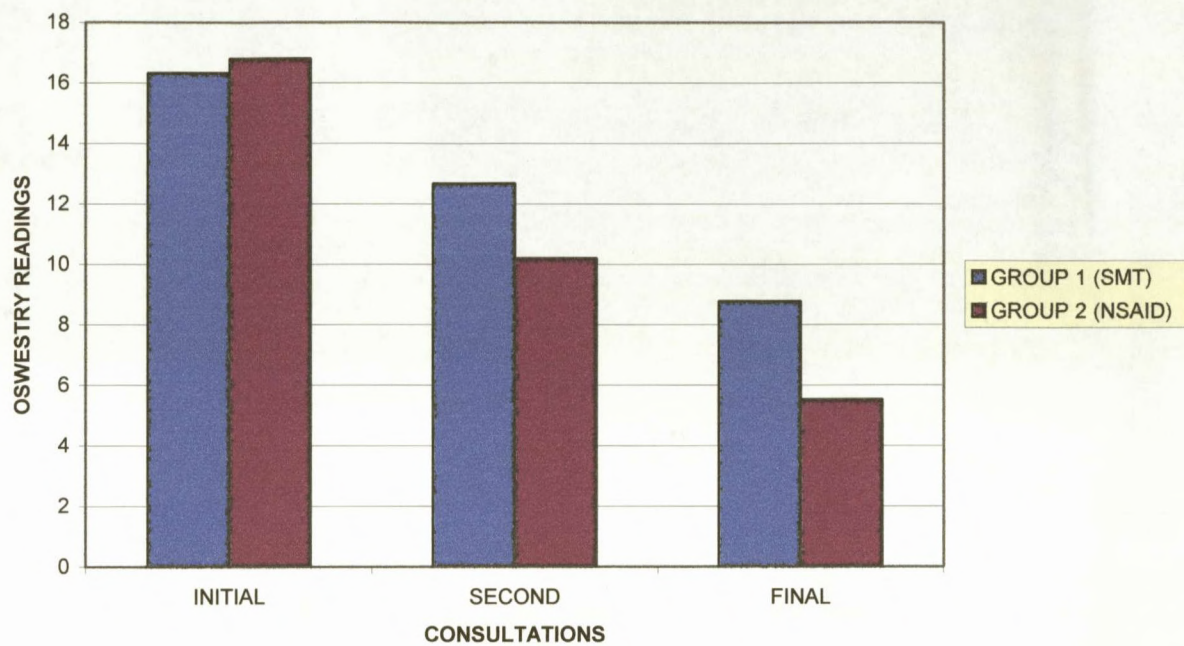


FIGURE 4.2. Mean values of the Oswestry Low Back Pain Disability Index at the initial, second and final consultations comparing the SMT and NSAID groups.

4.8.2. Analysis of the Objective Data.

Table 4.22. Comparison of the objective data for groups 1 and 2 at the initial consultation using the Unpaired t-test.

	TREATMENT GROUP1 (SMT) INITIAL CONSULTATION			P -VALUE	TREATMENT GROUP2 (NSAIDS) INITIAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	4.08	1.45	0.26	0.808	3.64	1.23	0.23
ORS (%)	78.53	10.76	1.97	0.015	85.83	11.75	2.15

The null hypothesis is accepted for the ALGOMETER READINGS, indicating that no statistically significant difference existed between group 1 and group 2, in terms of tenderness at the initial consultation. The null hypothesis was rejected for the ORS indicating there was a statistically significant difference between group 1 and group 2, in terms of positive orthopaedic findings at the initial consultation. This indicates that group 1 had fewer positive orthopaedic tests at the onset of the study.

Table 4.23. Comparison of the objective data for groups 1 and 2 at the second consultation using the Unpaired t-test.

	TREATMENT GROUP1 (SMT) SECOND CONSULTATION			P -VALUE	TREATMENT GROUP2 (NSAIDS) SECOND CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	4.9	1.37	0.25	0.018	4.08	1.23	0.22
ORS (PERCENTAGE ANALYSIS)	67.60	19.12	3.49	0.762	69.27	23.15	4.23

The null hypothesis is accepted for the ORS, indicating that no statistically significant difference existed between group 1 and group 2, in terms of orthopaedic findings at the second consultation. The null hypothesis was rejected for the ALGOMETER READINGS, indicating there was a statistically significant difference between group 1 and group 2, in terms of tenderness at the second consultation

Table 4.24. Comparison of the objective data for groups 1 and 2 at the final consultation using the Unpaired t-test.

	TREATMENT GROUP1 (SMT) FINAL CONSULTATION			P -VALUE	TREATMENT GROUP2 (NSAIDS) FINAL CONSULTATION		
	Me.	S.D.	S.E.		Me.	S.D.	S.E.
ALGOMETER	5.98	2.17	0.4	0.5633	5.42	1.79	0.33
ORS (PERCENTAGE ANALYSIS)	39.67	21.51	3.93	0.484	44.43	30.22	5.52

The null hypothesis is accepted for the ALGOMETER READINGS and the ORS, indicating that no statistically significant difference existed between group 1 and group 2, in terms of tenderness and orthopaedic findings at the final consultation.

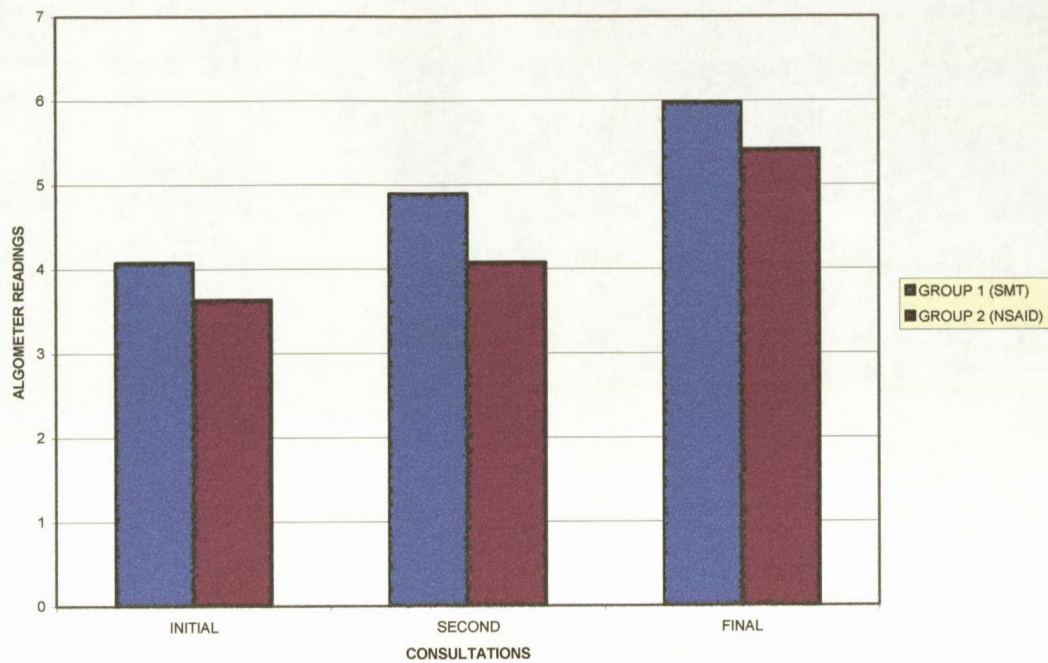


FIGURE 4.3. Mean values of the Algometer Readings at the initial, second and final consultations comparing the SMT and NSAID groups.

