

THE RELATIVE EFFECTIVENESS OF
ACTION POTENTIAL THERAPY
COMPARED TO DICLOFENAC SODIUM IN
THE TREATMENT OF MECHANICAL LOW
BACK PAIN

By

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DEDICATION

I dedicate this to my mother, without whose love and support I
would not have been able to achieve my dream.

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ABSTRACT

Low back pain is a major health problem worldwide, and considerable amounts of money are spent on a variety of practitioners including medical practitioners, chiropractors, osteopaths, physiotherapists and others. There is a lack of consensus among these groups regarding the most appropriate therapy or management for low back pain. This disparity leads to the meritable conclusion that more research is required to accurately identify solutions for the management of low back pain (Walker, 1997:95-96).

This study was designed to determine the relative effectiveness of combined "*Action Potential*" therapy and placebo diclofenac sodium versus combined placebo "*Action Potential*" therapy and diclofenac sodium in the treatment of mechanical low back pain.

A recent review of 51 randomized controlled trials points out that nonsteroidal anti-inflammatory drugs are slightly effective for short-term improvement in patients with acute low back pain, highlighting the need for ongoing scientific investigation utilizing non-pharmacological means (Van Tulder et al., 2000:2512).

"*Action Potential*" therapy, a relatively new high-frequency low intensity electric current therapy, which has demonstrated a possible use in the management of acute painful musculoskeletal disorders of the low back (Atkinson 2000), could possibly alleviate the pain and discomfort experienced by patients in the dysfunctional phase of mechanical low back pain as described by Kirkaldy-Willis (1992:105).

This randomized placebo-controlled clinical trial consisted of sixty voluntary subjects. Each of these candidates was diagnosed as either suffering from a posterior facet syndrome, a sacroiliac syndrome or a myofascial pain syndrome or a combination of two or all three of these syndromes. There were

two groups of thirty subjects, each of whom received four treatment consultations over a ten-day period, and a final consultation to collect the last set of data. Group 1 received active "*Action Potential*" therapy and placebo diclofenac sodium whilst group 2 received placebo "*Action Potential*" therapy and diclofenac sodium 50mg.

The outcome measurements included the response of subjects to the Numerical Pain Rating Scale-101 and the Revised Oswestry Low Back Pain and Disability Pain Questionnaire. Objective data was gathered from the Orthopaedic Assessment Rating and digital algometry measurements. Data was collected prior to the initial consultation, before the second consultation, and approximately 24 hours after the fourth consultation.

Statistically both groups showed improvements, subjectively and objectively, with regards to mechanical low back pain. Inter-group findings indicated that a slight difference existed in favour of the NSAID group but not sufficient enough to conclude that one intervention was superior to the other. The mean of the outcome measures, suggested that diclofenac sodium was the more effective treatment approach than "*Action Potential*" therapy in the treatment of mechanical low back pain.

TABLE OF CONTENTS

CHAPTER ONE

1.0	Introduction	1
1.1	The problem and its setting	1
1.2	Aim and objectives of the study	4
1.3	Benefits of the study	4

CHAPTER TWO

2.0	Review of the related literature	5
2.1	Introduction	5
2.2	Mechanical low back pain	5
2.2.1	Epidemiology	5
2.2.2	The cost to society	6
2.2.3	Aetiology and diagnosis of low back pain	7
2.2.4	Posterior facet syndrome	9
2.2.5	Sacroiliac syndrome	10
2.3	Myofascial pain syndrome	10
2.3.1	Myofascial trigger points	11
2.3.2	Treatment of trigger points	11
2.4	Electrophysical modalities	12
2.4.1	Action Potential Therapy	12
2.4.2	Ultrasound	13
2.4.3	Transcutaneous electrical nerve stimulation	14
2.4.4	Interferential therapy	14
2.5	Nonsteroidal anti-inflammatory drugs	14
2.5.1	Effectiveness of nonsteroidal anti-inflammatory drugs for acute low back pain	14
2.5.2	Complications of diclofenac sodium	16
2.5.3	Mechanism of action of diclofenac sodium	17
2.6	Summary of the literature review	18

CHAPTER THREE

3.0	Methodology	20
3.1	Ethical considerations	31
3.2	Statistical analysis of the data	31
3.2.1	Paired t-test (Intra-group)	32
3.2.2	Unpaired t-test (Inter-group)	33
3.3	The specific treatment of each objective	35
3.3.1	Objective one	35
3.3.2	The data required	35
3.3.3	How the data was secured	35
3.3.4	Objective two	35
3.3.5	The data required	36
3.3.6	How the data was secured	36
3.3.7	Objective three	36
3.3.8	The data required	36
3.3.9	How the data was secured	36

CHAPTER FOUR

4.0	The results	37
4.1	Introduction	37
4.1.1	The use of parametric tests	37
4.2	Parametric intra-group analysis for group 1 (APT)	39
4.2.1	Analysis of the subjective data	39
4.3	Parametric intra-group analysis for group 2 (NSAIDs)	41
4.3.1	Analysis of the subjective data	41
4.4	Parametric intra-group analysis for group 1 (APT)	43
4.4.1	Analysis of the objective data	43
4.5	Parametric intra-group analysis for group 2 (NSAIDs)	45
4.5.1	Analysis of the objective data	45
4.6	Parametric inter-group analysis	47
4.6.1	Analysis of the subjective data	47
4.6.2	Analysis of the objective data	51

CHAPTER FIVE

5.0	Discussion	59
5.1	Introduction	59
5.2	Intra-group comparison for group 1 (APT) and group 2 (NSAIDs)	60
5.2.1	The subjective data	60
5.2.2	The objective data	61
5.3	Parametric inter-group analysis	62
5.3.1	The subjective data	62
5.3.2	The objective data	62
5.4	Descriptive statistics	63
5.5	Summary	64

CHAPTER SIX

6.0	Recommendations and conclusions	65
6.1	Recommendations	65
6.2	Conclusions	68

REFERENCES	69
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ADDENDA	74
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LIST OF TABLES

Table 4.1	Comparison of the subjective data between the initial and second consultations, using the paired t-test.....	39
Table 4.2	Comparison of the subjective data between the initial and final consultations, using the paired t-test.....	40
Table 4.3	Comparison of the subjective data between the second and final consultations, using the paired t-test.....	40
Table 4.4	Comparison of the subjective data between the initial and second consultations, using the paired t-test.....	41
Table 4.5	Comparison of the subjective data between the initial and final consultations, using the paired t-test.....	41
Table 4.6	Comparison of the subjective data between the second and final consultations, using the paired t-test.....	42
Table 4.7	Comparison of the objective data between the initial and second consultations, using the paired t-test.....	43
Table 4.8	Comparison of the objective data between the initial and final consultations, using the paired t-test.....	43
Table 4.9	Comparison of the objective data between the second and final consultations, using the paired t-test.....	44
Table 4.10	Comparison of the objective data between the initial and second consultations, using the paired t-test.....	45
Table 4.11	Comparison of the objective data between the initial and final consultations, using the paired t-test.....	45
Table 4.12	Comparison of the objective data between the second and final consultations, using the paired t-test.....	46
Table 4.13	Comparison of the subjective data for groups 1 and 2 at the initial consultation using the unpaired t-test.....	47
Table 4.14	Comparison of the subjective data for groups 1 and 2 at the second consultation using the unpaired t-test.....	47
Table 4.15	Comparison of the subjective data for groups 1 and 2 at the final consultation using the unpaired t-test.....	48

Table 4.16	Comparison of the objective data for groups 1 and 2 at the initial consultation using the unpaired t-test.....	51
Table 4.17	Comparison of the objective data for groups 1 and 2 at the second consultation using the unpaired t-test.....	51
Table 4.18	Comparison of the objective data for groups 1 and 2 at the final consultation using the unpaired t-test.....	52
Table 4.19	Subjects excluded at telephonic interview.....	57
Table 4.20	Drop out from group 1 (APT).....	57
Table 4.21	Drop out from group 2 (diclofenac sodium).....	57

LIST OF FIGURES

FIGURE 4.1 Mean values of the Numerical Pain Rating Scale-101 at the initial, second and final consultations, comparing the APT and NSAIDs group.....	49
FIGURE 4.2 Mean values of the Revised Oswestry Low Back Pain Disability Index at the initial, second and final consultations, comparing the APT and NSAIDs group.....	50
FIGURE 4.3 Mean values of the Algometer Readings at the initial, second and final consultations, comparing the APT and NSAIDs groups.....	53
FIGURE 4.4 Mean values of the Orthopaedic Rating Scale (Percentage Analysis) at the initial, second and final consultations comparing the APT and NSAIDs group.....	54
FIGURE 4.5 Race.....	55
FIGURE 4.6 Age.....	55
FIGURE 4.7 Gender.....	56
FIGURE 4.8 Syndromes.....	56

LIST OF APPENDICES

Appendix A Adco-Diclofenac Insert.....	74
Appendix B Case history.....	76
Appendix C Physical Examination.....	81
Appendix D Low Back Regional.....	88
Appendix E Orthopaedic Rating Scale.....	92
Appendix F Letter of Information.....	94
Appendix G Informed Consent.....	96
Appendix H Indemnity Form.....	98
Appendix I Drug-screening Questionnaire.....	100
Appendix J Revised Oswestry Low Back Pain & Disability Questionnaire..	103
Appendix K Numerical Pain Rating Scale-101.....	105
Appendix L Algometer reading.....	107

DEFINITION OF TERMS

Action Potential Current is a high-frequency low intensity current that simulates or mimics the naturally occurring action potential in a neuron. It is applied to the affected area via electrodes and is associated with pain alleviation, enhanced joint flexibility, a decrease in oedema due to improved circulation and possibly, reduced inflammation (Berger, 1999:11).

Acute low back pain is defined as the duration of the complaint usually lasting less than six weeks (Koes, et al. 1996:2861).

Chronic low back pain is defined as the duration of the complaint being present for more than six weeks (Koes, et al. 1996:2861).

Flat palpation is examination by finger pressure that proceeds across the muscle fibers at a right angle to their length, while compressing them against a firm underlying structure, such as a bone. It is used to detect taut bands and trigger points (Gatterman, 1990:408).

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

Lifetime prevalence refers to the number of people who have experienced back pain ever, even if they do not have it at present (Giles and Singer, 1997:18).

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

Myofascial pain syndrome is a pain syndrome characterized by pain in regional muscles accompanied by trigger points that refer pain specifically to each muscle (Gatterman, 1990:411).

Myofascial trigger point is a hyperirritable spot, usually within a taut band of skeletal muscle or in the muscle's fascia, that is painful to compression and that can give rise to characteristic referred pain, tenderness, and autonomic phenomena (Gatterman, 1990:411).

Placebo is defined as an intervention that is believed to lack a specific effect i.e. an effect for which an empirically supported theory exists for its mechanism of action on the condition in question, but which has been demonstrated to be better than no intervention (Gotzsche, 1994:925).

Point prevalence refers to the proportion of people who have back pain at any given moment (Giles and Singer, 1997:18).

Referred trigger point pain is pain that arises in a trigger point but is felt at a distance, often entirely remote from its source of origin. The distribution of referred trigger point pain rarely coincides with the entire distribution of a peripheral nerve or dermatomal segment (Gatterman, 1990:413).

Single-blinding is when the subject is unaware of the group that he/she is assigned to in the study, however the researcher is unblinded (Haldeman, 1992:418).

CHAPTER ONE

1.0 Introduction

1.1 The problem and its setting

Musculoskeletal disorders are frequently reported as being one of the most commonly encountered ailments, the primary site being the lower back (Weiner and McCulloch, 2000).

Little is known about the epidemiology of low back pain in certain parts of the world, except that it is common. Data reviewed over the last 20 years on epidemiology mainly originates from North America, the UK and Scandinavian countries. Estimates of the yearly incidence range from 1.4 to 4.9%, point prevalence ranges from 10 to over 50%, and lifetime prevalence ranges from 14 to over 70% (Giles and Singer, 1997:19).

The literature on the epidemiology of low back pain is mainly restricted to high-income countries, which make up less than 15% of the world's population (Volinn, 1997).

Practitioners classify back pain into clinical syndromes. Syndromes consist of a group of signs and symptoms that implicate an anatomical source of pain (Giles and Singer, 1997:345). For the purpose of this study, mechanical low back pain will refer to posterior facet syndrome, sacroiliac syndrome and myofascial pain syndrome.

One of the accepted models used to describe the pathology and pathogenesis of mechanical low back pain (LBP) are the phases of degeneration as suggested by Kirkaldy-Willis (1992:55).

Drug therapy is one of the many possible treatments for patients experiencing LBP, and considering that there is a wide variety of drugs available on the market, reflecting that there is no uniquely successful form of drug therapy for low back pain (Deyo, 1996). Furthermore, a review by Van Tulder et al. 2000 concluded that there does not appear to be any specific type of nonsteroidal anti-inflammatory drug (NSAID) that is clearly more effective than others in treating low back pain.

NSAIDs are the most commonly used agents in the treatment of musculoskeletal pain and inflammation, as estimates indicate that approximately 30 million people worldwide contribute to a \$2 billion market (Gabriel, 1997).

In clinical conditions marked by acute or chronic pain and inflammation, such as LBP, diclofenac sodium, has shown to be an effective analgesic agent (Kantor, 1986). When compared with placebo, diclofenac 50mg provided consistently superior relief of symptoms which was demonstrated in a double-blind trial of twenty subjects with tooth pulp pain, the difference between the two groups was statistically significant ($p < 0.001$), in favor of diclofenac (Kantor, 1986). A double-blind study comparing the effects of diclofenac (150mg daily) and aspirin (2.7mg daily) in 160 patients with acute lumbar pain demonstrated that diclofenac provided significantly greater relief ($p = 0.056$) than aspirin (Kantor, 1986).

