THE RELATIVE EFFECTIVENESS OF COMBINED SPINAL MANIPULATIVE THERAPY AND *ACTION POTENTIAL THERAPY* VERSUS COMBINED SPINAL MANIPULATIVE THERAPY AND PLACEBO *ACTION POTENTIAL THERAPY* IN THE TREATMENT OF MECHANICAL LOW BACK PAIN

By
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A dissertation presented to the faculty of Health at Technikon Natal in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic

I, Micah Justin Atkinson do declare that this dissertation is representative of my own work.

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DEDICATION

I give the glory to the Lord and the dedication to my family. To my inspiration while conducting this study and completing my degree, my girlfriend Leisha, who made it all worthwhile. And to my mother, who always believed in me and never let me down. To my brother Ivan, my best friend, for his encouragement and friendship. I would also like to extend a special mention to my friend Corrie Myburgh for his tireless support and guidance in completing my studies.

ACKNOWLEDGEMENTS

To my Gran, for putting up with me during the typing and completion of this dissertation.

To my friend and mentor, Dr. Corrie Myburgh, who despite his heavy schedule, always found the time to offer help and guidance during this study.

To Dr. Jonothan Perkin, for sharing the hard times with me and for his support and advice.

To my training partners for believing. You are my second family. This includes Chris, Ketha, Abdul, Asogan and Quintin.

To the patients who participated in this study, for your gifts of patience and time.

I would also like to thank the many fine and dedicated lecturers that I was privileged to have through my years of study. Especially those with years of experience which they so readily imparted to us, namely Drs Glynn Till, Rob Smith, Brian Nook, Jim Brantingham and Rob Matthews.

I would also like to thank Dr. Glenda Matthews for her help and enthusiasm in the analysis of the data during the final stages of this dissertation.

Abstract

Lower back pain represents as a common disorder, with between 60% and 80% of the general population being affected (Kirkaldy-Willis 1992:2). This, apart from just the health aspects, has serious financial implications which are an ongoing concern to industry (Frymoyer 1991:137).

This study was designed to determine the effectiveness of combined spinal manipulation and "Action Potential" therapy versus spinal manipulative therapy and placebo "Action Potential" therapy in the treatment of mechanical lower back pain.

It is currently accepted that spinal manipulation is of great benefit in the treatment of lower back pain (Di Fabio 1992), and it appears that "Action Potential Simulation" therapy, a new low-frequency electrical current therapy, would fit the criteria necessary to address the dysfunctional phase of low back pain as set out by the authors such as Kirkaldy-Willis (1988).

This randomized placebo-controlled clinical trial consisted of a study population of sixty patients. Each of these voluntary patients were diagnosed as either suffering from a Posterior facet syndrome of the lumbar spine, a Sacro-iliac joint syndrome or a combination of both. There were two groups of thirty patients, each of whom received four consultations over a two week period. Group 1 received spinal manipulative therapy according to their diagnosis and active "Action Potential" therapy while group 2 received a spinal manipulation and a placebo "Action Potential" therapy. The spinal manipulative procedure was performed at the initial consultation only, which was followed by three more consultations consisting of either active or placebo "Action Potential" therapy.

The outcome measurements included the response of patients to the NRS-101 pain intensity scale and the Ostwestry Back Disability Index. Objective data was gathered from goniometric and pressure algometry measurements. All the above were taken at the initial consultation, prior to the second consultation, the fourth and final visit.

Intra-group comparisons revealed that group 1 (experimental group) showed a progressive, significant improvement in all variables tested over the treatment intervals, except for the Ostwestry questionnaire, at the second measurement interval. This was attributed to the large negative change that took place during the first measurement interval. Patients often had no significant disability at the second treatment.
Group 2 (control group) also presented with a uniform, significant change in the variables tested, however right rotation did not significantly change within the group for the second measurement interval.

The inter-group comparison revealed a significant difference between the two groups in all areas but two, namely right lateral flexion and the Oswestry questionnaire. These results indicated that the experimental group improved significantly beyond the control group in almost every facet investigated. It is important to note that the left lateral flexion values as well as the NRS-101 values were not significantly different initially, but were so by the end of the study (a significance was almost established with right lateral flexion). This indicates a positive change from the baseline, as opposed to a change due to variance. This was further confirmed by the one-tailed version of the t-tests performed. Furthermore, on intra-group assessment, no significant change occurred within the control group, where as a highly significant change had taken place at the same time within the experimental group. This strengthens the argument for a greater degree of improvement within the experimental group.

It was therefore concluded that the combination of spinal manipulative therapy and active "Action Potential" therapy enabled patients to improve to a greater extent at the end of the set treatment period, when compared to the spinal manipulative procedure combined with a placebo treatment.

For further studies observer bias could be eliminated by not informing the examiner collecting and collating the data as to which group the patient falls within.
Individual patient characteristics such as age, sex, race and history of complaint should also be taken into account in future studies.

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Chapter 1

1.0 Introduction

1.1 The problem and it's setting:

Current literature reveals that between 60% and 80% of the general population will at some stage of their lives suffer with low back pain (Kirkaldy-Willis 1992: 2).
Apart from just the health aspects associated with low back pain, there are also substantial financial implications associated with it as well. These financial implications are well documented and are a major ongoing concern to industry (Frymoyer 1991: 137).

A well established model exists describing the patho-anatomy and patho-physiology of mechanical low back pain (Kirkaldy-Wllis 1988: 134), however no standardized and effectively proven treatment protocol has as yet been agreed upon to treat even the least complicated of mechanical back pain syndromes, namely spinal dysfunction (Van Tulder et al. 1997).

Various forms of manual therapy have been widely used to treat somatic pain syndromes and associated disorders of the back (Di Fabio 1992). Increasing ranges of motion, whilst at the same time decreasing muscle spasm and pain, is used to counter the patho-anatomy and patho-physiology of the dysfunctional phase of low back pain represented by the phenomena of facet subluxation, synovitis and segmental muscle spasm (Kirkaldy-Willis 1988: 133-135).