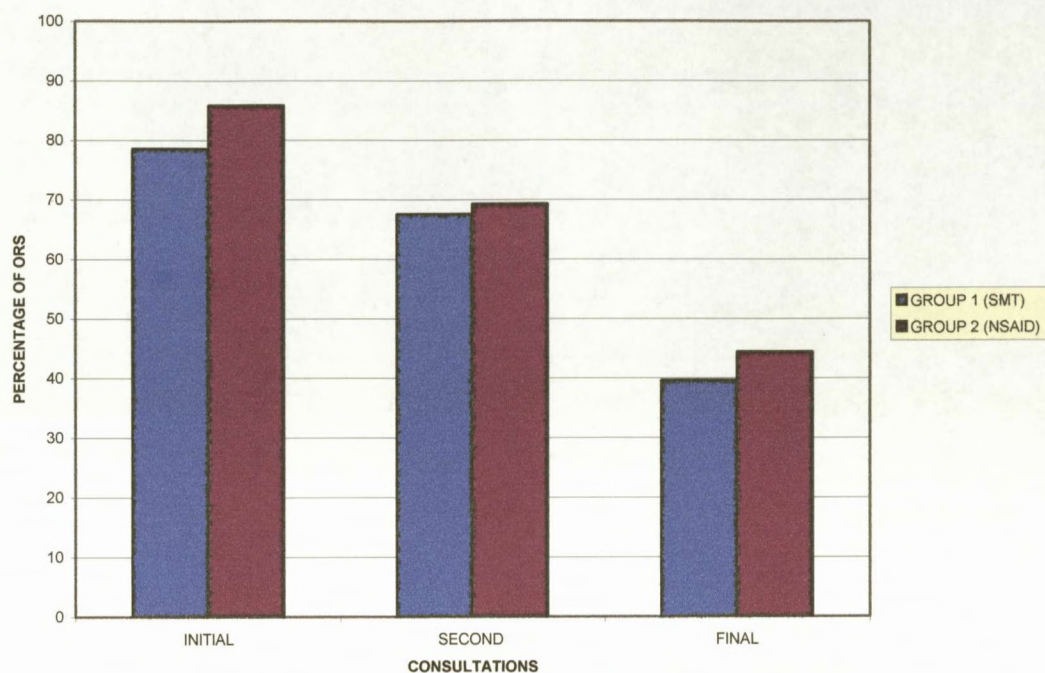


FIGURE 4.4. Mean values of the Orthopaedic Rating Scale (Percentage Analysis) at the initial, second and final consultations comparing the SMT and NSAID groups.

4.9. NON-PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1 (SMT):

4.9.1. Analysis of the Objective Data from the ORTHOPAEDIC RATING SCALE for:

- **Sacroiliac Syndrome (SIS),**
- **Lumbar Facet Syndrome (LFS),**
- **Sacroiliac Syndrome with Myofascial Pain Syndrome (SIS & MFPS),**
- **Sacroiliac Syndrome with Lumbar Facet Syndrome (SIS & LFS),**
- **Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),**
- **Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS).**

The data gained from patients with SIS alone (n=1), as well as those with SIS combined with MFPS (n=1) could not be statistically analysed due to the small sample size in each group. There were no patients suffering from MFPS alone therefore no data will be analysed for this syndrome.

Table 4.25. Comparison of the ORS between the initial and second consultations, using the Wilcoxin Signed Rank test.

	TREATMENTGROUP1: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP1: SECOND CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS – (SIS).	10.00	0.00	1		2.00	0.00	1
ORS – (LFS).	8.00	1.41	9	0.408	7.33	2.24	9
ORS – (SIS & MFPS).	16.00	0.00	1		12.00	0.00	1
ORS – (SIS & LFS).	15.00	1.42	2	0.317	16.00	0.00	2
ORS – (LFS & MFPS).	15.10	1.66	10	0.074	13.00	3.019	10
ORS – (SIS, LFS & MFPS).	23.71	2.69	7	0.042	16.00	11.55	7

In the group with (LFS & MFPS) and that with (SIS, LFS & MFPS) the null hypothesis is rejected for the ORS. This indicates that a statistically significant improvement took place between the initial and second consultations.

In the group with LFS alone and that with (SIS & LFS) the null hypothesis is accepted for the ORS. This indicates that no statistically significant improvement took place between the initial and second consultations.

Table 4.26. Comparison of the ORS between the initial and final consultations, using the Wilcoxin Signed Rank test.

	TREATMENT GROUP1: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP1: FINAL CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS – (SIS).	10.00	0.00	1		4.00	0.00	1
ORS – (LFS).	8.00	1.41	9	0.010	4.67	3.00	9
ORS – (SIS & MFPS).	16.00	0.00	1		10.00	0.00	1
ORS – (SIS & LFS).	15.00	1.41	2	0.157	5.00	1.41	2
ORS – (LFS & MFPS).	15,10	1,66	10	0.007	7,20	2,86	10
ORS – (SIS, LFS & MFPS).	23.71	2.69	7	0.027	3.71	9.83	7

In the group with LFS alone and that with (LFS & MFPS) and (SIS, LFS & MFPS) the null hypothesis is rejected for the ORS. This indicates that a statistically significant improvement took place between the initial and final consultations.

In the group with (SIS & LFS) the null hypothesis is accepted for the ORS. This indicates that no statistically significant improvement took place between the initial and final consultations.

Table 4.27. Comparison of the ORS between the second and final consultations, using the Wilcoxin Signed Rank test.

	TREATMENTGROUP1: SECOND CONSULTATION			P-VALUE	TREATMENT GROUP1: FINAL CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS –(SIS).	2.00	0.00	1		4.00	0.00	1
ORS – (LFS).	7.33	2.24	9	0.026	4.67	3.00	9
ORS – (SIS & MFPS).	12.00	0.00	1		10.00	0.00	1
ORS – (SIS & LFS).	15.00	1.41	2	0.180	5.00	1.41	2
ORS – (LFS & MFPS).	13.00	3.02	10	0.012	7.20	2.86	10
ORS – (SIS, LFS & MFPS).	16.00	11.55	7	0.066	3.71	9.83	7

In the group with LFS alone and that with (LFS & MFPS) and (SIS, LFS & MFPS) the null hypothesis is rejected for the ORS. This indicates that a statistically significant improvement took place between the second and final consultations.