Iatrogenically induced gastro-intestinal side effects are, however, an ongoing concern especially in chronic cases (Gabriel, 1997).

Gatterman (1990:331-337) states that the most common treatment modalities used by chiropractors include heat, cryotherapy, electrotherapy, meridian therapy, ultrasound, phototherapy, biofeedback, spinal traction and massage. However, there is no research proving non-pharmacological interventions to be superior to others in the treatment of LBP (Koes, et al. 1996).

“Action Potential” therapy (APT) is a relatively new modality aimed at pain relief in acute and chronic conditions.

The APT unit has a pulse repetition of 166Hz, an amplitude of 0 to 5 mA (into a 1 kilo-ohm load) and a voltage of 48 volts d.c. It has an open circuit output format. The pulse produced is of a continuous value with a monophasic square pulse waveform and exponential build-up and decay (Medi Pulse Pty Ltd, Private Bag X1116, Halfway House, 1685, South Africa).

Early studies conducted by De Wet and Oosthuizen (1997) investigating possible neurohormonal consequences with the application of this modality revealed that APT had several beneficial effects in the pain management of acute and chronic pain conditions, including chronic back pain. The methodological integrity of these studies was, however, questionable.

Whilst early studies conducted with the purpose of clarifying the mechanism(s) of action are yet inconclusive, a prospective randomised controlled trial was conducted to determine the usefulness of APT as an adjunct to spinal manipulative therapy for low back pain has yielded some interesting results (Atkinson, 2000). It was found that although both treatment groups responded favorably there was a significantly greater improvement noted in the group receiving active APT as opposed to the group receiving a placebo in terms of both subjective and objective measures (Atkinson, 2000). According to Atkinson (2000), APT provided a clinically useful adjunct to mechanical intervention for the management of mechanical low back pain and recommended that future research frontiers investigating this modality be explored.

It could therefore be postulated that should APT have an similar anti-inflammatory function to diclofenac sodium, that it should be considered as a non-pharmacological alternative due to its reduced risk of iatrogenesis in pain sufferance.

1.2 Aim and objectives of the study

The aim of this investigation is to determine the relative effectiveness of APT compared to diclofenac sodium in the treatment of mechanical low back pain.

Objective one will be to determine the relative effectiveness of combined APT and placebo diclofenac sodium compared to combined placebo APT and diclofenac sodium, in terms of subjective clinical measures.

Objective two will be to determine the relative effectiveness of combined APT and placebo diclofenac sodium compared to combined placebo APT and diclofenac sodium, in terms of objective clinical measures.

1.3 Benefits of the study

One of the challenges facing researchers in the field of low back pain is to provide evidence showing which treatment is most effective for patients with LBP (Van Tulder, 2000).

Low back pain causes major medical and economical problems in Western industrialized countries, which is portrayed by the high direct and indirect costs and the wide variety of therapeutic interventions available for its treatment. The effectiveness of most of these interventions, however, has not been demonstrated beyond doubt (Van Tulder, et al. 1997).

The aim of this research was to evaluate the efficacy of the APT modality versus diclofenac sodium, in order to find cost-effective solutions by researching the effectiveness of alternative therapies for low back pain (Manga, et al. 1993). If shown to be effective, it can be argued that APT may be used in the treatment of low back pain as an alternative treatment for individuals who are contra-indicated to the use NSAIDs.

CHAPTER TWO

2.0 Review of the related literature

2.1 Introduction

The following is a review of the current literature and clinical trials conducted on the subject of APT and NSAIDs in the treatment of mechanical LBP.

2.2 Mechanical low back pain

2.2.1 Epidemiology

Low back pain is second only to the common cold as the population's most common affliction (Weiner and McCulloch, 2000).

Low back pain is an enormous health problem worldwide. A review of the literature states that it has a point prevalence of between 11% and 33%, a one-year prevalence between 16% and 64%, and lifetime prevalence between 31% and 80%. Furthermore, the annual incidence is demonstrated to be between 1% and 8% (Walker, 1997).

According to the literature, about 80% of the population in Western societies will experience one or more episodes of LBP during their lives. These episodes are usually self-limiting as 90% of patients recover within 6 weeks, regardless of the type of treatment given (Koes, et al. 1996).

However, according to Volinn (1997), the literature on the epidemiology of LBP is mainly restricted to high-income countries, which make up less than 15% of the world's population. The author further states in low-income countries, rates are higher among urban populations than among rural populations, and consequently low back pain prevalence may be on the rise among vast number of workers as urbanization and rapid industrialization proceed (Volinn, 1997).

Van der Meulen (1997) suggested the incidence in Chesterville, a black township in South Africa to be 57.6% and the point prevalence, 53.1%, and therefore correlates with developed countries.

Approximately 60% of people report LBP at some stage of their lives. It is likely that minor episodes are not reported so this figure is possibly higher (Waddell, 1995). Furthermore, Waddell feels that although traditional teaching is that 90% of episodes of LBP resolve within 6 weeks, natural history studies have shown that 50% of episodes of LBP improve within 4 weeks.

It would therefore seem that despite modern medicine's best efforts, epidemiological statistics seem to suggest that health care professionals are not gaining ground.

2.2.2 The cost to society

Low back pain causes major medical and economical problems in Western industrialized countries; this is demonstrated by the continually increasing direct and indirect costs and the different types of therapeutic modalities available for its treatment. Concrete proof of effectiveness of most of these interventions has not been yet shown (Van Tulder, et al. 1997).

Estimates show that more than 30 billion people worldwide take NSAIDs, contributing to a \$2 billion market (Gabriel, 1997).

The annual incidence of clinically significant side-effect complications associated with NSAIDs amounts to \$4 billion of health care spent annually (Goldstein, et al. 1997).

It is therefore important to find cost-effective solutions by researching the effectiveness of various treatment interventions for LBP (Manga, et al. 1993).

2.2.3 Aetiology and diagnosis of low back pain

Musculoskeletal disorders are amongst the most common medical conditions reported, the primary site being the lower back. Around ninety percent of patients with LBP can be attributed to mechanical causes (Weiner and McCulloch, 2000). It has been found that mechanical disorders of the low back are quite specific and local in nature, affecting certain anatomical regions (Giles and Singer, 1997:334).

It was found that of 1293 patients treated at the Royal University Hospital Low Back Pain Clinic in Saskatoon, over a 12 year period, posterior (lumbar) facet syndrome (22%), sacroiliac syndrome (23%) and muscle syndromes (6%) were found to be the more common diagnoses (Kirkaldy-Willis 1992:210). However, Frymoyer (1988) states that the most common diagnoses in cases of acute low back pain are unspecific, such as lumbosacral strain and sprain, and only 10 to 20% of patients can be given a precise diagnosis.

Acute LBP results from excessive or unusual movement or strain of normal structures in the lumbar vertebral column or from normal physical forces acting on abnormal structures. The innervation of the lumbar region may cause direct stimulation of local pain receptors. In addition, stimulation of spinal nerves may lead to inflammation and oedema, resulting in further nerve stimulation and therefore pain (Bosch, et al. 1997).

The classification of LBP used in this study is that as set out by Kirkaldy-Willis (1992:105), which classifies LBP into three stages of dysfunction, instability and stabilization. The majority of patients with acute low back pain are in the dysfunctional stage according to Kirkaldy-Willis.

This is when there is posterior joint strain and small capsular tears leading to minor joint subluxation. Inflammation occurs in the posterior joint synovium,

known as synovitis. The muscles surrounding the area involved may go into a protective muscle spasm or hypertonic contraction, resulting in muscle ischemia and further pain. An accumulation of metabolites in the muscle ensues adding to the painful event (Kirkaldy-Willis, 1992:105).

Back pain is a symptom and not a diagnosis, as a precise pathoanatomic or pathophysiologic diagnosis is usually elusive. Infectious and neoplastic causes of back pain are rare, as are inflammatory spondyloarthropathies such as ankylosing spondylitis. Thus, perhaps 95% of patients have what is referred to as "mechanical" LBP, although local inflammation and muscle tension tend to play important etiological roles (Deyo, 1996). The author further states that precise diagnoses are difficult for patients with LBP, due to a poor correlation between symptoms, pathology and image findings.

In many cases, the precise cause of pain cannot be determined. Due to this fact, approaches to diagnosis and treatment differ and confusion ensues. Difficulties arise with definition and classification. Devising a clear strategy for diagnosis of common LBP problems can lead to treatment that is more effective (Weiner and McCulloch, 2000:450). It is therefore more important to place LBP into a diagnostic category than to determine the precise aetiology (Giles and Singer, 1997:345).

Although almost a decade old, the Kirkaldy-Willis (1992:121) model for the description of a classification of LBP syndromes is still widely utilized. By grouping clinical lesions together that are most likely to occur within each phase of spinal degeneration at least some coherency has been achieved in diagnosis. This classification is helpful in that it allows the examiner to correlate the presenting clinical lesion with a particular phase and as a result allow him/her to better understand the pathological process and the possible effects they may have.

The first phase, dysfunction, includes the following conditions:

- Posterior facet syndrome
- Sacroiliac syndrome
- Maigne's syndrome
- Myofascial syndromes
- Disc herniation

The following muscles have been included in the myofascial syndrome associated with low back pain: gluteus maximus, gluteus medius, gluteus minimus, quadratus lumborum, piriformis, tensor fasciae latae and the hamstring.

2.2.4 Posterior facet syndrome

The posterior facet syndrome is a common condition. It causes referred pain to the buttocks, posterior thigh, and below the knee. The absence of nerve root tension signs helps to distinguish a posterior facet syndrome from a nerve root entrapment lesion (Kirkaldy-Willis, 1992:203).

A person suffering from 'facet syndrome' may complain of sudden onset of unilateral or bilateral LBP. Often there is referred pain, muscle spasm and usually no neurological findings. The episode is typically related to trunk flexion with rotation, as in bending over to pick up an object. Pain increases with movement and is relieved by rest. Unlike disc pain, coughing or sneezing does not aggravate it. Pain referred from the irritated facet and surrounding tissues is commonly felt proximal to the knee and sometimes radiates to the feet. Muscle spasm may occur in the back muscles, gluteal muscles or hamstrings (Peters, 1984).

2.2.5 Sacroiliac syndrome

The sacroiliac joint can cause back and leg pain. The differential diagnosis of low back pain should therefore always include sacroiliac joint involvement. The ability to diagnose and manage sacroiliac joint disease is therefore necessary for all clinicians who evaluate and treat patients with low back pain (Hendler, et al. 1995).

Although studies have detailed the anatomy of the sacroiliac joint, its biomechanical function and its role in the pathogenesis of low back pain are still not clear. Despite the lack of specific objective diagnostic criteria and our poor understanding of the pathogenesis of the mechanical back pain syndromes, many practitioners treat the sacroiliac joints in patients with mechanical low back pain and obtain good results (Cassidy and Burton, 1992:42).

Referred pain from the sacroiliac joint may radiate to the buttocks, posterior thigh, groin, and sometimes to the lateral calf and ankle. This pain pattern is similar to posterior facet syndrome and may imitate radicular pain from a herniated lumbar disc or lateral canal stenosis. The lack of nerve root tension signs help to rule out nerve root compression lesions (Kirkaldy-Willis, 1992:204).

2.3 Myofascial pain syndrome

2.3.1 Myofascial trigger points

According to Murphy (1989), trigger points develop in skeletal muscle due to prolonged muscle spasm, direct or indirect injuries, or orthopaedic anomalies resulting in muscle spasm and therefore a decrease in aerobic oxidation with increase in anaerobic oxidation. Murphy further states that this may cause inflammation to occur, and disruption of the sarcoplasmic reticulum with a calcium release which leads to taut muscle bands in which trigger points are often located (Murphy, 1989).

2.3.2 Treatment of trigger points

Trigger points may be treated by one of several methods, namely the spray and stretch technique, injection with a local anesthetic or dry needling (Murphy, 1989). Trigger points may also be treated with various electrotherapeutic devices, including high-voltage stimulation, transcutaneous electrical nerve stimulation (TENS), micro-amperage stimulation, and ultra-sound (Murphy, 1989). In some cases, NSAIDs are used (Murphy, 1989). There is no evidence to support the clinical efficacy of one treatment over another.

In a randomized double blind, placebo-controlled trial, the effects of diclofenac sodium on exercise-induced muscle damage in fifty-four volunteers was examined. Histological changes characterizing muscle inflammation were measured. The pre-exercise muscle samples revealed no difference in muscle damage between the two groups. The post-exercise muscle samples showed that the diclofenac-treated group had less muscle tissue damage than that of placebo-treated subjects ($p = 0.002$) (O'Grady, et al. 2000).

APT is an electrotherapeutic modality of which little is known of in the treatment of trigger points as a non-pharmacological form of intervention. This study has attempted to bridge the gap in the knowledge by determining whether APT or diclofenac sodium is effective in the treatment of trigger points that play a role in mechanical LBP.

2.4 Electrophysical Modalities

According to Rush and Shore (1994) a controversy existed within the medical community regarding the appropriate indications of non-pharmacological physical modalities in the treatment of musculoskeletal conditions. In their study, they found that there were variations of opinions as to the value of physical modalities amongst therapists involved in rehabilitation medicine for musculoskeletal

conditions. Furthermore there is a limited amount of consistent clinical research in this area, due primarily to the large placebo effect, difficulty in blinding, invalidated diagnostic criteria and natural history of the condition being researched (Deyo et al., 1990).