It is currently felt that spinal manipulation is of great benefit in the treatment of low back pain. This is largely due to the extensive studies conducted that have yielded significant

results when pitted against some type of spinal mobilization in a clinical trial setting (Di Fabio 1992). As a result, manual therapists have traditionally utilized spinal manipulation to reach this goal (Haldeman et al. 1993).

A new low-frequency electrical current therapy, "Action Potential Simulation" (APS) current, has been used as a stand-alone treatment, both by the lay public, health professionals, and in the physiotherapy arena, since 1994. (Berger 1999)
It appears that "Action Potential" current therapy is associated with pain alleviation, enhanced joint flexibility, a decrease in oedema due to improved circulation and possibly, reduced inflammation (Berger 1999).

It appears therefore that "Action Potential Simulation" therapy would fit the criteria necessary to address the dysfunctional phase of low back pain as set out by authors such as Kirkaldy-Willis (1988). However the major shortcomings in the research in the approach of both manipulation and "Action Potential Simulation" therapy is that the focus is given to only one approach rather than to a treatment involving a combination protocol.

This study will attempt to address some of these major research method shortcomings, whilst attempting to establish if spinal manipulative therapy in conjunction with "Action Potential Simulation" therapy is more effective as a treatment protocol, in the management of uncomplicated mechanical low back pain, than just manipulative therapy on it's own.

1.2 Aims and Objectives of the study:

The aim of this study is to determine the relative effectiveness of combined spinal manipulative therapy and "Action Potential" therapy versus spinal manipulative therapy and placebo "Action Potential" therapy in the treatment of mechanical low back pain.

Objective one will be to determine the relative effectiveness of combined spinal manipulative therapy and "Action Potential" therapy versus spinal manipulative therapy and placebo "Action Potential" therapy, in terms of subjective measures.

Objective two will be to determine the relative effectiveness of combined spinal manipulative therapy and "Action Potential" therapy versus spinal manipulative therapy and placebo "Action Potential" therapy, in terms of objective measures.

1.3 Benefits of the study:

This study should add to the pool of knowledge with regards to the topic of mechanical low back pain by confirming trends as found by authors such as Di Fabio (1992) and it aims to accomplish this using the research method oulines suggested by authors such as Koes et al. (1996) and Van Tulder et al. (1997).
A well-designed randomized clinical trial could serve as a "blue print" for future studies to be fashioned, taking into account the methodological principles proposed by the author, to attain results that are both conclusive as well as repeatable.

The author hopes that this investigation will serve to inspire those affected to search for answers to the many questions that still elude us regarding the treatment of mechanical low back pain.

Chapter 2

2.0 Review of the related literature

2.1 Introduction:

The following is an overview of the related literature concerned with clinical trials on the topics of spinal manipulative therapy and the use of "Action Potential" therapy in the treatment of mechanical low back pain. The theoretic basis for the action and effects of spinal manipulation and "Action Potential" therapy as well as the basic clinical, etiological and epidemiological aspects of each are presented.

2.2 Spinal degeneration and the need for effective treatment:

The classification of low back pain utilised by this study is that as set out by Kirkaldy-Willis (1988: 117-131), which categorizes low back pain into three separate stages, namely: **dysfunction, instability and stabilization.**

Stage 1 Dysfunction:
The cause of pathology during this phase is said to be due possibly to sprains, synovitis and associated synovial fringe nipping of the facet joints, para-spinal muscle spasm resulting in joint dysfunction and entrapment of the facet joint meniscoids. The aforementioned result in intra-articular adhesions and slight degeneration of the articular cartilage.
The intervertebral disc is affected as it develops circumferential tears within the substance of the annulus fibrosis, which when they increase in number, coalesce to form radial tears. These weaken the disc and predispose it to bulging and even herniation of the inner nucleus pulposis.
This type of pathophysiology is associated with the following symptoms:

1) Facet joint inflammation which results in the production of inflammatory metabolites which in return stimulate pain sensitive nociceptors,

2) Muscle spasm which leads to ischaemia and subsequently the pooling of metabolites, the associated chemical irritation often results in the stimulation of pain sensitive nerve endings,
3) Joint dysfunction which results in a disturbance in proprioception and gate control which as a result augments the perception of pain, this is a scleratogenous pain and as a result may be referred or localized, and
4) The effect of disc pathology, if severe enough, can result in nerve root irritation following radicular pain characteristics.

Stage 2 Instability:

If the degeneration of stage 1 is allowed to continue the result is often gross disc disruption, which is characterized by a decrease in discal water, proteoglycans and a coalesence of radial annular tears. A loss of disc height and circumferential bulging of the annulus, hyperlaxity of the facet joint capsule and increased degeneration of the facet joint cartilage, oseous erosion and ultimately osteophyte formation soon follow. The final outcome is excessive intersegmental motion leading to subluxation and lateral canal entrapment.

This phase is associated with the following symptoms:

1) Coalescence of the radial tears resulting in disc herniation which results in nerve root compression and consequently muscle weakness, reduced tendon reflexes and dermatomal hypoaesthesia,
2) Inflammation resulting in muscle spasm and consequently antalgia, and
3) Excessive movement resulting in intermittent lateral nerve root entrapments at one level with radicular patterns of pain referral which are aggrevated by flexion, extension and rotational movements.

Stage 3 Stabilization:

This stage is characterized by the advancing pathology resulting in enlargement of the superior and inferior facets, the formation of osteophytes, a loss of articular cartilage and periarticular fibrosis.

Much of the disc is replaced by fibrous tissue which causes a substantial reduction in disc height. Radiographic examination reveals signs of subchondral sclerosis, peripheral osteophytes and a certain degree of ankylosis.

The symptoms for this phase include:

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

The symptoms related to this condition are partly due to impaired blood circulation and also partly due to nerve compression. The consequences can often include cauda equina syndrome and neurogenic claudication.