In the group with (SIS & LFS) the null hypothesis is accepted for the ORS. This indicates that no statistically significant improvement took place between the second and final consultations.

4.10. NON-PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 2 (NSAID):

4.10.1. Analysis of the Objective Data from the ORTHOPAEDIC RATING SCALE for:

- **Sacroiliac Syndrome (SIS),**
- **Lumbar Facet Syndrome (LFS),**
- **Sacroiliac Syndrome with Myofascial Pain Syndrome (SIS & MFPS),**
- **Sacroiliac Syndrome with Lumbar Facet Syndrome (SIS & LFS),**
- **Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),**
- **Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS).**

The data gained from patients with SIS alone (n=1), as well as those with SIS combined with MFPS (n=1) and SIS combined with LFS (n=1) could not be statistically analysed due to the small sample size in each group. There were no patients suffering from MFPS alone therefore no data was analysed for this syndrome.

Table 4.28. Comparison of the ORS between the initial and second consultations, using the Wilcoxin Signed Rank test.

	TREATMENTGROUP2: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP2: SECOND CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS – (SIS).	6.00	0.00	1		2.00	0.00	1
ORS – (LFS).	10.00	0.00	5	0.109	7.60	2.61	5
ORS – (SIS & MFPS).	20.00	0.00	1		16.00	0.00	1
ORS – (SIS & LFS).	18.00	0.00	1		8.00	0.00	1
ORS – (LFS & MFPS).	17.33	1.97	12	0.023	15.17	3.56	12
ORS – (SIS, LFS & MFPS).	25.00	3.56	10	0.028	14.20	12.42	10

In the group with (LFS & MFPS) and (SIS, LFS & MFPS) the null hypothesis is rejected for the ORS. This indicates that a statistically significant improvement took place between the initial and second consultations.

In the group with LFS alone the null hypothesis is accepted for the ORS. This indicates that no statistically significant improvement took place between the initial and second consultations.

Table 4.29. Comparison of the ORS between the initial and final consultations, using the Wilcoxin Signed Rank test.

	TREATMENTGROUP2: INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP2: FINAL CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS – (SIS).	6.00	0.00	1		0.00	0.00	1
ORS – (LFS).	10.00	0.00	5	0.038	5.20	1.10	5
ORS – (SIS & MFPS).	20.00	0.00	1		14.00	0.00	1
ORS – (SIS & LFS).	18.00	0.00	1		4.00	0.00	1
ORS – (LFS & MFPS).	17.33	1.97	12	0.005	10.67	5.93	12
ORS – (SIS, LFS & MFPS).	25.00	3.56	10	0.005	8.00	10.46	10

In the group with LFS alone and that with (LFS & MFPS) and (SIS, LFS & MFPS) the null hypothesis is rejected for the ORS. This indicates that a statistically significant improvement took place between the initial and final consultations.

Table 4.30. Comparison of the ORS between the second and final consultations, using the Wilcoxin Signed Rank test.

	TREATMENTGROUP2: SECOND CONSULTATION			P-VALUE	TREATMENT GROUP2: FINAL CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS – (SIS).	2.00	0.00	1		0.00	0.00	1
ORS – (LFS).	7.60	2.61	5	0.109	5.20	1.10	5
ORS – (SIS & MFPS).	16.00	0.00	1		14.00	0.00	1
ORS – (SIS & LFS).	8.00	0.00	1		4.00	0.00	1
ORS – (LFS & MFPS).	15.17	3.56	12	0.023	10.67	5.93	12
ORS – (SIS, LFS & MFPS).	14.20	12.42	10	0.107	8.00	10.46	10

In the group with (LFS & MFPS) the null hypothesis is rejected for the ORS. This indicates that a statistically significant improvement took place between the second and final consultations.

In the group with LFS alone and that with (SIS, LFS & MFPS) the null hypothesis is accepted for the ORS. This indicates that no statistically significant improvement took place between the second and final consultations.

4.11. NON-PARAMETRIC INTER-GROUP ANALYSIS:

4.11.1. Analysis of the Objective Data from the ORTHOPAEDIC RATING SCALE for:

- Sacroiliac Syndrome (SIS),
- Lumbar Facet Syndrome (LFS),
- Sacroiliac Syndrome with Myofascial Pain Syndrome (SIS & MFPS),
- Sacroiliac Syndrome with Lumbar Facet Syndrome (SIS & LFS),
- Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),
- Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS).

Table 4.31. Comparison of ORS for groups 1 and 2 at the initial consultation, using the Mann-Whitney U-test.

	TREATMENT GROUP 1 (SMT) INITIAL CONSULTATION			P-VALUE	TREATMENT GROUP 2 (NSAID) INITIAL CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS – (SIS).	10.00	0.00	1	0.317	6.00	0.00	1
ORS – (LFS).	8.00	1.41	9	0.010	10.00	0.00	5
ORS – (SIS & MFPS).	16.00	0.00	1	0.317	20.00	0.00	1
ORS – (SIS & LFS).	15.00	1.41	2	0.221	18.00	0.00	2
ORS – (LFS & MFPS).	15.10	1.66	10	0.013	17.33	1.97	12
ORS – (SIS, LFS & MFPS).	23.71	2.69	7	0.339	25.00	3.56	10

When comparing group 1 and group 2 at the initial consultation, the null hypothesis is accepted for the ORS including the (SIS), and the combinations of (SIS & MFPS), (SIS & LFS), and (SIS, LFS & MFPS) indicating no statistically significant difference.

The null hypothesis is rejected for the ORS including (LFS) and the combination of (LFS and MFPS), which indicates that a statistically significant difference existed between group 1 and group 2 at the initial consultation.

The mean values indicate that group 1 had less positive orthopaedic tests at the beginning of the treatment period.

Table 4.32. Comparison of the ORS for groups 1 and 2 at the second consultation, using the Mann-Whitney U-test.

	TREATMENT GROUP 1 (SMT) SECOND CONSULTATION			P-VALUE	TREATMENT GROUP 2 (NSAID) SECOND CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS – (SIS).	2.00	0.00	1	1.000	2.00	0.00	1
ORS – (LFS).	7.33	2.24	9	0.781	7.60	2.61	5
ORS – (SIS & MFPS).	12.00	0.00	1	0.317	16.00	0.00	1
ORS – (SIS & LFS).	16.00	0.00	2	0.667	8.00	0.00	1
ORS – (LFS & MFPS).	13.00	3.02	10	0.154	15.17	3.56	12
ORS – (SIS, LFS & MFPS).	16.00	11.54	7	0.841	14.20	12.42	10

The null hypothesis is accepted for all the above syndromes and the combination of syndromes. This indicates that no statistically significant difference existed between group 1 and group 2 at the second consultation.