2.4.1 Action Potential Therapy

The APS (Action Potential Stimulation) and more recently APT (Action Potential Therapy) units are a relatively new modality aimed at pain relief in acute and chronic pain conditions, without the potential side effects of drug use.

Neurohormones are implicated in the physiology of pain. APS trials have shown that it is effective in pain relief. The APS therapy device works by imitating the body's natural electrical impulses. A double blind, placebo controlled, randomized study was developed by De Wet and Oosthuizen (1997) to evaluate the neurohormonal effects of APS therapy in patients with chronic low back pain due to osteoporosis. They used beta-endorphins, leucine enkephalin, melatonin, serotonin and cortisol as neurochemical and endocrinological markers of clinical effectivity.

Based on their results, De Wet and Oosthuizen (1998) recommended that the APS therapy device could be used for pain management in acute and chronic pain conditions, including sport injuries.

They found that APS therapy caused a decrease in beta-endorphin secretions with increases in leucine enkephalin and melatonin secretion. They therefore deduced that APS therapy had the following beneficial effects in pain alleviation:

- 1) Analgesia - due to effective utilization of the endogenous opioids and the inhibition of pain transmission.
- 2) Reduction of anxiety and more realistic self-assessment of pain.

- 3) Limitation of tissue damage at sites of inflammation and/or hypoxia due to local vasodilatation and better perfusion of the affected areas.
- 4) Anti-inflammatory effects due to beneficial influences on the prostaglandin mechanisms.

These results are regarded as anecdotal as the exact mechanism of action of this modality is not yet certain and further studies have to be conducted.

2.4.2 Ultrasound

Ultrasound is suggested as an effective anti-inflammatory agent and for that reason is frequently used for acute and subacute inflammatory conditions. However these conclusions are drawn from clinical reports, uncontrolled studies, poorly formulated population and designs and therefore there is little substantial backing for this claim (Reid, 1992:42). This modality is widely used by physiotherapists, although there is limited clinical knowledge regarding its clinical effectiveness (Robertson and Spurrirt, 1998).

2.4.3 Transcutaneous electrical nerve stimulation

Clinical support for transcutaneous electrical nerve stimulation (TENS) use has accumulated since its development in the mid 1960s (Robertson and Spurrirt, 1998). A study by Li and Bombardier (2001) in Ontario, Canada concluded that 53% of the 785 physical therapists were of the opinion that TENS was effective in the management of patients with acute LBP.

2.4.4 Interferential therapy

Interferential therapy (IFT) is another form of transcutaneous nerve stimulation used for pain relief (Reid, 1992:54). Noble, et al. (2001) highlighted the popularity

of IFT as a treatment intervention amongst physiotherapists worldwide despite lack of published studies regarding its clinical effectiveness. Most studies on IFT instead concentrate on the effects of beat or carrier frequency or of current distribution in tissues (Laycock and Green, 1993; Nussbaum et al., 1990).

2.5 Nonsteroidal anti-inflammatory drugs

2.5.1 Effectiveness of nonsteroidal anti-inflammatory drugs for acute low back pain

Nonsteroidal anti-inflammatory drugs are the most widely used agents for treating musculoskeletal pain and inflammation (Gabriel, 1997).

Various types of NSAIDs, namely, piroxicam, ibuprofen, diclofenac, felbinac, and biarison, are equally effective for acute low back pain (Van Tulder et al., 1997).

The Quebec Task Force on Spinal Disorders regards the randomized controlled trial to be the strongest scientific proof of the effectiveness of an intervention. Van Tulder, Koes and Bouter to assess the effectiveness of common conservative types of treatment for acute and chronic nonspecific LBP conducted a systematic review of randomized controlled trials where acute low back pain was defined as persisting for 6 weeks or less. They found strong evidence that NSAIDs were more effective than placebo in patients with uncomplicated acute low back pain, but no more effective than analgesics (Van Tulder et al., 1997).

Diclofenac has been established as a leading NSAID in global studies and although the majority of published studies have been on its use in rheumatic conditions and degenerative joint disease, it has also been used with success in acute and chronic or relapsing conditions marked by pain and inflammation (Kantor, 1986). Diclofenac provides beneficial anti-inflammatory and analgesic effects when administered orally for the treatment of LBP (Kantor, 1986).

According to Deyo (1996), drug therapy for back pain is administered for symptomatic relief without a specific diagnostic target, as there is reason to believe that inflammation may play an important part in various pain syndromes. Likewise, the facet joints are true synovial joints, so we assume that they, like other synovial joints are susceptible to inflammation processes associated with degenerative joint disease, henceforth the rationale of NSAIDs for LBP (Deyo, 1996:2841).

Recurrent episodes of facet joint pain and synovitis cause posterior facet syndrome and in acute cases, administration of NSAIDs is one of the mainstay forms of treatment (Reid 1992:829). According to Daum (1995) if contraindications to NSAIDs are excluded, they may be administered in the treatment of sacroiliac syndrome. Murphy (1989) recommends NSAID therapy for the treatment of trigger points.

Recently, guidelines for the management of low back pain in primary care have been published in the United States, United Kingdom, New Zealand and the Netherlands. All these guidelines recommend the use of NSAIDs as one option for symptomatic relief in the early management of LBP. The rationale behind this is that NSAIDs have an analgesic potential and an anti-inflammatory effect (Van Tulder, et al. 2000).

Although acute LBP is usually of short duration, typically resolved within two weeks, it is an extremely painful condition demands rapid relief. NSAIDs are frequently used to treat low back pain as they can provide analgesia (through the night) without the risks of opiate analgesics (Bosch, et al. 1997).

2.5.2 Complications of diclofenac sodium

The use of NSAIDs is associated with a 2% to 4% annual incidence of serious gastrointestinal complications (Goldstein, et al. 1997). These adverse clinical outcomes and the strategies used to prevent their occurrence, result in significant economic burden. The widespread use of NSAIDs is due to their success in alleviating pain and maintaining functional status. NSAIDs are one of the most frequently prescribed classes of medication. Chronic use of these drugs may cause serious gastrointestinal complications, which occur more frequently with this drug class than any other agent (Goldstein, et al. 1997).

The widespread use of NSAIDs augments the impact not only of their benefits but of their side effects as well. Their related side effects can occur anywhere that prostaglandins are produced. These most commonly involve the gastrointestinal, renal, hepatic, and haematological systems. Patients treated with NSAIDs can also experience hypersensitivity and cutaneous reactions and problems related to drug interactions. Of greatest concern is the potential for gastrointestinal toxicity, which includes gastric irritation, exacerbation of peptic ulcer, bleeding and perforation. Such toxicity can occur without warning (Gabriel, 1997).

Gastric or intestinal ulceration with associated bleeding has been reported with ADCO-DICLOFENAC therapy. Skin rashes and gastrointestinal disturbances may also occur. Headaches, dizziness, oedema, nervousness, pruritis, tinnitus, insomnia, blurred vision and other ocular reactions, peripheral oedema, malaise, jaundice, elevated transaminase levels, drowsiness and hypersensitivity reactions (e.g. bronchospasm) have occurred. Blood counts and monitoring of hepatic and renal functioning are advised during prolonged therapy as blood dyscrasias have been reported. The safe use of ADCO-DICLOFENAC in pregnancy has not been demonstrated. Blood concentrations of lithium are increased when ADCO-DICLOFENAC is administered concomitantly. ADCO-

DICLOFENAC should be given with care to patients with bleeding disorders, cardiovascular disease, and in those who are receiving coumarin anticoagulants. Patients who are sensitive to aspirin generally should not be given ADCO-DICLOFENAC (Appendix A - Adco-Diclofenac Package Insert, 1990).

2.5.3 Mechanism of action of diclofenac sodium

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

2.6 Summary of Literature Review

Epidemiological statistics suggest that LBP is an enormous health problem experienced worldwide that causes a drain on the economy (Weiner and McCulloch, 2000:450). The health profession therefore needs to find cost effective forms of intervention.

As 90% of patients with low back pain are due to a mechanical cause (Weiner and McCulloch 2000:450), this condition was chosen for this study. A model devised by Kirkaldy-Willis (1992:105) was used in this study, of which the dysfunctional phase is the most common. It was decided to focus on posterior facet syndrome, sacroiliac syndrome and myofascial pain syndrome in the treatment of mechanical low back pain. An overview of each syndrome was then discussed.

A review on APT and diclofenac sodium in the treatment of LBP was discussed.

APT is a relatively new modality aimed at pain relief in acute and chronic conditions and has shown to be effective when used in conjunction with manipulation in the treatment of LBP (Atkinson 2000:45).

Electrophysical modalities are widely used in the treatment of musculoskeletal conditions although there are limited published clinical studies on their effectiveness (Noble et al., 2001).

As NSAIDs are the most frequently prescribed drugs in the medical management of LBP (Van Tulder, et al. 2000:2501), this form of intervention was chosen for this trial, in order to establish the more effective treatment protocol when compared to a non-drug intervention.

It was shown that various NSAIDs are equally effective in the treatment of LBP (Van Tulder, et al. 1997:2132); therefore, diclofenac sodium was used to represent NSAIDs.

In conducting a study on the relative effectiveness of APT to diclofenac sodium in the treatment of mechanical LBP, it is likely that both forms of therapy will be beneficial. However, it will be interesting to note which of the two is more effective in terms of the amount relief experienced by the subject and cost effectiveness in the amount of time the subject is disabled by mechanical LBP.

CHAPTER THREE

3.0 Methodology

The objective of this study was to determine the relative effectiveness of *"Action Potential" therapy* to diclofenac sodium in the treatment of mechanical LBP, in terms of subjective and objective clinical findings.

A purposive convenience sampling method was used to secure subjects for the clinical trial. The subjects were drawn from the greater Durban area by means of advertisement in the local newspapers and on billboards.

Upon reply, each subject was telephonically interviewed to explain the conditions of the study and as an initial screening process to eliminate those subjects falling outside the range of the study.

Subjects were excluded for the following reasons:

- If they were younger than 18 or older than 65 years of age (Meade, et al. 1990:1432; Atkinson, 2000:20).
- Any female applicant who was pregnant or breastfeeding
- If their condition exhibited neurological deficit or a vascular deficiency involving the lower limb and was diagnosed before applying to enter the study
- If their symptoms had been present for longer than six weeks
- If they were taking any other medication besides oral contraceptive pills or injection
- If they were receiving any other forms of treatment for the low back pain that they presented with
- If they suffered from epilepsy
- If they were predisposed to thrombolytic episodes

- If they had any medical implant (e.g. a pacemaker)
- If they had received electro-therapy within the prior three months
- If they had any of the following contra-indications as stated in the package insert:

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

After agreeing to participate, an initial consultation was scheduled for the prospective participant.

At the initial consultation, the candidate was evaluated by means of a full case history (Appendix B), a relevant physical examination (Appendix C) and low back regional examination (Appendix D). For the purpose of this study, one of three syndromes was screened for to arrive at a diagnosis of mechanical low back pain. The three conditions considered were posterior facet syndrome, sacroiliac syndrome and the myofascial pain syndrome (Kirkaldy-Willis, 1992:85). During the low back regional examination, specific tests were performed to diagnose mechanical low back pain.

The orthopaedic tests used to specifically diagnose posterior facet syndrome were: Kemp's Test (axial compression), Facet Joint Challenge Test (joint springing) and hyperextension in a prone position.

Kemp's test requires the patient to be seated and the examiner standing behind. The examiner reaches around the patient's shoulders and upper chest and the patient is instructed to lean forward to one side and then to bend obliquely

backwards as far as possible. Axial pressure is applied to compress the side of rotation. If this maneuver produces or aggravates radicular pain in the thigh or leg it may be indicative of nerve root compression (Schafer and Faye, 1989:208-209).

Radicular pain suggests nerve root compression possibly from a herniated disc and should therefore be distinguished from referred pain experienced in a lumbar facet lesion (Gatterman, 1990:141).

Referred pain has a similar pattern to the innervation of the affected posterior joint. Subjective sensory changes in the relevant dermatome may be present. Motor and reflex changes are rare (Kirkaldy-Willis, 1992:141).

Radicular pain causes sensory, motor and reflex changes to occur. There is decreased straight leg raising, Lasegue or Bragard test, which comprises of dorsiflexion of the foot with maximum straight leg raising, is positive (Kirkaldy-Willis, 1992:141).

Lumbar facet joint challenge is conducted with the patient in the prone position. The examiner places a thumb on the spinous process tip and applies a varying force, which may increase the pain experienced by the patient (Gatterman 1990:84). Kenna and Murtagh (1989:104) describe the test as an application of transverse pressure to the spinous process causing local pain aggravation indicative of a lumbar facet syndrome.

Hyperextension in a prone position is done with patient lying face down. Pain is increased when the spinal column is placed in full extension (Gatterman, 1990: 161-162).

The orthopaedic tests used to diagnose sacroiliac syndrome were: Gaenslen's test (pelvic torsion), Patrick's test (Faber or Figure-4 test), Erichson's test and the posterior shear ("thigh thrust") test.

Gaenslen's test is done with the patient lying supine with the test hip beyond the edge of the table. The patient draws both legs up onto the chest and then slowly lowers the test leg down into extension. The other leg is tested in a similar fashion for comparison. Pain in the sacroiliac joint indicates a positive test (Magee, 1992:319).