2.2.1 Clinical considerations:

Kirkaldy-Willis (1992: 121) went further to expand on his model for low back pain by grouping specific clinical lesions together that are most likely to occur within each phase of spinal degeneration. 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

Sacroilac syndrome

Maigne's syndrome

Various myofascial dysfunction syndromes of the following muscles: gluteus maximus, gluteus medius, gluteus minimus, quadratus lumborum, piriformis, tensor Fascia latae and the hamstring group.

In the second phase, instability, the following are included:

Disc herniation

Facet and disc degeneration

Lateral stenosis

Central stenosis

In the third and final stage, stabilization, the following conditions are included:

Lateral stenosis

Central stenosis

Multilevel stenosis

Disc herniation

2.2.2 Diagnostic criteria:

As this focuses primarily on the first phase, that of dysfunction, and even more specifically on the Posterior facet syndrome of the lumbar spine and the Sacroiliac syndrome, the criteria for their diagnosis will be most pertinent.

The Posterior facet is characterized by localized pain over the involved area and is usually experienced unilaterally. Referred pain is experienced into the buttock region, posterior and lateral thigh, and is rarely felt below the level of the knee.
The nature of the pain experienced is sclerotogenous i.e. a dull, deep and poorly defined pain. The severity of the pain varies from fairly mild to severe. The condition is aggravated by movement whilst rest relieves the pain. The associated clinical *signs* include localized tenderness to palpation over the affected areas, hypertonic paraspinal musculature, and reduced range of motion in the lumbar spine, namely in extension, which aggravates the condition due to compression of the facet joints. Kemp's test and

facet joint challenge in the lumbar region are usually positive (Kirkaldy-Willis 1992: 122-126).

The typical symptoms of Sacroiliac joint syndrome are pain of varying severity over the back of the involved sacroiliac joint. The pain is often referred into the groin, over the greater trochanter, down the posterior thigh, to the knee and occasionally, down the lateral or posterior calf to the ankle, foot and toes.
The clinical signs include tenderness to pressure applied over the region of the sacroiliac joint or in the buttock. Motion palpation often indicates a reduction in motion in the sagittal plane. The diagnosis of the sacroiliac joint syndrome is usually confirmed by positive findings in the following orthopaedic tests: the Patrick Faber, Gaenslen's, Erichsen's and lateral recumbent sacroilaic compression (Kirkaldy-Willis 1992: 123-124).

These two conditions are often complicated by the development of the other at a later stage (Kirkaldy-Willis 1988: 133).

2.2.3 The economic implications of low back pain:

It can be clearly seen from the previous discussion that the relatively "benign" phase of dysfunction has the ability to progress into a major disability associated with the instability and stabilization phase, if not effectively dealt with from the onset.

This seems to hold true when we consider the natural history of low back pain complaints.
Also although it is generally understood that low back pain is a fairly common condition it's true impact on the cost of health care is often not fully appreciated.
A controlled prospective study by Bergquist-Ullman and Larson (1977), as sited in Di Fabio (1992), involving 217 acute- and subacute low back pain sufferers found that out of

the 184 patients who complied to the study, the mean sick leave duration was 21 days. It is also interesting to note that, 151 of them also suffered a recurrence within 1 year, causing a further average of 16 days absenteeism from work. This study indicated that for the 82% of patients suffering a recurrence, the absenteeism almost doubled. It could thus be extrapolated that the treatment strategies implemented were not adequate to sustain long-term health in the majority of the patients.

Frymoyer (1991: 10-19), stated that following an attempt to describe the costs involved in the management of low back pain disorders he found the following:

1. In subjects aged 25 – 44 years, the average lost work days per 100 workers was calculated at 28.6 days per year,
2. That of the 50 million working males aged between 18 and 55 years old in the U.S.A., low back pain resulted in a total of 17 million work days lost each year, and
3. The total cost for low back disorders in the U.S.A. is estimated to range between 16 and 60 million dollars a year.

Although Halder et al. (1987) suggests that there is spontaneous recovery rate of 80% for patients suffering from mechanical low back pain of less than four weeks duration, Kirkaldy-Willis (1992), states that 60% of these patients have a chance of recurrence in their low back pain over the following two years.
The above studies also, although indirectly, give an indication of the great costs involved. These costs are due to the amount of treatment required and indirectly, yet more importantly as a result of the workers compensation and loss of productivity from the complications encountered after the initial treatment of low back pain.

2.3 Spinal Manipulation:

Spinal manipulation involves carrying the joint deep into the para-physiological range of motion for a very short time, the process of which can often be identified by a cracking sound within the joint (Sandoz 1976). The result is an increase in the passive range of

motion of the joint in all directions. The possible effects of manipulation according to Calliet (1981: 129-130) are as follows:

1. A facet joint is immobilized by an acute synovial reaction and adherence of the joint surfaces of the facets takes place. The passive movement of the manipulation separates these surfaces,
2. manipulation allows an entrapped meniscus to exit the facet joint in which it became entrapped,
3. the capsule of the facet joint becomes lodged between two adjacent articular surfaces and the manipulative process allows this capsule to be freed,
4. the mechano-receptors of the joint are desensitized by the abrupt movement of the joint (manipulation), and reflex protective spasm is eliminated and allows the joint to move again,
5. the spindle systems of the adjacent muscles are reflexly stimulated by the dynamic thrust of the manipulation and reciprocally relax the extrafusal muscle fibers, and
6. the mal-aligned spinal segments are realigned to conform to the centre of gravity.

Wyke (1985:75) suggests that the mechanoreceptor system has collateral branches of innervation which synapse on the nociceptor system, and that these synapses are inhibitory because of the type of neurotransmitter substance they release. Therefore, stimulation of the peripheral mechanoreceptor system through the manipulation will cause a pre-synaptic inhibition of nociceptive activity before it can be transmitted up into the central nervous system and be perceived as pain.
However, Bergmann et al. (1993: 139) reports that the specific mechanical and physiological changes that take place to relieve the signs and symptoms of joint dysfunction have not been accurately determined.