Table 4.33. Comparison of the ORS for groups 1 and 2 at the final consultation, using the Mann-Whitney U-test.

	TREATMENT GROUP 1 (SMT) FINAL CONSULTATION			P-VALUE	TREATMENT GROUP 2 (NSAID) FINAL CONSULTATION		
	Me.	S.D.	n.		Me.	S.D.	n.
ORS – (SIS).	4.00	0.00	1	0.317	0.00	0.00	1
ORS – (LFS).	4.67	3.00	9	1.00	5.20	1.095	5
ORS – (SIS & MFPS).	10.00	0.00	1	0.317	14.00	0.00	1
ORS – (SIS & LFS).	5.00	1.41	2	0.480	4.00	0.00	1
ORS – (LFS & MFPS).	7.20	2.86	10	0.227	10.67	5.93	12
ORS – (SIS, LFS & MFPS).	3.71	9.83	7	0.396	8.00	10.46	10

The null hypothesis is accepted for all the above syndromes and combination of syndromes. This indicates that no statistically significant difference existed between group 1 and group 2 at the final consultation.

CHAPTER

FIVE

CHAPTER FIVE

5. DISCUSSION OF RESULTS

5.1. REDEFINING THE STUDY OBJECTIVES

The aim of this study was to determine whether either of the following treatments was more effective in the management of mechanical LBP:

1. Spinal Manipulative Therapy (SMT) alone, or
2. Diclofenac Sodium (NSAID) alone.

The results are discussed in separate sections, as outlined below:

1. Discussion of Parametric Results:
 - Intra-group comparison.
 - Inter-group comparison.
2. Discussion of Non-parametric Results:
 - Intra-group comparison.
 - Inter-group comparison.

5.2. PARAMETRIC INTRA-GROUP COMPARISON FOR GROUP 1 (SMT) AND GROUP 2 (NSAID).

5.2.1. The Subjective Data

5.2.1.1. Numerical Pain Rating Scale-101 Questionnaire (NRS-101).

To determine the patient's perception of pain throughout the study, the NRS-101 was statistically analysed using the Paired t-test.

Within group 1 and group 2 a statistically significant improvement in the patient's level of pain occurred between the initial and second consultations (Table 4.7 and 4.10), and the second and final consultations (Table 4.9 and 4.12).

A significant reduction in the level of pain experienced between the initial and final (Tables 4.8 and 4.11) consultation indicated that patients in both groups benefited from the treatment they received.

On average the patients who received SMT experienced a reduction of 18,23% in their perceived level of pain. This is markedly lower than McMorland et al. (2000) who quote an average figure of 52,5% reduction in pain within LBP sufferers receiving similar treatment. A reason for this differences maybe due to the fact that McMorland et al. (2000) patient's received an average of twelve treatments over a four week period, whereas patient's within this study only received four treatments within a seven to ten day period.

Subjects in group 2 who received Diclofenac Sodium, reported a significant reduction ($p=0.000$) in their subjective pain levels. Szpalski et al. (1994) reported a similar improvement ($p=0.043$) in a group of LBP sufferers, after a course of the NSAID Tenoxicam.

5.2.1.2. Oswestry Low Back Pain Disability Index Questionnaire (OSWESTRY).

To assess the patient's disability throughout the study the Oswestry questionnaire was analysed using the Paired t-test.

The study showed a statistically significant improvement during the entire treatment period for both group 1 and group 2. When the initial and the second consultations (Table 4.7 and 4.10) were analyzed there was a significant decrease in the patient's disability. Having completed the course of treatments, patients from both groups were able to carry out activities that they previously had difficulty with. This was also the case when comparing the second and final consultations (Table 4.9 and 4.12) and when comparing the initial and final consultations (Table 4.8 and 4.11).

The effectiveness of chiropractic SMT in improving the functional ability of LBP patients was similarly demonstrated by McMorland et al. (2000) who reported a 52,9% average reduction in subjective disability. In this study patients in group 1 of this study experienced an average improvement in disability of 7,6%. This difference could again be attributed to the shorter treatment period of four treatments within seven to ten days as apposed to twelve treatments within four weeks as was used in the McMorland et al. (2000) study.

Studies reviewed by Koes et al. (1997), which made use of disability assessment techniques to evaluate the effectiveness of NSAIDs in the management of mechanical LBP, also found them effective in reducing disability levels associated with LBP.

5.2.2. The Objective Data

5.2.2.1. Algometer Readings.

Using the Paired t-test for statistically analysis in this study, a reduction in the patient's level of tenderness over the course of the treatment period within group 1 and group 2 was evident.

When the initial and the second consultations (Table 4.13 and Table 4.16) were analyzed there was a statistically significant improvement, as was the case when comparing the second and final consultations (Table 4.15 and 4.18). It was noted that the patients felt far less tenderness at the final consultation than when compared to the initial consultation (Table 4.14 and 4.17).

The data obtained from group 1 is supported by Manga et al. (1993) who assessed several trials, which indicated that SMT was effective in managing mechanical LBP. Similarly group 2's results are backed up by Kantor (1986) who states that in clinical conditions marked by acute or chronic pain such as LBP, the use of NSAIDs reduces the amount of pain within that area.

5.2.2.2. The Orthopaedic Rating Scale (Percentage Analysis).

The Paired t-test was used to compare the data between each consecutive consultation for group 1 and group 2. Both groups showed a significant reduction in the number of positive orthopaedic tests between the initial and the second consultation (Table 4.13 and 4.16), and between the second and the final consultations (Table 4.15 and 4.18).

More importantly there was a statistically significant improvement noted from the initial to the final consultations (Table 4.14 and 4.17). Both groups had an equal reduction in the amount of positive orthopaedic tests, suggesting that both forms

of treatment were effective in reducing the amount of inflammation, tenderness and muscle spasms associated with mechanical LBP.

These findings concur with those of Di Fabio (1992), who reported that SMT is an effective manual therapy for LBP, and with Deyo (1996) who found NSAIDs effective in the management of LBP.

5.3. PARAMETRIC INTER-GROUP ANALYSIS

5.3.1. The Subjective Data

5.3.1.1. Numerical Pain Rating Scale-101 Questionnaire (NRS-101).

The results for the NRS-101 were compared using the Unpaired t-test. It was discovered that at the initial (Table 4.19), the second (Table 4.20) and the final consultations (Table 4.21) there was no significant difference between group 1 and group 2, indicating that both treatment protocols were equally effective in decreasing the severity of pain associated with mechanical LBP.