Posterior rotation of the ilium on the sacrum is achieved by flexion of the involved hip and knee and simultaneous opposite hip extension. Overpressure is applied to force the sacroiliac joint to its end range (Laslett and Williams, 1994:1245).

Patrick's test is conducted with the patient lying supine. The examiner then places the patient's test leg's foot on top of the knee of the opposite leg. The examiner lowers the test leg in abduction toward the examining table. If the test leg falls towards the table or is at least parallel to the opposite leg the test is negative. If the test leg remains above the opposite straight leg a positive test is indicated. If positive, the hip joint, iliopsoas muscle, or the sacroiliac joint may be involved (Magee, 1992:343).

Erichson's test requires the patient in the supine position; the examiner places his/her hands on the patient's iliac crests and thumbs on the lateral aspect of the anterior superior iliac spines. The pelvis is then forcibly compressed towards the midline, which causes posterior separation of the sacroiliac joints. Pain experienced over either sacroiliac joint is positive for a sacroiliac joint lesion (Schafer and Faye, 1989:270).

Posterior shear test is conducted with the patient supine. The examiner applies a posterior shearing stress to the sacroiliac joint through the adducted femur of the test leg. Excessive adduction of the hip is avoided because flexion and adduction combined normally is uncomfortable or painful (Laslett and Williams, 1994:1244-5).

Specific procedures were conducted for myofascial pain dysfunction syndrome: eliciting a pattern of referred pain, a local twitch response, a taut palpable band and exquisite focal tenderness to digital pressure.

Referred pain from a myofascial trigger point is usually dull and aching. The referred pain may be elicited or increased in intensity by digital pressure on the trigger point (Travell and Simons, 1983:13).

Local twitch response is a transient contraction of muscle fibers in a tense band that possess a trigger point. It is produced by a transverse snapping palpation with the muscle in a neutral position. If the muscle is superficial then flat palpation is used, otherwise the pincer grasp is utilized. A local twitch response is useful for identifying trigger points clinically (Travell and Simons, 1983:61-62).

Taut palpable band location is done by flat or pincer palpation. The muscle is placed under stretch to the point of discomfort and the examiner feels for a taut cord of tense muscle fibers (Travell and Simons, 1983:59).

Exquisite focal tenderness refers to a spot of maximum tenderness palpated in a muscle (Travell and Simons, 1983:59).

Locating trigger points could involve one of three techniques, firstly using direct palpation of the muscle to locate points of tenderness, secondly applying direct digital pressure by walking the fingers across the muscle and applying pressure

to elicit pain, and thirdly flat palpation, in which the examiner rubs the taut band of muscle that may contain trigger points.

Once the trigger point is located in a taut palpable band of muscle there may be exquisite focal tenderness, the patient may experience referred pain to a remote site, or a twitch response may be elicited in which there is transient contraction of the muscle which is felt by the examiner (Murphy, 1989).

Each of these orthopaedic tests was allocated with a weighted score on eliciting a positive response, which then made up a grading for each syndrome. The Orthopaedic Rating Scale (Appendix E) comprised of the three syndromes.

For Posterior Facet Syndrome, lateral flexion in extension, known as Kemp's Test, often causes the most pain (Peters, 1984). Kemp's test is a commonly used test according to Schafer and Faye (1990:217), Magee, (1992:274) and Gatterman (1990:141), therefore received a score of four when positive. Facet Joint Challenge test, which involves repeated springing pressure across the spinous processes, is commonly used when assessing the lumbar spine according to LaBoeuf (Giles and Singer, 1997:346), therefore was given a grading of 4 when positive. The hyperextension test, as it is not commonly used or causes the most pain only received a score of two when positive.

When assessing for Sacroiliac Syndrome the most sensitive test according to Laslett and Williams (1994) is the posterior shear test that will therefore receive a score of four when positive. Gaenslen's, Patrick Fabere and Erichson's test will therefore only be allocated a score of two when positive.

According to Travell and Simons (1983:46) the referral of pain is the most important indicator of myofascial pain syndrome, therefore will receive a score of four when positive. The remainder, namely, local twitch response, taut palpable band and exquisite focal tenderness shall only receive a grading of two when

positive. Therefore, an orthopaedic assessment rating out of 10 was allocated to each syndrome.

The Orthopaedic Rating Scale determined the participant's entry into the study and as an assessment tool. As to date, the Orthopaedic Rating Scale has not been validated by research. If the subject only presented with one of the syndromes mentioned, they needed a score of 6 out of 10 or higher for eligibility. If they presented with two syndromes they needed a score of 12 out of 20 or higher, and if they presented with all three syndromes they needed a grading of 18 out of 30 or higher to ensure participation in the study. It was decided that each syndrome needed a rating out of 6 or higher at the initial visit. These ratings were done again before the second treatment and after the final treatment. This indicated whether there had been an improvement in their overall condition for which they had been diagnosed.

As patients were examined and found suitable for the study, they were given a letter of information (Appendix F) and asked to complete an informed consent form (Appendix G). They were also given an indemnity form (Appendix H) and a drug-screening questionnaire (Appendix I) to complete as devised by a medical practitioner. A telephonic interview was conducted with the medical practitioner for subjects who were in the diclofenac sodium 50mg group.

Random allocation was utilized to allocate patients to either the active APT and placebo diclofenac sodium group (group 1) or the placebo APT and diclofenac sodium 50mg group (group 2), to create two groups of 30 patients each. This sample size allowed for the use of parametric statistics as this approximated normal assumption sufficiently.

A single blinded procedure was used to assure the placebo nature of the study.

The manufacturer (Medi Pulse Pty Ltd, Private Bag X1116, Halfway House, 1685, South Africa) made four units available for the study. Only two of which was able to deliver an active treatment. The units were marked as "a, b, c or d" and each participant was assigned a number between 1 and 60. They were randomly allocated to a unit via an independent observer who picked a letter out of a hat, of which there were 15 groups each of "a, b, c and d." The active units were paired with the inactive medication and vice versa. The participant was treated with the same unit on each visit. After the data was collected and analyzed, the true nature of the units was revealed. However, due to the manual intervention used initially the study must be viewed, as "pragmatic" and therefore complete blinding was not possible. Patient naivety was ensured by excluding patients who had manual therapy within a three-month period preceding this study (Assendelft et al., 1992).

The initial treatment consisted of APT and placebo diclofenac sodium, or placebo APT and diclofenac sodium 50mg; depending on which group they were in. The participants were instructed to swallow the tablets with a glass of water three times daily for the duration of the trial. On the three subsequent visits, the patient received either active or placebo APT.

The modality setting was standardized to eight minutes, as recommended by Berger (1990:57), for acute conditions. The current intensity was standardized to 2mA (Berger, 1990:57).

The electrode placement was according to the manufacturer's guidelines. The positive electrodes were placed bilaterally over the quadratus lumborum region and one negative electrode over the L1 spinous process and the other over S1. This procedure was then duplicated at subsequent visits.

According to the manufacturers guidelines there was a twenty-four hour window period between scheduled visits.

If participants developed an allergic response or experienced an acute exacerbation, they were excluded from the trial. Participants who developed any side effects to diclofenac sodium were also excluded. The side effects are stated as follows in the package insert:

- Gastric or intestinal ulceration with associated bleeding
- Gastro-intestinal disturbances
- Headache, dizziness, oedema, nervousness, pruritis, tinnitus, insomnia, blurred vision and other ocular reactions, peripheral oedema, malaise, jaundice, elevated transaminase levels, drowsiness and hypersensitivity reactions (e.g. bronchospasm)

Participants were warned against major changes in lifestyle habits, especially those relating to diet and exercise. The participants were also informed that they would be excluded from the study if any other pain or anti-inflammatory medication was taken during the course of the trial.

The subjective measures consisted of the Revised Oswestry Low Back Pain and Disability Questionnaire (Appendix J) and the Numerical Pain Rating Scale - 101 (Appendix K). The Revised Oswestry Low Back Pain Questionnaire has shown to be a valid and reliable method to measure the percentage disability suffered by patients with low back pain (Hsieh, et al. 1992; Haas, et al. 1995).

The Numerical Pain Rating Scale (NRS-101) was used to measure the subjective response of the patients to treatments in terms of their perception of pain intensity (Jensen et al. 1986).

The original Oswestry was designed to measure the effects of low back pain on functional disability and became established as an outcome measure. It was revised to enhance compliance by eliminating inquiry into sexual activity and use of painkillers; both versions are found to be reliable, valid and internally consistent. The revised Oswestry consists of 10 categories related to normal

daily activities, such as, pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling and changing degree of pain. Each section has a six-point scale, therefore has more responsiveness than a yes/no format (Haas, et al. 1995). Data showed that the Revised Oswestry Low Back Pain Questionnaire has a reliable internal consistency. It is a reliable instrument in assessing low back pain disability (Hsieh, et al. 1992).

Within the ten categories, there are six possible responses. The patient chooses one response. Scores of 0 (Response 1) to 5 (Response 6) are possible. Thus if all sections are completed a score of 50 (100%) is possible. If one section is not completed then the totaled response is graded out of 45.

A study comparing the responsiveness of visual analogue scale (VAS), verbal rating scale (VRS) and numerical rating scale (NRS) scales was conducted by Bolton and Wilkinson (1998:1). The responsiveness of the NRS and VAS were shown to be consistently similar. The VRS was shown to be less responsive than either the VAS or NRS. The NRS was shown to be as responsive, if not more responsive, as the VAS in this study. The NRS and VAS are equally sensitive in their ability to detect change. The NRS is easier to use and less time consuming to score, therefore is better than the VAS in measuring treatment outcome in terms of pain levels (Bolton, et al. 1998).

The NRS-101 rates the level of pain intensity experienced by the patient on a numerical scale between 0 and 100. With zero representing, "no pain" and 100 "pain as bad as it could be". The NRS-101 has numerous practical advantages over other similar measures. It is simple to administer and score in either written or numerical form. The NRS-101 does not appear to be associated more with incorrect responding more than another scale. Difficulty in scoring also does not appear to be associated with age. The NRS-101 facilitates comparison of treatment effects (Jensen, et al. 1986).

The objective assessment (Appendix L) consisted of pain sensitivity measurements using the digital Algometer™ Commander (Jtech Medical Industries; 4314 ZEVEX Park Lane; Salt Lake City; UT 84123; 801-264-1001), which was used to measure pain perception over the area of initial tenderness (Nussbaum and Downes, 1998). The subject lay prone, exposing the area to be tested. They then pointed to the area of discomfort, the examiner palpated the point of maximum sensitivity. It was marked with a pen and its location documented with reference to a landmark for future testing. The applicator tip was placed over the mark and a force perpendicular to the skin's surface was gradually applied. The subject was instructed to verbally indicate the onset of pain with a "yes". The reading was taken three times to improve reliability and the average was recorded as data.

The Orthopaedic Rating Scale was graded once the relevant orthopaedic tests were found to be positive for mechanical low back pain. As an objective measurement, it has not yet been validated by research. There are three syndromes or categories each with a possible score of ten. It was decided to use these scores as a percentage of mechanical low back pain. If the subject presented with one syndrome, the total for that syndrome was divided by ten and multiplied by one hundred, to achieve a percentage. This was done if they presented with two or all three of the specified syndromes. The subjective and objective measurements were done before the initial, before the second treatment consultation, and at the final consultation.

To fall within the natural history of the condition, each participant received four treatments, over a seven to ten day period (Kirkaldy-Willis, 1992). There was also a final consultation, approximately twenty-four hours after the final consultation at which the final set of data was collected.

3.1 Ethical considerations

The rights and welfare of the subject was protected:

- Informed consent was obtained (Appendix G)
- The subject was not be coerced into participating in the study
- Information was given to the patient in an understandable language
- The research involved no more than minimal risk
- Confidentiality was maintained
- Participation was voluntary and did not involve financial benefit
- The subject was free to withdraw from the study at any stage
(Pak and Adams, 1994).

3.2 Statistical analysis of the data

The SPSS based 9.0 statistical package (SPSS Inc. 444N. Michigan Avenue, Chicago, Illinois, 60611, USA) was used for data analysis using parametric tests.

Parametric tests, namely the paired t-test and unpaired t-test, were used to analyze the data collected from the Revised Oswestry Low Back Pain Questionnaire, Numerical Pain Rating Scale-101, digital algometer readings and Orthopaedic Rating Scale.

The statistical evaluation was aimed at measuring whether significant changes had occurred between the initial and second consultation, the initial and final consultation as well as the second and the final consultation, within each study group and between the respective groups.

3.2.1 Paired t-test (Intra-group)

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

Ho: There is no improvement between the consultations.

Ha: There is an improvement between the consultations.

$\alpha = 0.05$, one-tailed test

Decision rule:

If $p < \alpha$, reject H_0 .

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

(i) $p = \frac{\text{reported } p\text{-value}}{2}$

If H_a is of form $>$ and z is positive
If H_a is of form $<$ and z is negative

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

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

3.2.2 Unpaired t-test (Inter-group)

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

Ho: There is no difference between the two groups.

Ha: There is a difference between the two groups.

$$\alpha = 0.05$$

Decision rule:

If $p < \alpha$, reject Ho.

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

Where p is the reported p-value.

Descriptive statistics incorporating mean, standard deviation and standard error were used to analyze the data in order to further interpret the results.

The measurement of the central tendency found, within the raw data, was interpreted by calculating the mean value. This was done in order to provide a practical quantitative summary of each group's characteristics.