Contra-indications to spinal manipultion:

As previously discussed the selection criteria for subjects aimed at admitting only those suffering from simple mechanical low back pain, however manipulation has been thought to be contra-indicated in more ominous conditions where the indiscriminate application

of dynamic thrust may lead to adverse effects on the patient (Haldeman et al. 1993: 170-172).

Gatterman (1990: 67) lists the contra-indications to manipulaion of the lumbar spine as follows:

Athero-sclerosis of major blood vessels, abdominal aneurism, prostate and bone tumours, bone infections (e.g. T.B., osteomyilitis), traumatic injuries (e.g. fractures, instability), arthritis (e.g. ankylosing spondylitis), psychological disorders (e.g. malingering), metabollic disorders (e.g. clotting disorders) and neurological disorders (e.g. space occupying lesions).

2.3.1 The efficacy of spinal manipulation:

There have been several studies conducted indicating that spinal manipulation on the low back is an effective treatment when compared to a placebo-control group (Di Fabio 1992)

In a review of relevant studies by Haldeman and Phillips (1991 2: 1582-1583), the authors suggest that manipulation is a significantly more effective treatment than bed rest and analgesia, analgesia alone, short wave therapy, heat, exercises and massage, or mobilization, in the treatment of low back pain. Di-Fabio (1992), in an analysis of valid trials of manual therapy in the treatment of low back pain, concluded that manipulation particularly, is an effective modality. In a study concerning clinical trials of spinal manipulative therapy, using meta-analytical techniques, Anderson et al. (1992) found spinal manipulative therapy to be consistently more effective in the treatment of low back pain than any of the array of comparison treatments. In a review of relevant randomized clinical trials by Assendelft et al. (1992), in which the efficacy of chiropractic manipulation for low back pain was assessed, it was concluded that chiropractic seemed to be an effective treatment of low back pain.

The Rand Corporation of Santa Monica, California, a highly respected multi-disciplinary research organisation, published a report in 1991 entitled "The Appropriateness of Spinal Manipulation for Low-Back pain". This report reviewed all the medical research that

existed on low-back pain from 1955-1991, scientifically comparing spinal manipulation with other methods of treatment for low back pain. The report concluded that spinal manipulation gave the most relief to patients who had a particular kind of low back pain, specifically if there were no fracture or tumor and if the pain was of a fairly short duration. They found in these patients, manipulation was better than conventional medical treatment such as bed rest and analgesics. (Shekelle et al. 1991)

Glover et al. (1974) as well as Fisk (1979), both also noted the immediate reduction in pain symptoms in low back pain following manipulation, as cited in Di Fabio (1992).

Nwuga (1982) conducted a clinical trial in Nigeria comparing the relative therapeutic efficacy of vertebral manipulation versus a conventional treatment consisting of short wave diathermy followed by gentle isometric exercises and education in the proper mechanics of lifting and posture. A total of 51 patients with acute low back pain were randomly allocated to one of two groups.
All patients were, treated by the same therapist. The results showed
(highly) significant differences between the two groups with regards to post-treatment differences in total flexion and extension, lateral flexion, rotation and straight leg raising in favor of the manipulated patients. The manipulated group showed flexion and extension improved by 34% as opposed to only 13% in the conventional treatment group. Side flexion was 9% in the manipulation group and only 3% in the conventional treatment group and rotation in the manipulated group 7% as opposed to 2% in the conventional treatment group. Straight leg raising improved 39% in the manipulated group and 4% in the conventional treatment group. The author concluded that, "manipulation therapy as shown by this study was superior to the conventional method in the treatment described" (Nwuga, 1982).
A study conducted by Seferlis et al. (1998), evaluating three different conservative treatment methods for patients sick listed for low back pain, found that after one month all groups improved significantly.
However the manipulation group reported the most satisfaction with their treatment as opposed to the general practitioner program and the intensive training program.

A review of 35 randomized trials by Koes et al. (1991), comparing spinal manipulative techniques with other forms of conservative therapy concluded that the efficacy of manipulative treatment for patients with back and neck pain had not been convincingly demonstrated. The papers assessed included physiotherapists, osteopaths and chiropractors.
This study was not aimed at discrediting previous studies, but was aimed at making researchers aware of improvements needed in research design and as a result render future results achieved less vulnerable to technical error criticism.

In a Canadian study conducted by Kirkaldy-Willis, a specialist in orthopedics, and Cassidy, a chiropractor, 283 patients with chronic low back pain and leg pain were treated by spinal manipulation for 2-3 weeks. Results showed that 81% of the patients with referred pain improved markedly and had no pain, or mild intermittent pain and no restriction for work or other activities; and 48% of patients with nerve compression experienced a similar marked improvement in their condition (Kirkaldy-Willis and Cassidy 1985).

They went on to say that in most cases there was an initial increase in symptoms after manipulation, but the increase is temporary and in their opinion was easily controlled with the application of ice.
This principle of pain control is one item that this study will be seeking to ascertain. Namely to determine that with the use of Action Potential therapy there will not be a perceived increase in symptoms, post manipulation in the initial stages.

2.3.2. Cost Effectiveness of Manipulation:

According to a study by Meade (1990) there is economic support for the use of chiropractic in the management of low back pain, though the obvious clinical improvement in pain and disability attributable to chiropractic treatment is in itself an adequate reason for considering the use of chiropractic (Meade 1990).

These conclusions were also arrived at in the Rand Report and the Californian studies mentioned in 2.3.1 above.

2.3.3. Electotherapy theory and practice:

A study conducted by Lindsay et al. (1990) entitled: "A survey of electromodality usage in private physiotherapy practices", found that Transcutaneous electrical stimulation and interferential current units were two extensively used forms of electrotherapy modalities.