Similarly, Brontfort (1989) made use of subjective questionnaires to compare SMT with traditional medical treatment of LBP. It was concluded, after a treatment period of one month, that neither form of treatment showed a subjective advantage.

5.3.1.2. Oswestry Low Back Pain Disability Index Questionnaire (OSWESTRY).

Statistical analysis using the Unpaired t-test revealed no significant difference between the SMT and NSAID groups regarding the patient's reported functional disability due to LBP. The two treatments were equally effective in decreasing

disability in patients suffering with mechanical LBP at the initial ($p=0.831$), second ($p=0.226$) and final ($p=0.057$) consultations of the study.

Giles et al. (1997) however, reported that SMT ($p=0.004$) was more effective in the reduction of patient disability when compared to NSAIDs ($p=0.77$). The treatment period of 30 days used by Giles et al. (1997) when compared to the seven to ten days used for this study may be the reason for the difference in results.

5.3.2. The Objective Data

5.3.2.1. Algometer readings.

Using the Unpaired t-test, it was noted there was no statistically significant difference between the two groups at the initial consultation (Table 4.22).

At the second consultation (Table 4.23) the SMT group had less tenderness associated with mechanical LBP when compared to the NSAID group. Supporting this, studies reviewed by Anderson et al. (1992) reported a greater reduction in pain following SMT when compared to medication.

Although the SMT group was initially more responsive in this study, the readings taken from those patients in group 1 and group 2 at the final consultation (Table 4.24) showed similar pain tolerance levels.

5.3.2.2. The Orthopaedic Rating Scale (Percentage Analysis).

When the results of the Orthopaedic Rating Scale were compared using the Unpaired t-test prior to any treatment, patients in group 1 showed significantly fewer subjective signs of LBP than the patients in group 2.

Patients treated with NSAIDs enjoyed a faster recovery over the initial stages (Table 4.22) of the treatment period. This is indicated by a greater reduction in positive orthopaedic tests for this group leading up to the second consultation (Table 4.23). However by the final consultation (Table 4.24) both forms of treatment were equally effective in reducing the signs of mechanical LBP.

Studies reviewed by Assendelft *et al.* (1992) supported the use of SMT as an effective method in managing mechanical LBP when compared to the use of drug therapy. The reason why no conclusive advantage could be attributed to either of the two therapies may be due to the fact that this study analyses the short term benefits of SMT and NSAIDs, while Assendelft *et al.* (1992) reviewed studies that used follow-up periods of up to six months.

5.4. NON-PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1 (SMT) AND GROUP 2 (NSAID)

5.4.1. The Objective Data:

The data obtained from patients with SIS alone (n=1), MFPS alone (n=0) as well as those with SIS combined with MFPS (n=1) could not be statistically analysed due to the small sample size within each group. SIS combined with LFS (n=1) could not be statistically analysed within group 2 due to the small sample size.

<u>SYNDROMES:</u>	<u>NUMBER OF PATIENTS WITHIN GROUP 1:</u>	<u>NUMBER OF PATIENTS WITHIN GROUP 2:</u>
SIS alone.	1	1
MFPS alone.	0	0
SIS & MFPS.	1	1
SIS & LFS.	2	1

5.4.1.1. Discussion of the ORS used within group 1 for:

- **Lumbar Facet Syndrome (LFS),**
- **Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),**
- **Sacroiliac Syndrome (SIS) with Lumbar Facet Syndrome (LFS),**
- **Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS).**

When comparing the intra-group statistics for group 1 using the Wilcoxin signed Rank test, it was noted that there was a significant improvement throughout the treatment period. The syndromes and their combinations had a reduction in the amount of positive orthopaedic tests.

Within group 1 there were only two patients suffering with the combination of SIS and LFS. They both received SMT, however they showed no reduction in the amount of positive orthopaedic tests. The failure to resolve these two patient's LBP could possibly be due to the fact that their LBP was of a chronic nature. Kirkaldy-Willis et al. (1985) observed 283 patients receiving SMT for chronic LBP. It was noted that within their experience any treatment program less than two weeks long is inadequate for chronic LBP suffers.

The remaining syndromes and their combinations improved following each spinal manipulation, with this reduction in the positive orthopaedic tests occurring consistently throughout the treatment period. Although those patients suffering from LFS alone did not show a statistically significant improvement between the initial and second consultation they showed a marked reduction in the amount of positive orthopaedic tests from the initial to the final consultation. McMorland et al. (2000) provides evidence to support the effectiveness of SMT in managing mechanical LBP.

5.4.1.2. Discussion of the ORS used within group 2 or:

- Lumbar Facet Syndrome (LFS),
- Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),
- Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS).

When comparing the intra-group statistics for group 2 using the Wilcoxin Signed Rank test, Diclofenac Sodium proved to be an effective treatment for mechanical LBP. The patients suffering from LBP had a consistent reduction in the amount of positive orthopaedic tests between each consultation.

The patients suffering from LFS alone had a slow response to the medication (Diclofenac Sodium) at the initial stages of the study (Table 4.28). However the amount of positive orthopaedic tests did reduce between the initial and final consultations.

The remaining syndromes and their combinations had a statistically significant improvement between the initial and final consultations (Table 4.29) resulting in the reduction of mechanical LBP. Deyo (1996) and Koes et al. (1997) state that NSAIDs provide relief to those patients suffering from mechanical LBP, which supports this study's objective findings.

5.5. NON-PARAMETRIC INTER-GROUP ANALYSIS

5.5.1. The Objective Data

The data gained from those patients suffering from MFPS alone (n=0) could not be statistically analysed as no patients were diagnosed with suffering from MFPS alone.

5.5.1.1. Discussion of the ORS for:

- **Sacroiliac Syndrome (SIS),**
- **Lumbar Facet Syndrome (LFS),**
- **Sacroiliac Syndrome with Myofascial Pain Syndrome (SIS & MFPS),**
- **Sacroiliac Syndrome with Lumbar Facet Syndrome (SIS & LFS),**
- **Lumbar Facet Syndrome with Myofascial Pain Syndrome (LFS & MFPS),**
- **Sacroiliac Syndrome with Lumbar Facet Syndrome and with Myofascial Pain Syndrome (SIS, LFS & MFPS).**

When the two groups were statistically analysed using the Mann Whitney U-test there was no significant difference between the treatment protocols.

At the initial consultation (Table 4.31) the patients suffering from LFS alone and the combination of LFS and MFPS, showed a significant difference between group 1 and group 2, with the latter having more positive orthopaedic tests. As the treatment progressed each group was as effective as the other at the second (Table 4.32) and final consultation (Table 4.33). There was no difference between the amount of positive orthopaedic tests present within group 1 and group 2 at these stages.