From the data, the standard deviation (s.d.) was calculated in order to measure the variation of the data from the mean values acquired.

Standard error (s.e.) of measurement was used to indicate the response stability within the measured data. If we were to administer a test to one individual an infinite amount of times, we can assume that the response would vary from trial to trial. These differences would be a function of random measurement error. If a graph could be drawn to plot these responses, the distribution would represent a normal curve, with the mean equal to the true score and errors falling above and below the mean.

This distribution of measurement errors is a theoretical distribution that represents the population of all possible measurement errors that could occur for that variable. With a more reliable measurement, errors would be smaller and the distribution will be less variable.

Therefore, the standard deviation of the measurement errors, called the standard error of measurement reflects the reliability of the response.

The results obtained from these tests were then used to discuss and draw conclusions as to the relative effectiveness of "*Action Potential*" Therapy compared to diclofenac sodium in the treatment of mechanical low back pain.

3.3 The Specific Treatment of each Objective

3.3.1 Objective One

The first objective was to determine the relative effectiveness of combined "*Action Potential*" therapy and placebo diclofenac sodium compared to combined placebo "*Action Potential*" therapy and diclofenac sodium, in terms of subjective clinical measures in the treatment of mechanical low back pain.

3.3.2 The Data Required

The data required for testing the hypothesis of the first objective was attained from the subjects in response to the Revised Oswestry Low Back Pain Disability Questionnaire and Numerical Pain Rating Scale-101.

3.3.3 How the Data Was Secured

All data was gathered from participating candidates and recorded in their respective files at the Technikon Natal Chiropractic Day Clinic. The questionnaires were completed at the consultations under the supervision of the researcher.

3.3.4 Objective Two

The second objective was to determine the relative effectiveness of combined APT and placebo Diclofenac sodium compared to placebo APT and Diclofenac sodium, in terms of objective clinical measures in the treatment of mechanical low back pain.

3.3.5 The Data Required

The data required for testing the hypothesis of the second objective was collected from the subjects using the digital algometer readings and performing orthopaedic tests as set out in the Orthopaedic Rating Scale.

3.3.6 How the Data Was Secured

All data was collated and recorded by the researcher in the participant's file at the Technikon Natal Chiropractic Day Clinic, at the relevant appointments.

3.3.7 Objective Three

The third objective was to integrate the results of objective one and objective two in order to determine which of the two treatments was more effective in terms of subjective and objective clinical findings in the treatment of mechanical low back pain.

3.3.8 The Required Data

The relevant data for testing the third hypothesis was collected from the response of subjects to the Revised Oswestry Low Back Pain Disability Questionnaire, Numerical Pain Rating Scale-101, digital algometer readings (Appendix M) and the Orthopaedic Rating Scale where relevant.

3.3.9 How the Data was Secured

The data was located in the participant's file after capture.

CHAPTER FOUR

4.0 The results

4.1 Introduction

This chapter deals with the results obtained after statistical analysis of the data from the measurement criteria, as follows:

- Revised Oswestry Low Back Pain Disability Questionnaire
- Numerical Pain Rating Scale-101
- Algometer
- Orthopaedic Rating Scale
- Age, gender and race distribution

The sample size was variable in this study, thus both parametric and non-parametric tests were utilized to analyse the data, in order to accept or reject the null hypothesis. This study comprised of 60 subjects, with 30 in group 1 and 30 in group 2. The results from the inter-group and intra-group analysis were represented in tables. The tabulated statistical results included the level of significance (p-value). The descriptive data was represented in pie and bar charts.

4.1.1 The use of parametric tests

The parametric tests were used for continuous variables. If the sample size was greater than 30 ($n > 30$), the unpaired t-test and paired t-test were utilized.

The two-sample paired t-test was used for intra-group comparison, to determine whether any change had occurred between:

- the initial and second consultation
- the initial and final consultation
- the second and final consultation

In each of these tests the null hypothesis stated that there was no improvement between the two samples being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis stated that there was improvement between the two samples being compared (Fisher and Van Belle 1993:315-319).

The two-sample unpaired t-test was used as an inter-group comparison, to determine whether any differences occurred between the two groups at the initial, second and final consultation. In each of these tests, the null hypothesis stated that there was no difference between group1 and group 2, with regards to which variable was being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis stated that there was a difference between the two groups being compared (Fisher and Van Belle 1993:315-319).

4.2 PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1 (APT)

4.2.1 Analysis of the subjective data

Table 4.1 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	
	Mean	S.D.		Mean	S.D.
NRS-101	41.12	14.80	0.038	37.92	14.81
OSWESTRY	27.73	13.89	0.001	24.07	13.65

The null hypothesis is rejected according to the defined decision rule for both the NRS-101 and the OSWESTRY questionnaires, which indicates that an improvement took place between the initial and second consultations within group 1 (APT).

Table 4.2 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	
	Mean	S.D.		Mean	S.D.
NRS-101	41.12	14.80	0.000	27.50	15.77
OSWESTRY	27.73	13.89	0.000	18.53	2.88

The null hypothesis is rejected according to the defined decision rule for both the NRS-101 and the OSWESTRY questionnaires, which indicates that an improvement took place between the initial and final consultations within group 1 (APT).

Table 4.3 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	
	Mean	S.D.		Mean	S.D.
NRS-101	37.92	14.81	0.000	27.50	15.77
OSWESTRY	24.07	13.65	0.004	18.53	15.76

The null hypothesis is rejected according to the defined decision rule for both the NRS-101 and the OSWESTRY questionnaires, which indicates that an improvement took place between the second and final consultations within group 1 (APT).

4.3 PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 2 (NSAIDs)

4.3.1 Analysis of the subjective data

Table 4.4 Comparison of the subjective data between the initial and second consultations, using the paired t-test

	TREATMENT GROUP 2: INITIAL CONSULTATION		P-VALUE	TREATMENT GROUP 2: SECOND CONSULTATION	
	Mean	S.D.		Mean	S.D.
NRS-101	41.70	13.58	0.000	33.53	16.49
OSWESTRY	30.80	14.40	0.0015	24.93	14.97

The null hypothesis is rejected according to the defined decision rule for both the NRS-101 and OSWESTRY questionnaires, which indicates that an improvement took place between the initial and second consultations within group 2 (NSAIDs).

Table 4.5 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	
	Mean	S.D.		Mean	S.D.
NRS-101	41.70	13.57	0.000	18.38	18.03
OSWESTRY	30.80	14.41	0.000	14.45	13.79

The null hypothesis is rejected according to the defined decision rule for both the NRS-101 and OSWESTRY questionnaires, which indicates that an improvement took place between the initial and final consultations within group 2 (NSAIDs).

Table 4.6 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	
	Mean	S.D.		Mean	S.D.
NRS-101	33.53	16.49	0.000	18.38	18.03
OSWESTRY	24.93	14.97	0.000	14.45	13.79

The null hypothesis is rejected according to the defined decision rule for both the NRS-101 and OSWESTRY questionnaires, which indicates that an improvement took place between the second and final consultations within group 2 (NSAIDs).

4.4 PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 1 (APT)

4.4.1 Analysis of the objective data

Table 4.7 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: SECOND CONSULTATION	
	Mean	S.D.		Mean	S.D.
ALGOMETER	43.13	18.29	0.049	47.52	18.47
ORS (%)	84.55	8.50	0.000	74.11	12.76

The null hypothesis is rejected according to the defined decision rule for both the ALGOMETER and ORTHOPAEDIC RATING SCALE (percentage analysis) results indicating an improvement between the initial and second consultations within group 1 (APT).

Table 4.8 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	
	Mean	S.D.		Mean	S.D.
ALGOMETER	43.13	18.29	0.000	58.36	21.65
ORS (%)	84.55	8.50	0.000	48.11	20.69

The null hypothesis is rejected according to the defined decision rule for both the ALGOMETER and ORTHOPAEDIC RATING SCALE (percentage analysis) results indicating an improvement between the initial and final consultations within group 1 (APT).

Table 4.9 Comparison of the objective data between the second and final consultations, using the paired t-test

	TREATMENT GROUP 1: SECOND CONSULTATION		P-VALUE	TREATMENT GROUP 1: FINAL CONSULTATION	
	Mean	S.D.		Mean	S.D.
ALGOMETER	47.52	18.47	0.001	58.36	21.65
ORS (%)	74.11	12.77	0.000	48.11	20.69

The null hypothesis is rejected according to the defined decision rule for both the ALGOMETER and ORTHOPAEDIC RATING SCALE (percentage analysis) results indicating an improvement between the second and final consultations within group 1 (APT).

4.5 PARAMETRIC INTRA-GROUP ANALYSIS FOR GROUP 2 (NSAIDs)

4.5.1 Analysis of the objective data

Table 4.10 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	
	Mean	S.D.		Mean	S.D.
ALGOMETER	46.62	22.30	0.024	53.37	20.33
ORS (%)	85.33	12.09	0.000	68.56	20.60

The null hypothesis is rejected according to the defined decision rule for both the ALGOMETER and ORTHOPAEDIC RATING SCALE (percentage analysis) results indicating an improvement between the initial and second consultations within group 2 (NSAIDs).

Table 4.11 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	
	Mean	S.D.		Mean	S.D.
ALGOMETER	46.62	22.30	0.003	59.54	20.81
ORS (%)	85.33	12.09	0.000	41.33	19.68

The null hypothesis is rejected according to the defined decision rule for both the ALGOMETER and ORTHOPAEDIC RATING SCALE (percentage analysis) results indicating an improvement between the initial and final consultations within group 2 (NSAIDs).

Table 4.12 Comparison of the objective data between the second and final consultations, using the paired t-test

	TREATMENT GROUP 2: SECOND CONSULTATION		P-VALUE	TREATMENT GROUP 2: FINAL CONSULTATION	
	Mean	S.D.		Mean	S.D.
ALGOMETER	53.37	20.33	0.032	59.54	20.81
ORS (%)	68.56	20.60	0.000	41.33	19.68

The null hypothesis is rejected according to the defined decision rule for both the ALGOMETER and ORTHOPAEDIC RATING SCALE (percentage analysis) results indicating an improvement between the second and final consultations within group 2 (NSAIDs).

4.6 PARAMETRIC INTER-GROUP ANALYSIS

4.6.1 Analysis of the subjective data

Table 4.13 Comparison of the subjective data for groups 1 and 2 at the initial consultation using the unpaired t-test

	TREATMENT GROUP 1 (APT): INITIAL CONSULTATION		P-VALUE	TREATMENT GROUP 2 (NSAIDs): INITIAL CONSULTATION	
	Mean	S.D.		Mean	S.D.
NRS-101	41.12	14.80	0.874	41.70	13.58
OSWESTRY	27.73	13.89	0.405	30.80	14.41

The null hypothesis is accepted according to the defined decision rule for both the NRS-101 and the OSWESTRY questionnaires indicating that there was no difference at the time of the initial consultation between group 1 (APT) and group 2 (NSAIDs). This suggests that each group was similarly matched regarding the severity of their LBP at the onset of the study.

Table 4.14 Comparison of the subjective data for groups 1 and 2 at the second consultation using the unpaired t-test

	TREATMENT GROUP 1 (APT): SECOND CONSULTATION		P-VALUE	TREATMENT GROUP 2 (NSAIDs): SECOND CONSULTATION	
	Mean	S.D.		Mean	S.D.
NRS-101	37.92	14.81	0.283	33.53	16.49
OSWESTRY	24.07	13.65	0.816	24.93	14.97

The null hypothesis is accepted according to the defined decision rule for both the NRS-101 and the OSWESTRY questionnaires indicating that there was no difference at the time of the second consultation between group 1 (APT) and group 2 (NSAIDs).

Table 4.15 Comparison of the subjective data for groups 1 and 2 at the final consultation using the unpaired t-test

	TREATMENT GROUP 1 (APT): FINAL CONSULTATION		P-VALUE	TREATMENT GROUP 2 (NSAIDs): FINAL CONSULTATION	
	Mean	S.D.		Mean	S.D.
NRS-101	27.50	15.77	0.042	18.38	18.03
OSWESTRY	18.53	15.75	0.290	14.45	13.79

The null hypothesis was rejected according to the defined decision rule for the NRS-101 questionnaire indicating that a difference existed between group 1 and 2 at the final consultation, in terms of pain intensity. This indicates that group 2 (NSAIDs) had less pain at the final consultation than group 1 (APT).

The null hypothesis is accepted according to the defined decision rule for the OSWESTRY questionnaire indicating that no difference existed between group 1 and 2 at the final consultation.