Foster and Palatanga (1985) state that Transcutaneous electrical nerve stimulation can be a useful method of reducing or even removing pain in chronic pain syndromes. They go on to state, however, that in order to achieve successful results the treatment parameters need to be altered with considerable experimentation in pulse widths, frequency and intensity.

Interferential Therapy is based on the principle, according to Foster and Palastanga (1985), that interference is produced where two medium frequency currents cross in the patients tissues. They state pain may be effectively relieved due to stimulation of large diameter nerve fibers which have an effect on the pain gate in the posterior horn and inhibit transmission of small diameter nociceptive impulses.

A study by Ganne (1975) : Interferential therapy. The Australian Journal of Physio therapy found that provided it is applied correctly interferential therapy is undoubtedly an effective therapy for pain control. It went on to state, however, that there was scant literature available on the specificity of its clinical effects.

It can, therefore, be seen due to the disparity in research it is important for us to look for specificity in the use of electrotherapy in pain relief.

2.4 *Action Potential Current* therapy:

2.4.1 Introduction:

The concept of Action Potential Simulation current therapy was initiated in 1992 by A Lubbe, a technician in the employ of a parastatal telecommunications company in South Africa (Berger 1999). He had read in a medical journal, that the body's natural nerve impulses are restricted or diminished by waste products and that if it was possible to simulate a current that was the same as the body's normal nerve impulse (action potential), and apply it to the body in the correct area, it would ease pain.
He developed this concept, and it was found that some patients did indeed experience relief. It was also notable that, in some patients, there was dramatic relief of symptoms even after one treatment and even in patients who had obtained little relief from other therapies.

The original prototype of this treatment was then tested at various universities in South Africa.

Action Potential Simulation therapy was tested at the HF Verwoerd Hospital, Department of Neurosurgey, University of Pretoria. It was used on a variety of patients with intractable pain and had obtained little relief from other therapies including surgery. These patients suffered from a variety of painful conditions including low back pain, intercostal neuralgia, carpal tunnel syndrome and muscular spasm headaches. It is reported, by Berger (1999), that many of these patients responded favorably to the Action Potential therapy, with no recorded side effects, and the economic implications of the treatment were minimal.

Berger (1999) also noted that, a general practitioner made an assessment of the effects of Action Potential therapy in the treatment of painful musculo-skeletal conditions on 500 patients. It is reported that he found an improvement in pain relief, a reduction in swelling in inflamed joints and improvement in mobility in many of these patients.

2.4.2 *Action Potential Current* Therapy:

According to Lubbe, "Action Potential" therapy is a low-frequency current that simulates the naturally occurring action potential in a neuron Berger (1999).

Reed (1995; 1:2-7), states that action potential (AP) is a wave of electrochemical activity that passes along the nerve fiber due to the reversal of the membrane potential. A potential difference exists between the concentration of ions in- and out-side of the cell membrane and the movements of these ions is referred to as the sodium-potassium pump. In the normal polarized state of the neuronal cell there are relatively more sodium ions outside the cell membrane than potassium ions (the opposite is true for within the cell body). Depolarization occurs when this situation is reversed and there are relatively more sodium ions than potassium ions within the cell. As a result there is a release of energy stored within the cell membrane created by the potential difference that occurs as a result of the ions charges on either side of the cell membrane.
The cell automatically re-polarizes as the sodium and potassium ions are restored to their former concentrations.
The sodium-potassium pump continues it's action until sufficient energy is released for depolarization and re-polarization to occur automatically (Reed 1995).
This discharge of energy (the action potential) then passes along the axon of the neuron until the next synapse where the process is repeated along the neuron like a chain reaction.

Injury or disease processes can result in poor transmission or even cessation of the conduction of action potentials along the neuron. This may be due to damage to the Schwann protective sheath of the neuron itself or as a result of accumulated waste products in tissues due to inflammation (Berger 1999).

The current supplied by the "Action Potential" therapy modality is, according to Reed (1995), stronger than the normal current required to produce the action potential in the neuron and as a result depolarization takes place.
The resultant effect is an increase in the rate of action potentials produced, and since the action potential is an "all or nothing" phenomenon, it cannot be larger or smaller, it either is or is not present.

The current created by "Action Potential" therapy modalities is a mono-phasic square pulse with an exponential decay. It is neither direct, interrupted direct, alternating nor rectified alternating. It is a combination of direct and alternating current (Berger 1999).

The main aim of treatment, according to Berger (1999), is to place the negative electrodes on the painful region and the positive electrodes on the opposite side of the body, away from the negative. This prevents current passing only from negative to positive electrode and avoiding the actual area of treatment.

Berger (1999) lists the following as some of the physiological effects of Action Potential therapy:

1. Electrolytic effects in the treated area, it is postulated breaks down biochemical waste products from inflammation and excess fluid.
2. Leu-enkephalin, a spinal anti-inflammatory with (according to Melzack and Wall) pain modulating effects, levels are increased.
3. Increased melatonin levels. Melatonin is an anti-anxiolytic that induces relief from anxiety.
4. Improved circulation resulting in increased antibodies, enzymes, neuro-transmitters and hormones being transported to the treated area. Improved circulation also has a beneficial effect in the reduction of swelling which as a result may positively affect lymph drainage.

2.4.3 <u>The efficacy of Action Potential therapy:</u>

A double blinded, placebo controlled, randomised study, entitled: "*An investigation into the Neurohormonal Consequences of Action Potential Simulation Therapy*" by De Wet and Oosthuizen (in publication September 1999), was executed on 20 patients at the Pain Control Unit, National Hospital, University of the Orange Free State, Bloemfontein, in 1997. This study was part of a larger study of 78 patients with chronic back pain. This project was aimed at determining the neurohormonal effects of Action Potential therapy on beta-endorphin, leu-enkephalin, melatonin, seratonin and cortisol. Blood samples were collected and standard laboratory techniques and radio-immune assays were used to determine the hormone concentrations after Action Potential therapy.
The results demonstrated an increase in the serum concentration of melatonin after the second treatment, and in leu-enkephalin after the fourth treatment. Beta-endorphin concentrations decreased after five treatments and seratonin and cortisol levesl remained within normal limits after six treatments (in publication).