Studies reviewed by Manga et al. (1993) found that chiropractic management of LBP was more effective than the medical alternative. These studies made use of large sample sizes therefore gaining more statistical data and a more accurate comparison of the two forms of treatment.

CHAPTER

SIX

CHAPTER SIX

6. RECOMMENDATIONS AND CONCLUSIONS

6.1. RECOMMENDATIONS

It is well known that the use of an algometer can result in user error. This may contribute to variations within the study. To ensure that the clinical findings are of a higher standard and to minimize the chance of human error it is suggested that a digital algometer or more subjective measures in the form of questionnaires be used in future studies.

In a study of this nature, it is always preferable to have a larger sample size which would allow for more accurate results. Unfortunately, due to time and financial constraints, this was not possible. Further studies will benefit greatly from the use of larger sample sizes to improve the statistical relevance of the data.

This research study encompassed the assessment of three major contributors of mechanical LBP – Lumbar Facet, Sacroiliac and Myofascial Pain Syndromes. This resulted in variations in the sample sizes when identifying each individual syndrome or a combination of the various syndromes. The groups with the smaller sample sizes were subjected to subtle changes in the subjective and objective data. It is therefore recommended that each individual syndrome and the various combinations of syndromes be researched individually with the use of larger sample sizes to minimize the chance of incorrectly accepting the null hypothesis.

Despite the findings relating to the successful use of Diclofenac Sodium, the issue of safety and the possible iatrogenic side effects of the medication play an important part in prescribing the drug. The high incidence of dropouts, lack of

patient compliance and poor patient satisfaction within this group, is an indication of the patient's uncertainty of taking the medication. The possible cause of the poor satisfaction could be the public's increasing awareness of the high incidence of side effects the NSAID can cause. Deyo (1996) described that the most common side effect of NSAIDs is gastrointestinal irritation and bleeding. Within this study a large number of patients were excluded due to the fact that they suffered from recurrent heartburn, peptic ulcers and allergic reactions to Aspirin. In order to gauge the level of discomfort that a patient experiences when prescribed NSAIDs it is recommended that future studies employ an additional placebo group. This group would receive placebo medication at the same recommended doses and intervals during the treatment period as that of the control group. This may allow the researcher to compare perceived and actual side effects.

It is recommended that in future studies, stratification of patients be employed, according to the patient's age, gender, acute and chronic nature of the problem, disability and occupation. This would assist homogeneity with the groups and attempt to assist in the interpretation of any statistical variations. Within this study the assessment of the amount of LBP using the ORS showed a difference in the number of positive orthopaedic tests between group 1 and group 2 at the initiation of the study. This may have affected the conclusion drawn, when comparing outcomes of group 1 and group 2 at the final consultation. By avoiding randomization and classifying patients, homogeneity could be improved and a clearer comparison can be achieved.

In future research it is suggested that the emphasis be placed on the possible long-term results for both the SMT and Diclofenac Sodium treatments. Both groups did indicate an improvement however the question still remains; did either of the treatments have a lasting effect? It is therefore suggested that a follow up assessment at one week, or longer be implemented to evaluate, the long-term effects of these treatments.

Due to the broadening patient base into all races and cultures within South Africa it is recommended that the pain and disability questionnaires be multi-lingual. Indicative of this change is the fact that 23% of the patients in this study were Zulu speaking, which presented communication problems when discussing the questionnaires. Some patients found it difficult to give their pain or disability a value that fitted within the parameters of the questionnaires. It is recommended that alternative ways of measuring levels of pain and disability be explored.

A further recommendation for future research is that a third group be added besides those receiving SMT and NSAID treatment. These patients would not receive any specific treatment but could be used to monitor the natural history of LBP sufferers. This would be valuable, as it allows the researcher to compare the effectiveness of the two treatment protocols with natural rates of recovery.

6.2. CONCLUSION

The purpose of this study was to evaluate the relative effectiveness of SMT and Diclofenac Sodium in the management of mechanical LBP, in terms of subjective and objective findings.

In terms of these findings both forms of treatment were shown to be effective in relieving the symptoms and signs associated with mechanical LBP. However there was no conclusive proof that either method was more effective than the other.

Although Diclofenac Sodium does assist in managing mechanical LBP, the risk of the side effects obscure the potential benefits of the medication. The use of SMT could be a safer alternative for those patients with contra-indications to NSAIDs. Further studies need to be carried out in this area to determine a safer treatment protocol.

In planning future randomized clinical trials involving mechanical LBP, special attention should be paid to the duration of the complaint (it's acute or chronic nature), as well as the number of patients included into the study. In addition, more effort should be made to establish a long-term follow-up, because a lasting improvement will assist in estimating the most successful and cost-effective treatment protocol.

Combating high costs, work absenteeism and patient morbidity should be the doctor's priority. To determine the most effective treatment protocol more studies and research are necessary.

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APPENDIX

A

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient: _____ Date: _____
file #: _____ X-Ray#: _____
Age: _____ Sex: _____ Occupation: _____
Intern: _____ Signature: _____

FOR CLINICIAN'S USE ONLY

Initial visit clinician: _____ Signature: _____

Case History:

Examination:
Previous: _____ Current: _____

X-Ray Studies:
Previous: _____ Current: _____

Clinical Path. lab:
Previous: _____ Current: _____

Case Status:

PTT: _____ Conditional: _____ Signed Off: _____ Final Sign out: _____

Recommendations:

Intern's Case History

1. Source of History:
2. Chief Complaint: (patient's own words)

3. Present Illness:

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

4. Other Complaints:

5. Past Medical History:

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

6. Current health status and life-style:

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

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

APPENDIX

B

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient: _____ File#: _____ Date: _____
 Clinician: _____ Signature: _____
 Intern: _____ Signature: _____

1. VITALS

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

2. GENERAL EXAMINATION

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

3. CARDIOVASCULAR EXAMINATION

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

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

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

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

Percussion: - borders of heart

Auscultation: - heart valves (mitral, aortic, tricuspid, pulmonary)
- Murmurs (timing, systolic/diastolic, site, radiation, grade).

4. RESPIRATORY EXAMINATION

1) Is this patient in Respiratory Distress ?

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

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

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

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

5. ABDOMINAL EXAMINATION

1) Is this patient in Liver Failure ?