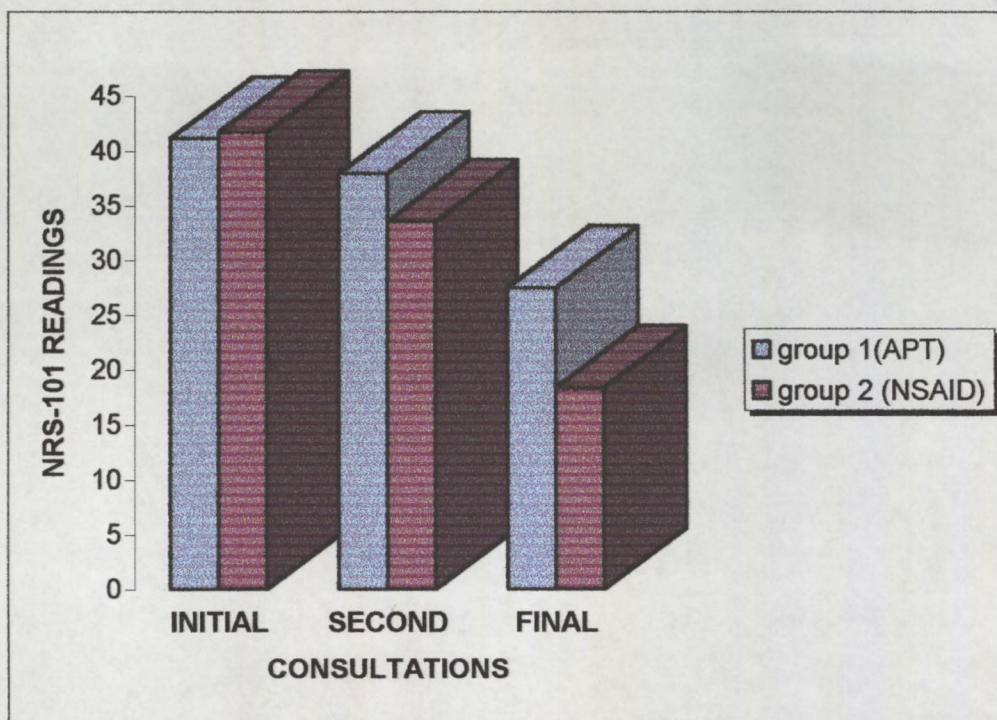


FIGURE 4.1 Mean values of the Numerical Pain Rating Scale-101 at the initial, second and final consultations, comparing the APT and NSAIDs group.

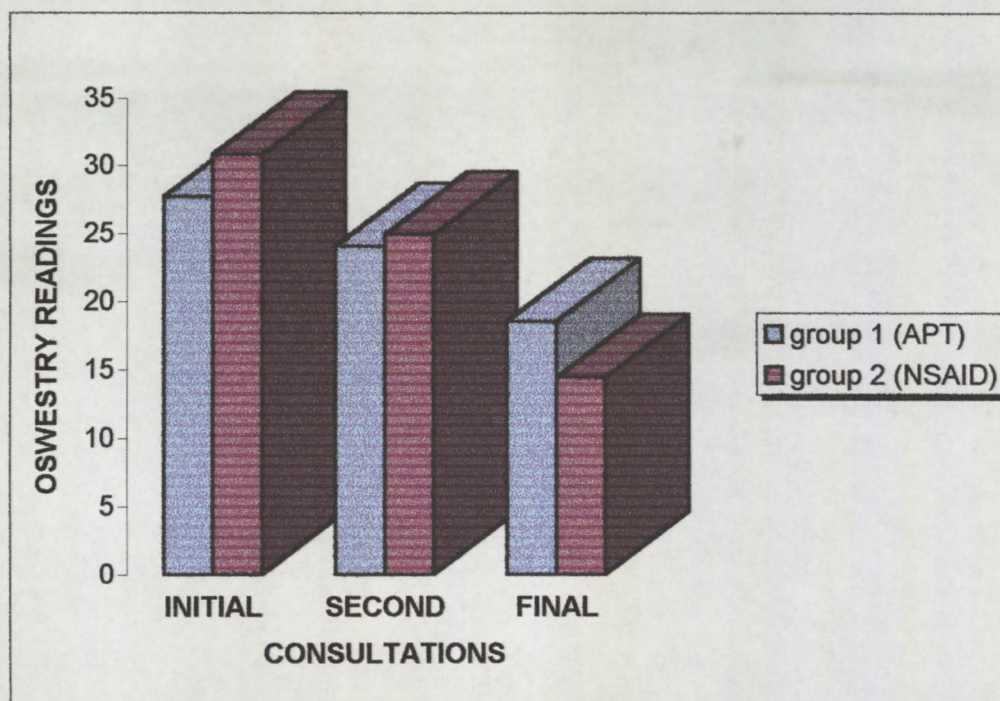


FIGURE 4.2 Mean values of the Revised Oswestry Low Back Pain Disability Index at the initial, second and final consultations, comparing the APT and NSAIDs group.

4.6.2 Analysis of the objective data

Table 4.16 Comparison of the objective data for groups 1 and 2 at the initial consultation using the unpaired t-test

	TREATMENT GROUP 1 (APT): INITIAL CONSULTATION		P-VALUE	TREATMENT GROUP 2 (NSAIDs): INITIAL CONSULTATION	
	Mean	S.D.		Mean	S.D.
ALGOMETER	43.13	18.29	0.510	46.62	22.31
ORS(%)	84.55	8.51	0.774	85.33	12.09

The null hypothesis is accepted according to the defined decision rule for both the ALGOMETER READINGS and the ORTHOPAEDIC RATING SCALE results indicating no difference existed at the initial consultation between group 1 (APT) and group 2 (NSAIDs). This suggests that each group was similarly matched regarding the severity of their LBP at the onset of the study.

Table 4.17 Comparison of the objective data for groups 1 and 2 at the second consultation using the unpaired t-test

	TREATMENT GROUP 1 (APT): SECOND CONSULTATION		P-VALUE	TREATMENT GROUP 2 (NSAIDs): SECOND CONSULTATION	
	Mean	S.D.		Mean	S.D.
ALGOMETER	47.52	18.47	0.248	53.37	20.33
ORS(%)	74.11	12.77	0.214	68.56	20.60

The null hypothesis is accepted according to the defined decision rule for both the ALGOMETER READINGS and the ORTHOPAEDIC RATING SCALE results indicating no difference existed between group 1 (APT) and group 2 (NSAIDs) at the second consultation.

Table 4.18 Comparison of the objective data for groups 1 and 2 at the final consultation using the unpaired t-test

	TREATMENT GROUP 1 (APT): FINAL CONSULTATION		P-VALUE	TREATMENT GROUP 2 (NSAIDs): FINAL CONSULTATION	
	Mean	S.D.		Mean	S.D.
ALGOMETER	58.36	21.65	0.831	59.54	20.81
ORS(%)	48.11	20.70	0.199	41.33	19.68

The null hypothesis is accepted according to the defined decision rule for both the ALGOMETER READINGS and the ORTHOPAEDIC RATING SCALE results indicating no difference existed between group 1 (APT) and group 2 (NSAIDs) at the final consultation.

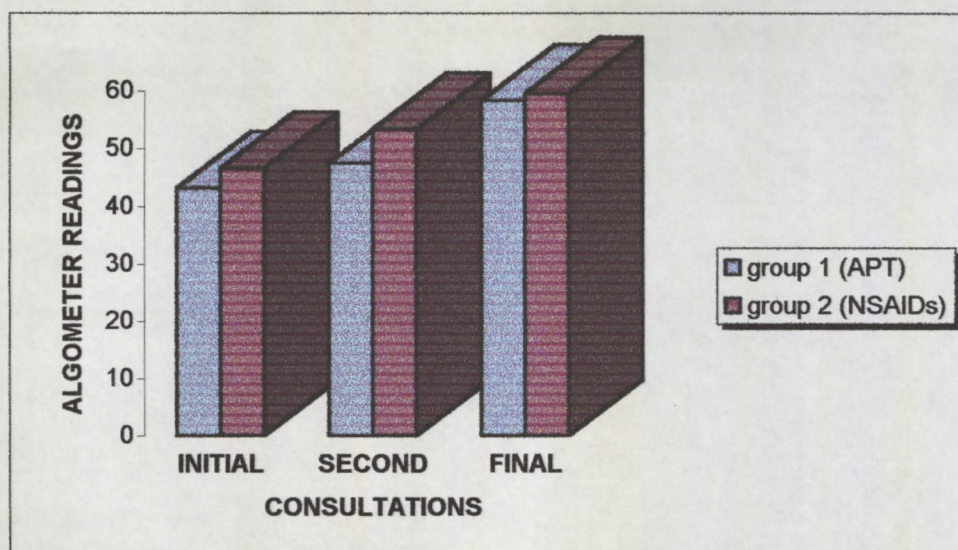


FIGURE 4.3 Mean values of the Algometer Readings at the initial, second and final consultations, comparing the APT and NSAIDs groups.

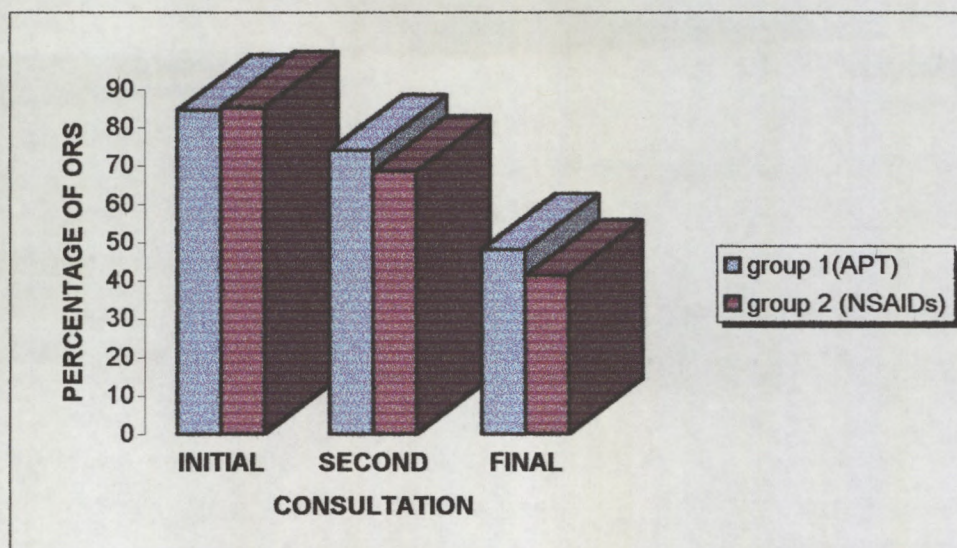


FIGURE 4.4 Mean values of the Orthopaedic Rating Scale (Percentage Analysis) at the initial, second and final consultations comparing the APT and NSAIDs group.