A randomised, patient-blinded, placebo-controlled study involving patients with chronic back –ache owing to stress fractures in the lumbar spine of osteoporosis patients was conducted at the Pain Control Unit, Department of Anaesthesiology, University of the Orange Free State, Bloemfontein (Oedendaal et al., 1999).
A total of 76 patients participated in the study (43 in the Action Potential therapy group and 33 in a placebo control group). After 6 treatments of 16 minutes each every second day a statistically highly significant result was obtained in the Action Potential therapy group. Visual analogue scale (VAS) evaluations were performed directly before each treatment reflecting the pain situation for the previous 24 hours. The improvement was reflected in the mean pre-treatment baseline VAS value of 57.79 in the Action Potential group, that diminished to a post-treatment value after the sixth treatment of 9.7 ($p=0.0001$).
Berger (1999) reports that Action Potential therapy can be used effectively in conjunction with other modalities. Keeping with the findings of de Wet and Oosthuizen (1999), that the neuro-hormonal effects could lead to the following beneficial effects:

1. Analgesia- due to more effective utilization of the endogenous opiods and the inhibition of pain transmission,

2. The 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 vasodilation and better perfusion of the affected areas,
4. And anti-inflammatory effects- due to beneficial influences on the prostaglandin mechanisms.

It is therefore felt that it may be best to use Action Potential therapy after other modalities such as manual therapy to target the exact region of pain (Berger 1999: 49).

Contra-indications to Action Potential therapy:

The manufacturers state that the use of Action Potential therapy is absolutely contra-indicated in patients with pacemakers, over the abdomen in pregnant patients and in epileptic sufferers.

It is also recommended that it be used with caution in patients who are on anticoagulant medication or who have allergies to any medications.

It is stated that Action Potential therapy can, however be safely used on patients that have Harrington rods or other metal surgical implants.

2.5 Summary:

The literature review started by giving the reader an insight into the current model for the approach to low back pain as set out by Kirkaldy-Willis (1988: 117-131). As part of this model the criteria enabling the diagnosis of the facet syndrome and sacro-iliac syndrome were discussed, which were to be the particular focus of this study.

The unique problem surrounding low back pain was then highlighted to illustrate that a short natural history and favorable prognosis were often followed by further and often costly, reoccurences (Bergquist-Ullman and Larson 1977 and Frymoyer 1991: 10-19).

A short review discussing manual therapy, namely, manipulation, as an effective treatment approach for low back pain (Di-Fabio 1992). The effects, contra-indications

and indications for the use of "Action Potential" therapy followed concluding with a review of clinical trials concerning it'' application and reported effects (Berger 1999).

The use of spinal manipulative therapy in combination with other effective therapies has , according to Ottenbacher and Di-Fabio (1985), been found to increase the effectiveness of the former.

Therefore, the purpose of this study is to evaluate the effects of spinal manipulative therapy and "Action Potential" therapy versus spinal manipulative therapy and placebo "Action Potential" therapy in the treatment of mechanical low back pain, in terms of objective and subjective clinical findings, in order to determine the more effective approach in the management of mechanical low back pain.

Chapter 3

3.0 Methodology

The objective of this study was to evaluate the relative effectiveness of combined spinal manipulative therapy and "Action Potential" therapy versus combined spinal manipulative therapy and placebo "Action Potential" therapy, in terms of objective and subjective findings, in order to determine if "Action Potential" therapy was an effective adjunct to spinal manipulative therapy in the management of mechanical low back pain.

Radio and newspaper advertising was used to attract prospective subjects suffering from low back pain in the dysfunctional stage according to the Kirkaldy-Willis classification (Kirkaldy-Willis 1992: 105). The advertisement called on patients having low back pain for a period of 4 weeks or less (Kirkaldy-Willis 1988: 8).

Upon reply, each subject was telephonically interviewed so as to explain the conditions of the study and as an initial screening process to eliminate those patients obviously falling outside the range of the study. Patients were excluded immediately for the following reasons:
If they were younger than 18 or older than 65 years of age.
Any female applicant if pregnant.
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 a duration of longer than one month.
However, due to the manual intervention used initially the study must be viewed as pragmatic and therefore complete blinding was not possible. Therefore patient naiveté was ensured, by excluding patients who had manual therapy within a three- month period proceeding the study.
The natural history of the chosen conditions indicated that patients should recover spontaneously within two months from initial onset (Kirkaldy-Willis 1988: 8). Thus,

anyone with pain for a period of more than four weeks was excluded from the study to ensure a minimal effect related to natural history. Furthermore, according to the Kirkaldy-Willis classification, a four- week period or less, is also the window of duration for the classification of the diagnosed conditions into the dysfunction stage.

After agreeing to participate an initial consultation was scheduled for the prospective participant.
At the initial consultation the candidate underwent a full case history (Appendix A), physical examination (Appendix B) and a regional low back examination (Appendix C). During this process the participant was screened for a posterior facet syndrome of the lumbar spine, a sacro-iliac syndrome or a combination of both (Kirkaldy-Willis 1988: 133-148).
When and if clinically indicated, patients underwent the relevant radiographic evaluation (lumbar spine and pelvis) for possible pathology contra-indicating manipulation or "Action Potential" therapy. Following examination, a diagnosis was dtermined and patients with the appropriate diagnosis were included into the study.

Patient's suffering from an associated myofascial pain dysfunction syndrome (Travel and Simon 1983: 1:1) were included, but the myofascial component was not treated. Patients were also not included if they were using any medication to alleviate the symptoms of their condition as it was felt this would alter the findings.

The orthopaedic procedures used to specifically diagnose the lumbar facet were: Kemp's (axial compression) test and lumbar facet joint challenge (joint springing).