Inspection - Shape:
- Scars:
- Hernias:

Palpation - Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:

- Ascites:
- Masses:

Auscultation - Bowel sounds:

- Arteries (aortic, renal, iliac, femoral, hepatic)

Rectal Examination

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

6. G.U.T EXAMINATION

External genitalia:

Hernias:

Masses:

Discharges:

7. NEUROLOGICAL EXAMINATION

Gait and Posture - Abnormalities in gait:

- Walking on heels (L4-L5):
- Walking on toes (S1-S2):
- Rombergs test (Pronator Drift):

Higher Mental Function - Information and Vocabulary:

- Calculating ability:
- Abstract Thinking:

G.C.S.: - Eyes:

- Motor:
- Verbal:

Evidence of head trauma:

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

Cranial Nerves:

Any loss of smell/taste:
Nose examination:

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

- Pupillary light reflexes = Direct:
 = Consensual:
- Fundoscopy findings:
- III Ocular Muscles:
 Eye opening strength:
- IV Inferior and Medial movement of eye:
- V a. Sensory - Ophthalmic:
 - Maxillary:
 - Mandibular:
 b. Motor - Masseter:
 - Jaw lateral movement:
 c. Reflexes - Corneal reflex
 - Jaw jerk
- VI Lateral movement of eyes
- VII a. Motor - Raise eyebrows:
 - Frown:
 - Close eyes against resistance:
 - Show teeth:
 - Blow out cheeks:
 b. Taste - Anterior two-thirds of tongue:
- VIII General Hearing:
 Rinnes = L: R:
 Webers lateralisation:
 Vestibular function - Nystagmus:
 - Rombergs:
 - Wallenbergs:
 Otoscope examination:
- IX & Gag reflex:
- X Uvula deviation:
 Speech quality:
- XI Shoulder lift:
 S.C.M. strength:
- XII Inspection of tongue (deviation):

Motor System:

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

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

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

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

Sensory System:

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

- b. Joint position sense
- Finger:
 - Toe:

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

Cerebellar function:

Obvious signs of cerebellar dysfunction:

- = Intention Tremor:
- = Nystagmus:
- = Truncal Ataxia:

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

8. SPINAL EXAMINATION:(See Regional examination)

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

9. BREAST EXAMINATION:

Summon female chaperon.

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

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

APPENDIX

C

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
REGIONAL EXAMINATION - LUMBAR SPINE AND PELVIS.

PATIENT: _____

FILE #: _____

DATE: _____

INTERN/RESIDENT: _____

SUPERVISING CLINICIAN: _____

STANDING:

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

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

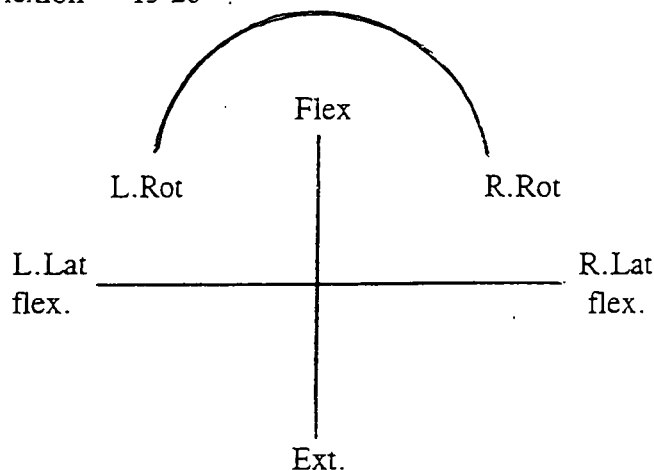
RANGE OF MOTION

Forward Flexion = 40-60° (15cm from floor)

Extension = 20-35°

L/R Rotation = 3-18°

L/R Lateral Flexion = 15-20°



SUPINE:

Skin
Hair
Nails
Palpate Abdomen/groin
Pulses (abdomen)

Observe abdomen
Fasciculations
Abdominal Reflexes

Pulses (extremities)

SLR

Bowstring

Plantar Reflex

Circumference (thigh, calf)

Leg Length:

actual

apparent

Sciatic Notch

Patrick FABERE

Gaenslen's Test

Gluteus Maximus Stretch

Hip Medial rotation

Psoas Test

Thomas' Test:

hip joint

Rectus Femoris

LATERAL RECUMBENT

S-I Compression

Ober's Test

Femoral Nerve stretch

Myotomes:

QL

Gluteus Medius

NON ORGANIC SIGNS

Pin Point Pain

Axial Compression

Trunk Rotation

Burn's Bench Test

Flip Test

Hoover's Test

Ankle Dorsiflexion Test.

GAIT

Rhythm

On toes (standing)

On Heels (standing)

Half squat on one leg

PRONE

Gluteal skyline

Skin rolling

Iliac crest compression

Facet joint challenge

S-I tenderness

Erichson's Test

Pheasant's Test

Myotome:

Glut. Max

Active MF Trigger Pts:

QL

Glut. Med

Glut. Min

Glut. Max

Piriformis

Hamstrings

TFL

NEUROLOGICAL EXAMINATION

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

Tripod
Kemp's Test

MOTION PALPATION and JOINT PLAY:

LEFT: Upper Thoracics:
 Lumbar Spine:
 Sacroiliac Joint:

RIGHT: Upper Thoracics:
 Lumbar Spine:
 Sacroiliac Joint:

Basic Exam: Hip
Case History:

ROM: Active:
 Passive:
 RIM:
Orthopaedic/Neuro/
Vascular:

Observ/Palpation:

Basic Exam: Thoracic Spine
Case History:

ROM: Motion Palp:
 Active:
 Passive:
Orthopaedic/Neuro/
Vascular:

Observ/Palpation:

APPENDIX

D

DR D.R. MOODLEY

(B. Med. Sc. Hons ; MBCHB) PRACTICE NO : 1565192
GENERAL MEDICAL PRACTITIONER & CLINICAL ANATOMIST

23 KLAARWATER RD
SHALLCROSS
4093
TEL : 491471
FAX : 491371

16 AUTUMN GROVE
MALVERN
4093
TEL : 4631162
CELL : 0824659742

VAT NO : 4560179642

PATIENT PROFILE AND DRUG INFORMATION SCREENING FOR PROSPECTIVE STUDIES INVOLVING ANTI-INFLAMMATORY DRUGS AT TECHNIKON NATAL CHIROPRACTIC DEPARTMENT

QUESTIONNAIRE :

1. Have you had any reaction, allergic or otherwise to any inflammatory drug, or drug used in the management of pain or musculo-skeletal disorders (e.g. Aspirin, Disprin, Voltaren, Feldene)?

YES ☐
NO ☐
2. Have you ever had any disorder of the liver, biliary tract or pancreas?

YES ☐
NO ☐
3. Have you ever suffered with recurrent heartburn, peptic ulcers, bleeding disorders, including the vomiting of blood or passage of blood rectally or otherwise?

YES ☐
NO ☐
4. Are you currently taking Warfarin, Aspirin, other anticoagulants or anti-inflammatory agents or any other drug at all, whether allopathic, herbal or otherwise, including steroid based agents?