Figure 4.5

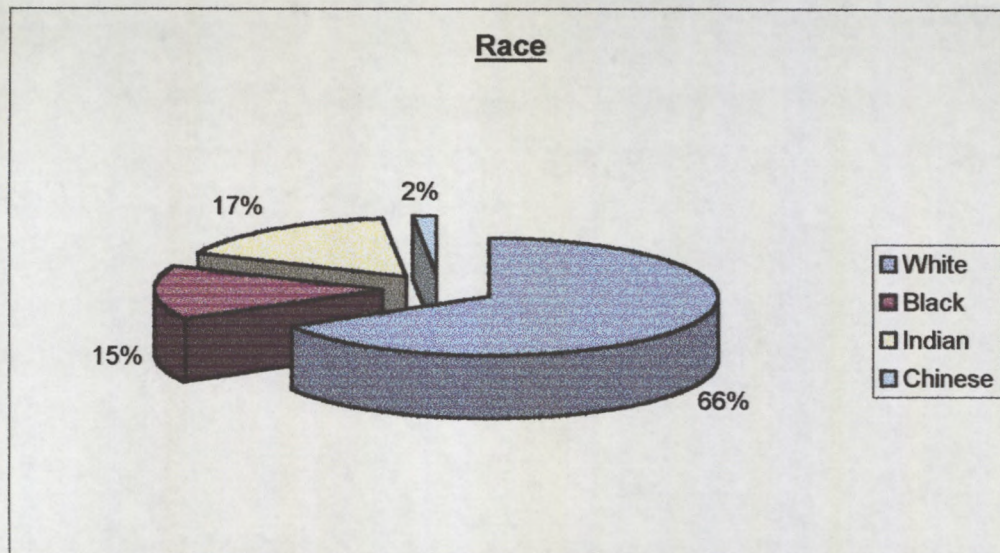


Figure 4.6

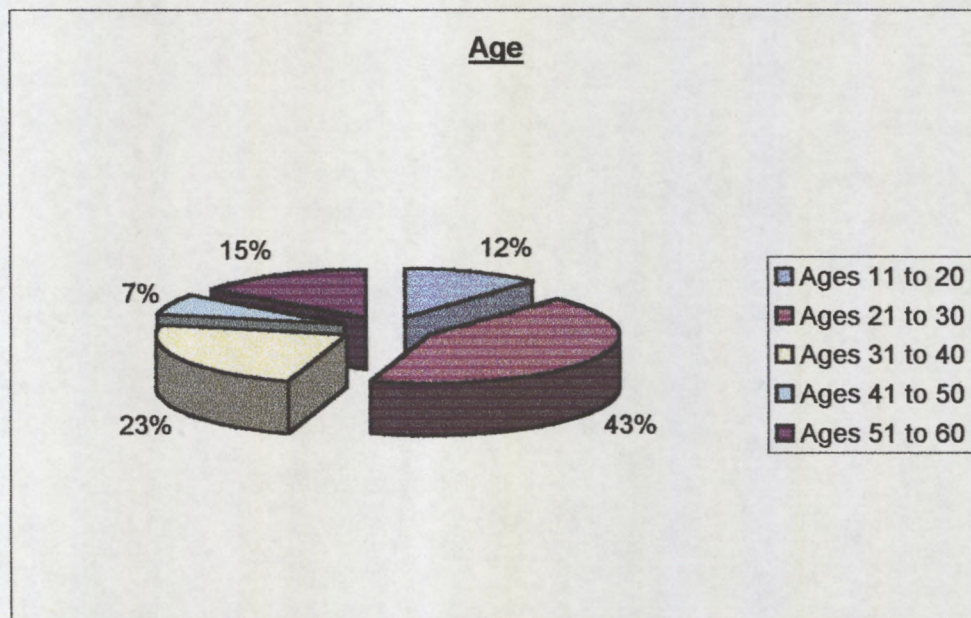


Figure 4.7

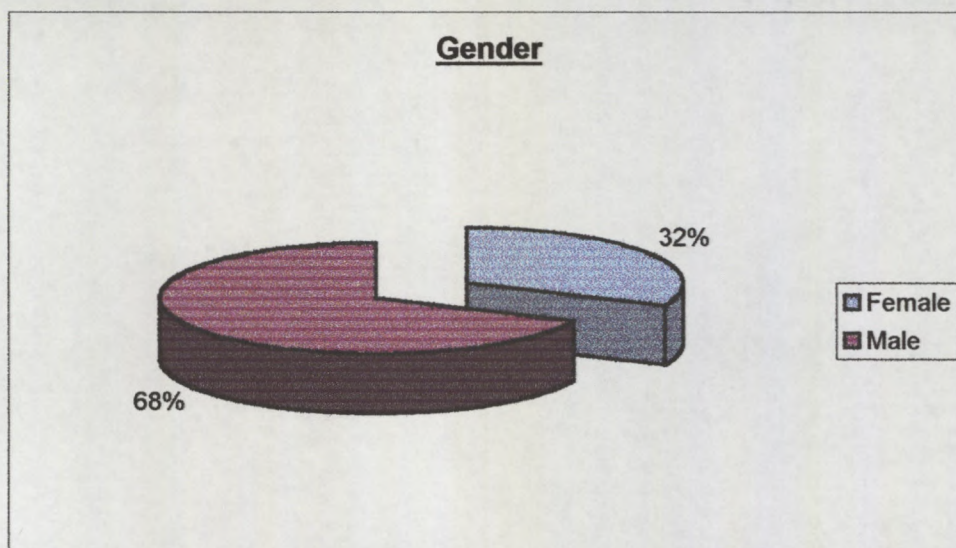
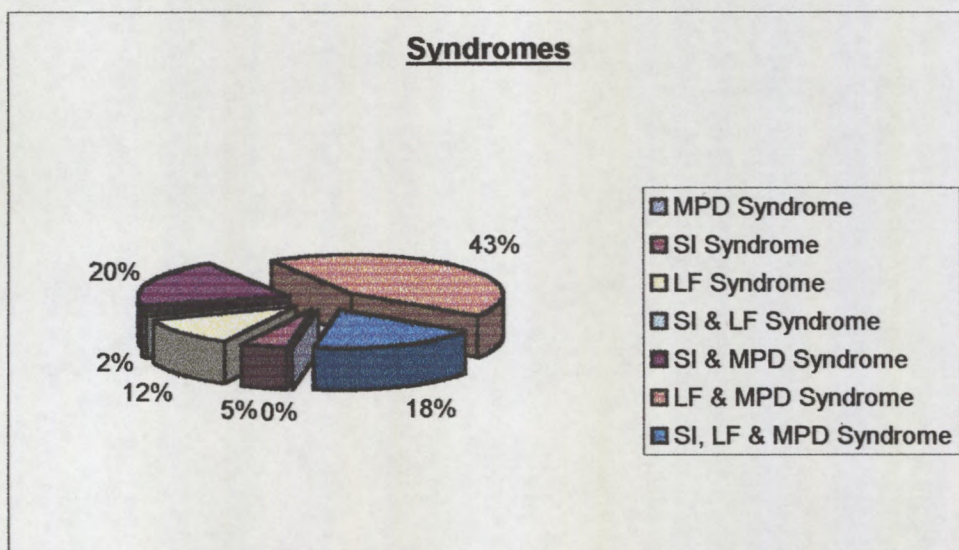


Figure 4.8



Key:	
SI Syndrome	Sacroiliac Syndrome
LF Syndrome	Lumbar Facet Syndrome
MPD Syndrome	Myofascial Pain Syndrome

Table 4.19 Subjects excluded at telephonic interview

Number of subjects excluded	Reason for exclusion
10	Symptoms present longer than 6 weeks
3	Younger than 18; older than 65
2	Diagnosed peptic ulcer
2	Spinal trauma
2	Anaemic
1	Porphyria
1	Breast-feeding

Table 4.20 Drop out from group 1 (APT)

Number of subjects excluded	Reason for exclusion
1	Death in the family
2	Lack of transport
3	Poor compliance
TOTAL: 6	

Table 4.21 Drop out from group 2 (diclofenac sodium)

Number of subjects excluded	Reason for exclusion
1	Horner's syndrome of unknown aetiology
1	Diabetic neuropathy
2	NSAIDs caused abdominal discomfort
1	Asthmatic
2	Poor compliance
TOTAL: 7	

CHAPTER FIVE

5.0 DISCUSSION

5.1 Introduction

This chapter will discuss the assessment of the relative effectiveness of APT compared to diclofenac sodium in the treatment of mechanical low back pain in terms of subjective and objective clinical findings. The subjective data comprised of the Revised Oswestry Low Back Pain and Disability Questionnaire and Numerical Pain Rating Scale-101, whilst the objective data analysed were the results from the algometer readings and the Orthopaedic Rating Scale.

In trying to critically compare APT as an effective modality to other devices for the treatment of low back pain, the evidence was lacking as outcome measures were not similar to this study, and other trials comparing a modality versus medication were not located. There is inconclusive evidence on the efficacy of modalities such as transcutaneous electrical nerve stimulation (TENS) for acute low back pain (Waddell, 2000:270).

APT has had successful results for the treatment of low back pain in combination with spinal manipulation (Atkinson, 2000). This was also indicated in this study, both subjectively and objectively, as a modality used singularly in the treatment of mechanical low back pain.

Studies reviewed by Koes et al. (1997) stated that NSAIDs were effective in the management of low back pain as subjects' disability levels were reduced. The findings of this study were consistent with those of Koes et al. (1997), as indicated by the results of the Oswestry measurements ($p=0.000$), which demonstrated a reduction in pain, and disability levels for group 2. Kantor (1986) also found the use of NSAIDs effective in the management of low back pain, as

did Deyo (1996), which supports the subjective and objective findings of this study.

5.2 PARAMETRIC INTRA-GROUP COMPARISON FOR GROUP 1 (APT) AND GROUP 2 (NSAIDs)

5.2.1 The subjective data

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

The NRS-101 was statistically analysed using the paired t-test.

Within group 1 and 2 an improvement occurred between the initial and second consultations (Table 4.1 and 4.4), and the second and final consultations (Table 4.3 and 4.6).

An improvement occurred between the initial and final consultation ($p=0.000$) (Table 4.2 and 4.5), indicating a reduction in the level of pain experienced for both groups. These findings were consistent with Atkinson (2000), who demonstrated that a significant improvement occurred within each group.

Oswestry Low Back Pain Disability Index Questionnaire (OSWESTRY)

The Oswestry questionnaire was statistically analysed using the paired t-test.

An improvement occurred over the treatment period for both groups, as they were able to carry out activities they previously had difficulty with due to mechanical LBP.

This is shown between the initial and second consultations (Table 4.1 and 4.4), the second and final consultations (Table 4.3 and 4.6), and overall between the

initial and final consultations for group 1 and group 2 ($p=0.000$) (Table 4.2 and 4.5).

5.2.2 The objective data

Algometer readings

The paired t-test was utilized to statistically analyze the data.

An improvement was indicated between the initial and second consultations (Table 4.7 and 4.10) and second and final consultations (Table 4.9 and 4.12), for both groups. The amount of tenderness experienced by the subjects at the initial consultation decreased by the final consultation for both groups. For group 1 ($p=0.000$) (Table 4.8) and group 2 ($p=0.003$) (Table 4.11). This indicates an overall objective improvement for both groups.

Orthopaedic Rating Scale (ORS)

The paired t-test analysis of the ORS indicated an improvement for both groups.

There was a decrease in orthopaedic tests recorded between the initial and second consultations (Table 4.7 and 4.10) and second and final consultations (Table 4.9 and 4.12), for both groups.

Between the initial and final consultations there was an improvement noted for group 1 ($p=0.000$) (Table 4.8) and group 2 ($p=0.000$) (Table 4.11). This indicates that both treatment protocols were effective in reducing the amount of inflammation and tenderness associated with mechanical low back pain.

5.3 PARAMETRIC INTER-GROUP ANALYSIS

5.3.1 The subjective data

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

The NRS-101 results were compared using the unpaired t-test.

At the initial (Table 4.13) and second (Table 4.14) consultations, it was found that there existed a similarity between the two groups. However, at the final consultation (Table 4.15) a difference existed between the two groups. This was as the NSAIDs group 2, perceived less pain intensity than the APT group 1 at the end of the treatment period. This indicates that the NSAID group showed more improvement than the APT group.

Oswestry Low Back Pain Disability Index Questionnaire (OSWESTRY)

Utilizing the unpaired t-test for the Oswestry results revealed that at the time of the initial (Table 4.13), second (Table 4.14) and final consultations (Table 4.15), there was no difference between the two groups. This indicates that in terms of functional disability, either treatment was equally effective.

5.3.2 The objective data

Algometer readings

In analyzing the algometer readings, using the unpaired t-test, no difference between the two groups was indicated at the initial reading (Table 4.16). This suggests that both groups were evenly matched in terms of perceived tenderness at the onset of this study.

Likewise, there was no difference between the two groups at the second (Table 4.17) and final consultations (Table 4.18), although a statistical improvement did occur within both groups.

Orthopaedic Rating Scale (ORS)

At the initial consultation, (Table 4.16) both groups were similar in the amount orthopaedic tests that were positive for mechanical low back pain. This was indicated using the unpaired t-test, which revealed no difference between the two groups. Furthermore, no difference existed between the two groups at the second (Table 4.17) and final consultations (Table 4.18).

5.4 Descriptive statistics

Increased age has been noted to be a risk factor for low back pain, beginning in the third decade of life and reaching a maximum frequency during middle age (Burton and Cassidy, 1992:4). In this study the largest group, 43%, presenting with mechanical low back pain was 21 to 30 years of age. The second largest group, 23%, was of age 31 to 40. The trend is for aging to be less of a risk factor in the elderly (Burton and Cassidy 1992:4). This was reflected in this study as only 7% were in the group 41 to 50, and 15% were 51 to 60 years of age.

According to Burton and Cassidy (1992:4), low back pain is not gender specific. In this study however, 68% of the subjects were male. This figure may not be reflective of the general population, as it is reported that women often experience low back pain during pregnancy, which was an exclusion criteria in this study.

It was found that the combination lumbar facet and myofascial pain dysfunction syndrome, 43%, constituted the greatest proportion of mechanical low back pain. The combination of sacroiliac and myofascial pain dysfunction syndrome was second by 20%, followed by the combinations of lumbar facet, sacroiliac and myofascial pain dysfunction syndromes of which 18% of the subjects in this study

presented with. For the combination of lumbar facet and sacroiliac syndrome, only 2% of subjects were diagnosed. In this study only 5% of subjects suffered from sacroiliac syndrome as a single entity, as opposed to 12% with lumbar facet syndrome and none presented with myofascial pain syndrome alone.

In a study of 1 293 patients treated at the Royal University Hospital Low Back Pain Clinic in Saskatoon over a 12 year period, the specific diagnosis of lesions were:

- 23% sacroiliac syndrome
- 22% posterior facet syndrome
- 6% muscle syndromes

One third of the patients presented with co-existing lesions, one of the most common being posterior facet and sacroiliac syndrome (Kirkaldy-Willis 1992:208). By comparison, 83% of subjects on this trial presented with co-existing lesions, which represents approximately four fifths of the sample size.

5.5 Summary

This study found that although slight differences did occur in favour of the NSAIDs group; it was not sufficient to conclude that one treatment was more effective than the other was.

Demographically, the largest group, 43%, presenting with acute mechanical low back pain was 21 to 30 years of age, 68% of the subjects were male and 83% of subjects had a combination of lumbar facet syndrome, sacroiliac syndrome and myofascial pain syndrome.

CHAPTER SIX

6.0 Recommendations and conclusions

6.1 Recommendations

The following improvements are suggested:

Homogeneity

Stricter inclusion and exclusion criteria with regards to using matched pairs with respect to age, gender, race, occupation and extent of pain and disability, would greatly enhance the strength of the study. It is therefore recommended that future studies include stratification to ensure homogeneity within the two groups. This would improve comparability of baseline patient characteristics.

Blinding

Observer bias could be eliminated by not informing the examiner collecting and collating the data as to which group the patient falls within.

Measurement error

Small but significant changes could be detected as more advanced technology is developed that is more accurate and sensitive.

Compliance

Patient compliance was not measured in this trial.

Orthopaedic Rating Scale

This assessment tool has not yet been validated, and therefore a future study is recommended.

Mechanical Low Back Pain Syndromes

As a number of syndromes constitute mechanical low back pain, it was decided for the purpose of this study to include subjects who had either one syndrome or a combination of two or all three syndromes, namely:

- Lumbar Facet Syndrome
- Sacroiliac Syndrome
- Myofascial Pain Syndrome

However, to statistically evaluate these syndromes was problematic as groups of less than 30 subjects occurred due to the nature of the mechanical low back pain associated with these syndromes. It would therefore have been more beneficial to evaluate one of these syndromes as opposed to a combination.

Sample size

The sample size of this study was limited to sixty subjects. This allowed for the use of parametric testing which enables the detection of subtle changes in the data. An even larger sample size is however recommended as it minimizes the possibility of a Type II error, which is incorrectly accepting the null hypothesis.