Kemp's test is conducted with the patient seated and the examiner standing behind the patient. The examiner then reaches around the patient's shoulders and upper chest from behind so as to support and control the patient. The patient is then directed to lean forward to one side and then to bend obliquely backwards as far as possible, at this point the examiner applies axial pressure so as to compress the side of rotation. If this

movement produces or aggravates local pain over the affected spinal segment(s) it may be indicative of a lumbar facet syndrome (Schafer and Faye 1989: 208-209).

Lumbar facet joint challenge is conducted with the patient in the prone position. The examiner then places a thumb on the spinous process tip and pushes laterally, varying the force. The joint may be bounced with a little more vigor if there is no pain response. This produces end-feel, which is never reached abruptly in a normal joint. A joint with restricted mobility has a loss of springiness at the end position. It is this springiness that one palpates for when performing facet joint challenge (Gatterman 1990: 49, 84). Kenna and Murtagh (1989: 104) describe the test as an application of transverse pressure to the spinous process with local pain aggravated or produced by this procedure indicating a lumbar spinal facet syndrome. They also state that this is a very sensitive movement for detecting pain in an affected spinal segment.

The orthopaedic tests used to specifically diagnose the sacro-iliac syndrome were: Patrick Faber's test, Gaenslen's test, Erichson's test and lateral recumbent sacro-iliac compression.

Patrick Faber's test is done with the patient lying supine, the affected side's hip joint is flexed, abducted and externally rotated with downward pressure applied by the examiner on the patient's knee. The eliciting or aggravation of pain over the sacro-iliac joint may be indicative of a sacro-iliac syndrome (Schafer and Faye 1989: 276).
For **Gaenslen's test** the patient once again lies supine, but is positioned so that the involved hip extends over the side of the examination table. The patient is then asked to draw both legs up to the chest and then let the leg under examination drop slowly. A positive test is constituted by pain in the ipsilateral sacroiliac joint.

Erichson's test requires the patient to remain supine, the examiner places his/her hands on the patient's iliac crests and anterior superior iliac spines. The pelvis is then forcibly

compressed towards the midline, which tends to separate the sacroiliac joints posteriorly. Pain experienced over either sacroiliac joint constitutes a positive test (Schafer and Faye 1989: 270).

The final test to confirm a sacro-iliac syndrome is **lateral recumbent compression** of the sacroiliac joint. The patient lies in the lateral recumbent position with the involved side uppermost. The examiner then stands facing the patient, but at right angles and then places a load force over the area between the greater trochanter of the femur and the patient's iliac crest.
Aggravation of pain due to the increased pressure constitutes a positive test and thus indicates a possible sacroiliac syndrome (Schafer and Faye 1989: 270).

As patients were examined and found suitable, they completed an informed consent form (Appendix D). Convenience sampling and random allocation was utilized to allocate patients to either the treatment or placebo- control group, so as to create two separate groups of 30 patients each. The method used was the "goldfish bowl technique" (Willemse 1990: 14).

A double blind procedure was used to assure the placebo nature of the study. The manufacturer made four units available for the study. Only they knew which two were able to give an active treatment. The units were then marked as "a, b, c or d" and each machine was randomly assigned to the sixty study subjects. The patient's were treated with the same unit for the duration of the study on each visit.
After the data was collected and analyzed, the true nature of the units was revealed and the results reported upon. The result was two equal groups; one receiving spinal manipulation and active "Action Potential" therapy and the other receiving spinal manipulation and placebo "Action Potential".

The "goldfish bowl" technique ensured equal distribution of the units by using a goldfish bowl containing 15 similar pieces of paper marked with an A (for unit A), 15 pieces with a B, 15 with a C and 15 with a D. Upon entering the study the patient was asked to

randomly select a piece of paper. This determined the unit they would be treated with and ensure equal distribution of the 4 units using the 60 patients.

The study made use of both experimental and descriptive survey techniques for data collection.

The experimental design of the study involved the measurement of lumbar spine ranges of motion (as determined by goniometer) and pain sensitivity (determined by use of an algometer).

The lumbar spine ranges of motion measured were: flexion, extension, left lateral flexion, right lateral flexion, left rotation and right rotation, with the use of a BROM II (back range of motion) goniometer.

The instrument was supplied by Performance Attainment Associates- 3600 LA Bore Rd, Suite 6, Saint Paul, MN 55110-4144. Although all ranges of motion were measured in this study, Breum et al. (1995) could only demonstrate accuracy in extension and lateral flexion measurements with the instrument.

The instrument consisted of two parts (A and B). (A) was used in flexion and extension measurements, while (B) was used in the measurements of rotation (using the horizontal facing compass) and lateral flexion (using the coronal facing compass).

Flexion and extension:
The patient was in a standing position, with the feet approximately shoulder width apart. The examiner palpated and marked the spinous process of S1 and T12, respectively. The fulcrum of part (A) was then placed over point one, covering S1, and the Velcro straps secured around the patients waist at an angle approximately parallel to the iliac crests. This was done in an effort to secure the contact point during flexion and extension. The l-shaped sliding arm was then placed over point two (T12). This point represented neutral

and a reading in degrees was taken from the outer dial. Whilst providing additional stability to the contact points, the examiner measured the amount of flexion and extension which a patient could actively induce.

Each measurement was confirmed and no more than three degrees variance was accepted, if a large disparity was found the measurements were repeated. In the case of minimal variance, the highest reading was taken.

Left and right lateral flexion was measured according to the BROM user manual:
The Velcro strap of part (B) was secured around the patient's waist between the areas of T12 and S1. A magnet was then attached to the strap. The part (B) instrument was then placed over the affected segment so that the coronal- facing compass faced the researcher in the coronal plane. In the event of more than one tender area, readings were taken over the most tender point.

With the compass needle facing down the initial reading was taken. Whilst the examiner fixed the goniometer to the patient's body, the patient was laterally flexed as far as possible by running their hand down the potero-lateral surface of their leg. Second readings were taken to the left and right and subtracted from the baseline measurement. Each measurement was confirmed and no more than three degrees of variance was accepted, if a large disparity was found the measurements were repeated. If the variance fell within the three degrees the highest measurement was taken.