YES ☐
NO ☐
5. Have you ever suffered any dysfunction of the kidneys, bladder or urinary system?

YES ☐
NO ☐
6. Have you ever suffered from any medical condition not disclosed above

YES ☐
NO ☐

DETAILS _____

7. Have you had any surgery previously ?

YES _____
NO _____

DETAILS _____

8. Have you received a blood transfusion in the last 5 years ?

YES _____
NO _____

REASON _____

9. Have you had endoscopy, radiographs or other investigations done to you ?

YES _____
NO _____

DETAILS _____

10. Are you asthmatic, or do you suffer with chronic disease of the lungs or respiratory system ?

YES _____
NO _____

11. Have you been diagnosed with any psychiatric disorder including depression, manic depression, or are you on anti-psychotic medication or Lithium therapy

YES _____
NO _____

FEMALE PATIENTS:

1. Are you pregnant now ?

YES _____
NO _____

2. State the onset date of your last period _____

3. Are your periods regular ? _____

THE ABOVE DETAILS ARE TRUE TO THE BEST OF MY ABILITY.

Patient _____ I.D. _____

Parent if under 21 _____ I.D. _____

DECLARATION :

I PARTAKE OF MY OWN FREE WILL IN THIS STUDY, HAVING BEEN DIAGNOSED WITH

AND MAY USE THE FOLLOWING DRUG

DOSAGE

PATIENT _____

PARENT _____

RESEARCH STUDENT _____

CLINICAL SUPERVISOR _____

DATE _____

INDEMNITY

WHERE THE FOLLOWING REQUIRE SIGNATURES. IT WILL BE THAT OF THE PATIENT IF OVER 21 YEARS OF AGE. OR BY THE PATIENT AND PARENT IF UNDER 21 YEARS

1. While every effort has been made to screen the patient for possible drug interactions or effects, the research team cannot be held responsible for ad hoc reactions that may develop. While all patients may be protected by common laws, it is also imperative that the patient specifically indemnifies the research team, including Doctor D.R. Moodley and Technikon Natal against prospective legal action.

2. Telephonic or other consultations are a necessary part of the research. The patient acknowledges this and makes no claim against default in such cases

3. Any consultation or special investigation deemed necessary by the research team will be followed by the patient concerned, failing which the patient is freely entitled to be excluded from the study. This clause does not revoke the constitutional rights of the patient in terms of freedom of will.

4. I am prepared to undertake emergency or other treatment at a government hospital should the need arise. Private or attached costs will not be borne by Technikon Natal, Dr Moodley or any member of the research team.

SIDE EFFECTS OF ANTI- INFLAMMATORY DRUGS :

1. Gastro-intestinal symptoms including heartburn, acid reflex, indigestion, nausea, vomiting, bleeding, peptic ulcers.
2. Oedema (swelling of body) especially at ankles.
3. Transcient hepatitis
4. Transcient renal dysfunction
5. Skin and allergic reactions including urticaria and angiooedema
6. Blood disorders e.g. anaemia, decreased platelets, decreased white blood cells
7. Wheeze related to bronchoconstriction
8. Dizziness and headaches

**I have been advised of all the above side-effects that can occur in a small minority of patients

**I will inform the research team should any of the above side-effects develop

PATIENT: _____

PARENT : _____

DATE : _____

APPENDIX E

INFORMED CONSENT FORM

Date : _____

Title of research project **THE RELATIVE EFFECTIVENESS OF SPINAL
MANIPULATIVE THERAPY COMPARED TO
DICLOFENAC SODIUM, IN THE MANAGEMENT OF
MECHANICAL LOW BACK PAIN.**

Name of supervisor : Dr. A. Van Der Meulen

Name of research student : Jacqueline Login

Please circle the appropriate answer

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

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

Please Print in block letters:

Patient /Subject Name: _____

Signature: _____

Witness Name: _____

Signature: _____

Research Student Name: _____

Signature: _____

APPENDIX

F

OSWESTRY BACK DISABILITY INDEX

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 very 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 need help every day in most aspects of self 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 by pain.
- ☐ 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 1/4 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

Numerical Rating Scale - 101 Questionnaire

Date: _____ File no: _____ Visit no: _____

Patient name: _____

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

Please write only **one** number.

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

Please write only **one** number.

APPENDIX

H

Patients Name :

Date :

File No :

MOTION PALPATION

	Initial Visit	2 nd Visit	Final Visit
Level			
Side			
Direction			

ALGOMETER :

	Initial Visit		2 nd Visit		Final Visit	
Readings	Left	Right	Left	Right	Left	Right

ORTHOPAEDIC ASSESSMENT RATING.

Myofascial Dysfunction Syndrome :

	INITIAL VISIT	2 nd VISIT	FINAL VISIT
REFERAL OF PAIN(4)			
LOCAL TWITCH RESPONSE (2)			
TAUT PALPABLE BAND (2)			
EXQUISITE FOCAL TENDERNESS(2)			
TOTAL OUT OF 10			

ORTHOPAEDIC ASSESSMENT RATING

Lumbar Facet Syndrome Rating :

	INITIAL VISIT	2 nd VISIT	FINAL VISIT
KEMPS TEST (4)			
LUMBAR FACET CHALLENGE TEST (4)			
PRONE HYPER- EXTENSION TEST (2)			
TOTAL OUT OF 10			

Sacroiliac Syndrome Rating :

	INITIAL VISIT	2 nd VISIT	FINAL VISIT
POSTERIOR SHEAR TEST (4)			
GAENSLENS TEST (2)			
PATRICK FABER TEST (2)			
ERICHSONS TEST (2)			
TOTAL OUT OF 10			

APPENDIX

I

Dear Participant.

The aim of this study is to compare the relative effectiveness of Nonsteroidal Anti-inflammatory drugs (Diclofenac sodium) and spinal manipulative therapy in the management of mechanical low back pain.

Sixty people will be required to complete the study. You will be randomly divided into two groups of thirty patients each.

Those of you in group one will receive spinal manipulative therapy of which you will require to be treated four times over a seven day period.

Those of you in group two will receive Diclofenac Sodium (the NSAID to be used in this study), which will be taken three times daily for seven days. This NSAID may produce side-effects in some patients. There will therefore be strict supervision of the drug prescription.

If you develop any symptoms during the course of the research project that are not related to the existing low back complaint, please inform me so that we make due arrangements to stop your medication and remove you from this clinical trial.

You are pleased asked not to alter your lifestyle for the sake of this research project e.g. if you are playing sport 3 times a week, then continue to play. You are also asked not to take any other medication while you are a candidate of this research project as it will alter the outcome of your treatment.

Finally, all treatments will be performed under the supervision of a qualified chiropractor and will be free of charge.

Thank you.

Yours faithfully,

Jacqueline Login

(6th year Chiropractic Resident)