Treatment frequency

For this study, a standard treatment frequency was chosen and as a result, the optimum number of visits it would require for a significant recovery was not addressed. It can therefore be assumed that the minimum number of consultations required for significant objective and subjective improvement would be the optimum treatment period.

Scheduled treatments

Each treatment should be scheduled as strictly as possible to ensure consistency and therefore validity of the treatment. This particular study allowed for four treatments over a ten day period with a fifth consultation approximately twenty-four hours after the final treatment to collect the final set of data. There was no

specification of when each treatment was to be administered, except to allow for a twenty-four period between scheduled consultations.

Follow-up consultations

No long-term follow up evaluation was done which would help to address the cost-effectiveness and general effectiveness of treatment protocol utilized. Follow-up consultations are recommended at one month, or possibly, even at a six-month interval, to evaluate the intermediate and long-term effects of the treatment protocol utilized in this study for mechanical low back pain.

Standardized outcome measurement

A standardized set of clinical outcomes would facilitate comparative results of clinical trials of similar studies, which allows for meta-analysis of results, comparison of cost-effectiveness and entails more complete reporting of relevant outcomes (Deyo, 1998:2004).

Epidemiological studies

Studies involving point prevalence and lifetime incidence around the greater Durban area would enhance the reporting of mechanical low back pain and allow for stratification of subjects presenting with this condition at the Natal Chiropractic Day Clinic.

6.2 Conclusions

The results of this study suggest that although there was statistically significant improvement for both *"Action Potential" therapy* and diclofenac sodium, diclofenac sodium proved to be the clinically more effective approach when treating mechanical low back pain. The implications are that *"Action Potential" therapy* could possibly be used as an alternative treatment for patients who may present with contra-indications to nonsteroidal anti-inflammatory drugs.

In future studies the assessment of chronic mechanical low back pain should be addressed, as well as the treatment frequency and long term follow-up. Furthermore, it would be interesting to assess either treatment as an adjunct to other forms of intervention when dealing with mechanical low back pain.

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Appendix A

DICLOFENAC PACKAGE INSERT

SCHEDULING STATUS:

S3

PROPRIETARY NAME:
(and dosage form)

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

COMPOSITION:

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

PHARMACOLOGICAL CLASSIFICATION:

A 3.1 Antirheumatics (Anti-inflammatory Agents)

PHARMACOLOGICAL ACTION:

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

INDICATIONS:

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

CONTRA-INDICATIONS:

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

WARNINGS:

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

DOSAGE AND DIRECTIONS FOR USE:

Usual Adult Dose:

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

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

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

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "Side-effects and special precautions". Treatment is symptomatic and supportive.

IDENTIFICATION:

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

PRESENTATION:

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

STORAGE INSTRUCTIONS:

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

REGISTRATION NUMBER:

ADCO-DICLOFENAC 25 mg: U/3.1/181
ADCO-DICLOFENAC 50 mg: U/3.1/182

NAME AND ADDRESS OF THE APPLICANT:

Adcock Ingram Limited

Adcock Ingram Park
17 Harrison Avenue
Bryanston Ext. 77
Private Bag X69
Bryanston, 2021

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

February 1990

280390 03/97

Excluded Data

Appendix B

CASE HISTORY

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

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

FOR CLINICIAN'S USE ONLY

Initial visit clinician: _____ Signature: _____

Case History:

Examination:

Previous:

Current:

X-Ray Studies:

Previous:

Current:

Clinical Path. Lab:

Previous:

Current:

Case Status:

PTT: Conditional: Signed Off: Final Sign Out:

Recommendations:

Intern's Case History

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

3. Present Illness:

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

4. Other Complaints:

5. Past Medical History:

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

6. Current health status and life-style:

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

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems

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

Appendix C

PHYSICAL EXAMINATION

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient: _____ File #: _____ Date: _____

Clinician: _____ Signature: _____

Intern: _____ Signature: _____

1. VITALS

Pulse rate:

Respiratory rate:

Blood pressure: R L

Temperature:

Height:

Weight:

2. GENERAL EXAMINATION

General Impression:

Skin:

Jaundice:

Pallor:

Clubbing:

Cyanosis (Central/Peripheral):

Oedema:

Lymph nodes: - Head and neck:
 - Axillary:
 - Epitrochlear:
 - Inguinal:

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

1) Is this patient in **Cardiac failure**?

2) Does this patient have signs of **Infective Endocarditis**?

3) Does this patient have **Rheumatic Heart Disease**?

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

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

- Pulses**
- General Impression:
 - Radio-femoral delay:
 - Carotid:
 - Radial:
 - Dorsalis Pedis:
 - Posterior tibial:
 - Popliteal:
 - Femoral:
- Percussion:** - borders of heart
- Auscultation:**
- heart valves (mitral, aortic, tricuspid, pulmonary)
 - Murmurs (timing, systolic/diastolic, site, radiation, grade).

4. RESPIRATORY EXAMINATION

1) Is this patient in Respiratory Distress?

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

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

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

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

5. ABDOMINAL EXAMINATION

1) Is this patient in Liver Failure?

- Inspection**
- Shape:
 - Scars:
 - Hernias:

- Palpation**
- Superficial:
 - Deep = Organomegaly:

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

- Percussion** - Rebound tenderness:
- Ascites:
 - Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

- I Any loss of smell/taste:
Nose examination:

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

- Pupillary light reflexes = Direct:
= Consensual:

- Fundoscopy findings:

III Ocular Muscles:

Eye opening strength:

IV Inferior and Medial movement of eye:

V a. Sensory - Ophthalmic:
- Maxillary:
- Mandibular:
b. Motor - Masseter:
- Jaw lateral movement:
c. Reflexes - Corneal reflex:
- Jaw jerk:

VI Lateral movement of eyes:

VII a. Motor - Raise eyebrows:
- Frown:
- Close eyes against resistance:
- Show teeth:
- Blow out teeth:
b. Taste - Anterior two-thirds of tongue:

VIII General Hearing:

Rinnes = L: R:

Webers lateralisation:

Vestibular function - Nystagmus:
- Rombergs:
- Wallenbergs:

Otoscope examination:

IX & Gag reflex:

X Uvula deviation:

Speech quality:

XI Shoulder lift:
SCM strength:

XII Inspection of tongue (deviation):

Motor System:

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

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

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

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

Sensory System:

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

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

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

Cerebellar function:

Obvious signs of cerebellar dysfunction:

- = Intention tremor:
- = Nystagmus:
- = Truncal Ataxia:

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

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

Obvious Abnormalities:
Spinous percussion:
ROM:
Other:

9. **BREAST EXAMINATION:**

Summon female chaperon.

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

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

Appendix D

LOW BACK REGIONAL EXAMINATION

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

REGIONAL EXAMINATION – LUMBAR SPINE AND PELVIS.

PATIENT: _____

FILE #: _____ DATE: _____

INTERN/RESIDENT: _____

SUPERVISING CLINICIAN: _____

STANDING:

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

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

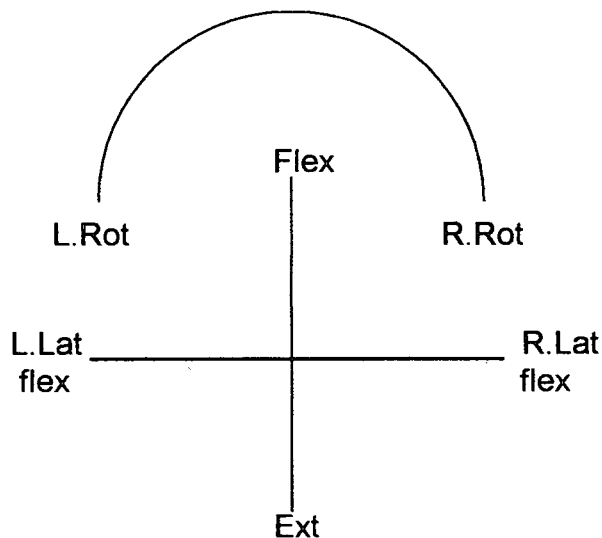
RANGE OF MOTION

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

Extension = 20-35°

L/R Rotation = 3-18°

L/R Lateral Flexion = 15-20°



SUPINE

Skin
Hair
Nails
Palpate Abdomen/groin
Pulses (abdomen)

Observe abdomen
Fasciculations
Abdominal Reflexes

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

Actual
Apparent

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

LATERAL RECUMBENT

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

NON ORGANIC SIGNS

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

GAIT

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

PRONE

Gluteal skyline
Skin rolling
Iliac crest compression
Facet joint challenge
S-I tenderness
Erichson's Test
Pheasant's Test
Myotome:
Glut. Max
Active MF Trigger Pts:
QL
Glut. Med
Glut Min
Glut Max
Piriformis
Hamstrings
TFL

NEUROLOGICAL EXAMINATION

DERMATOMES			MYOTOMES			REFLEXES		
	L	R		L	R		L	R
T12			Hip Flexion			Patella		
L1			Hip int. rotation			Achilles		
L2			Hip ext. rotation			Hamstring		
L3			Hip abduction					
L4			Hip adduction					
L5			Knee flexion					
S1			Knee extension					
S2			Dorsiflexion					
S3			Plantarflexion					
			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 E

ORTHOPAEDIC RATING SCALE

ORTHOPAEDIC ASSESSMENT RATING

LUMBAR FACET SYNDROME				SACROIL/AC SYNDROME				MYOFASCIAL DYSFUNCTION SYNDROME			
	1st visit	2nd visit	6th visit		1st visit	2nd visit	6th visit		1st visit	2nd visit	6th visit
KEMPS TEST [4]				POSTERIOR SHEAR TEST [4]				REFERRAL OF PAIN [4]			
LUMBAR FACET CHALLENGE [4]				GAENSLER'S TEST [2]				LOCAL TWITCH RESPONSE [2]			
PRONE HYPER-EXTENSION TEST [2]				PATRICK FABRE TEST [2]				TAUT PALPABLE BAND [2]			
				ERICHSON'S TEST [2]				EXQUISITE FOCAL TENDERNESS [2]			
TOTAL OUT OF 10 PER SYNDROME											

	1st visit	2nd visit	6th visit
MEAN RATING			

FILE NUMBER:

NAME:

Appendix F

LETTER OF INFORMATION

LETTER OF INFORMATION

Dear participant,

You are invited to participate in a research study entitled "The relative effectiveness of *Action Potential therapy* compared to Diclofenac sodium in the treatment of mechanical low back pain". This study will help determine which of the two are better suited for the treatment of low back pain.

Patients will be randomly assigned into two groups. Both will receive treatment.

One group will receive Diclofenac sodium (the drug used in this study) and placebo *Action Potential therapy*. This means that the *Action Potential* unit will not have any therapeutic benefit. The other group will receive a substance with no medicinal properties and active *Action Potential therapy*. Neither you, nor I (the researcher) will know which group you are in.

You will be required to take the medication three times daily with a glass of water, during or after meals, for seven days. Whilst on this research, if you develop any symptoms not related to your existing complaint or if it becomes worse, please inform me so that we can make arrangements to discontinue your treatment.

You are kindly asked not to alter your lifestyle or to take any other medication whilst you are a participant.

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

You are entitled to withdraw from this study at any time and if you have any questions please do not hesitate to ask me.

Thank-you.

Sonia Bowers

(Chiropractic Intern)

Appendix G

INFORMED CONSENT

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject)

Date : _____

Title of research project : The relative effectiveness of *Action Potential therapy* compared to diclofenac sodium in the treatment of mechanical low back pain

Name of supervisor : Dr C. Myburgh

Name of research student : S.C. Bowers

Please circle appropriate answer

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

INDEMNITY FORM

INDEMNITY

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

1. While every effort has been made to screen the patient for possible drug interactions or effects, the research team cannot be held responsible for ad hoc reactions that may develop. While all patients may be protected by common laws, it is also imperative that the patient specifically indemnifies the research team, including, 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 other member of the research team.

SIDE EFFECTS OF ANTI-INFLAMMATORY DRUGS

1. Gastro-intestinal symptoms including heartburn, acid reflex, indigestion, nausea, vomiting, bleeding and peptic ulcers.
2. Oedema (swelling of body) especially at ankles.
3. Transcient hepatitis.
4. Transcient renal dysfunction.
5. Skin and allergic reactions including uticaria and angioderma.
6. Blood disorders e.g. anaemia, decreased platelets, and 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 I

DRUG SCREENING QUESTIONNAIRE

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

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**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 musculoskeletal disorders (e.g. Aspirin, Dispirin, 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 _____

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

YES _____
NO _____

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

YES _____
NO _____

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. _____

Appendix J

REVISED OSWESTRY LOW BACK & DISABILITY QUESTIONNAIRE

Low back pain and Disability Questionnaire (Revised Oswestry)

Patient Name: _____ File no: _____ Date: _____

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

Section 1 – Pain Intensity

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

Section 2 – Personal Care

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

Section 3 – Lifting

- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I manage if they are conveniently positioned (e.g. on a table).
- ☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can only lift very light weights at the most.

Section 4 – Walking

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

Section 5 – Sitting

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

Section 6 – Standing

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

Section 7 – Sleeping

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

Section 8 – Social life

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

Section 9 – Traveling

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

Section 10 – Changing degrees of pain

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

Adapted from Hsieh et al 1992

Appendix K

NUMERICAL RATING SCALE 101

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 L

ALGOMETER READINGS

PATIENT NAME: _____

FILE NUMBER: _____

ALGOMETER READINGS

1 st READING	2 nd READING	FINAL READING