For left and right rotation:
Part (B) of the instrument was again used, but this time the horizontal-facing compass was utilized. The patient was in a seated position, with the arms crossed over the chest. Instrument fixation was as before. However, the compass was zeroed according to the magnet position. Maximal left and right rotation was then induced and the measurements were confirmed.

Once the initial ranges of motion were recorded, a pressure threshold reading (algometer) reading was obtained from each patient. Pain sensitivity was measured using the pressure algometer supplied by Wagner Instruments (P.O. Box 1217, Greenwich, CT 06836, USA). The patient was asked to indicate the area of most discomfort/pain. The patient was then instructed to immediately indicate when the pressure exerted with the algometer became painful by saying "yes".

Upon the patient's response the instrument was removed and the measurement was recorded in kg per square centimeter (maximum of 10 kg per square centimeter). In the event of two painful areas being indicated, measurements were taken from both and the average between the two, rounded off to the nearest decimal place, was used.
Fischer (1986) conducted a study on 50 patients in an attempt to quantify tender spots through the use of an algometer. His conclusion was that the unit yielded highly reproducible results and showed excellent validity of measurements obtained.
The descriptive survey design made use of the Ostwestry Low Back Disability Index (Appendix E) and the NRS-101, a numerical pain rating scale (Appendix F).

The Ostwestry questionnaire consists of six questions each. For each section, the total possible score is 5 points, with a point distribution ranging from zero (if the first statement of the representative section was marked) to five (if the sixth (last) statement was chosen). Upon completion of the questionnaire the points were added, with the maximum score possible, being fifty. The final score was then converted into a percentage for each patient, for that particular consultation. In the event that one section was not completed, the highest possible score became 45 and the total score was thus calculated out of 45, and then converted to a percentage.

If more than one section was not completed, five points were then deducted and a corresponding maximum was calculated, from which the percentage for the patient was then found.

The scores were calculated and recorded in the patient's file at the respective times of data collection.

Fairbank et al. (1980), confirms this questionnaire as being reliable and valid method of measuring the percentage disability suffered by patients with low back pain. Test re-test reliability of the questionnaire was measured at a correlation coefficient of 0.99 ($p<0.001$), when completed on two consecutive days by 22 patient's suffering from chronic low back pain.

The NRS-101, a numerical pain intensity scale was used to measure the subjective response of patients to treatments in terms of their perception of pain intensity. The questionnaire instructed the patient to rate their pain at its worst and at its least on a numerical scale of zero to one hundred, with zero representing "no pain at all" and one hundred indicating "pain as bad as it could be". The average pain intensity was calculated by adding the values representing worst and least pain and then dividing this value by two (Jensen et al. 1986). The average pain intensity experienced by each patient over the treatment and follow-up periods was then utilized for statistical analysis.

The above measures were taken before the initial visit, before the second consultation and at the follow-up consultation.

After the ranges of motion, algometer and questionnaire procedures were completed, patients were given their respective treatments.

To fall within the natural history of the condition, each patient received four treatments, over a seven to ten day period (Kirkaldy-Willis 1988: 8). There was also a follow- up consultation, approximately twenty- four hours after the final treatment, at which time the last set of data was collected.
Treatment one consisted of a combination treatment of spinal adjustment, according to Szaraz (1990), after which the patient received either placebo "Action Potential" therapy

or active "Action Potential" therapy, depending on their group. On the three, subsequent visits the patient received only placebo or active "Action Potential" therapy.

Motion palpation was utilized to identify segments with restricted or abnormal ranges of motion patterns in the lumbar spine and sacro-iliac joints (Schafer and Faye 1989: 211-216, 256-259).

This method is currently regarded by Chiropractors in Victoria as the most reliable test of identifying the restricted spinal entity that Chiropractors adjust (Walker and Buchbinder 1997). The motion palpation procedure is of further value in identifying the plane of articulation in which the adjustive technique should be applied, in order to maximally restore joint play, whilst causing the least amount of discomfort to the patient (Schafer and Faye 1989: 7).

Patients were positioned for their respective manipulations according to the diversified method of manipulative therapy.
The techniques were applied as described by Szaraz (1990). These included: the lumbar roll (pisiform-mamillary), spinous hook/push, sitting lumbar technique, upper sacro-iliac (flexed inominate) technique, and lower sacro-iliac joint (extended inominate) technique. Discrimination of the technique used was based on success on manipulation using the lumbar roll; if this failed (i.e.: no audible sound) after two attempts, the spinous hook was used and if this failed after two attempts the sitting lumbar technique was used.

The "Action Potential" modality settings were standardized to a time of eight minutes, as this is the recommended treatment duration for acute conditions according to Berger (1990). The preferred current intensity was also standardized for the condition according to Berger's clinical experience at 2mA.

The electrode placement was according to the manufacturers guidelines; with the positive electrodes placed bilaterally over the quadratus lumborum region and one negative

electrode placed over L1 spinous process and the other over S1. These were then marked with gention violet, so as to be duplicated at subsequent visits.

According to the manufacturers guidelines, there was a 24-hour window period between subsequent treatments.

Patients were advised against making major changes in lifestyle habits, especially those relating to diet and exercise. The patient was also made aware that should any pain or anti-inflammatory medication be taken during the course of the study, it would lead to their exclusion.
Patients that became asymptomatic during the course of their trial, still received their specific treatment until the protocol was completed. Patients that developed an allergic response or experienced an acute exacerbation, were excluded from the trial and their data reported on for demographical purposes.

Objective (BROM II and algometer) and subjective (Ostwestry disability Index and NRS 101) measures were taken before the initial visit, before the second consultation and at the follow-up consultation.

The SPSS statistical package was used utilized for data analysis. The statistical evaluation was aimed at measuring whether any significant changes occurred between the initial and second treatment, the initial and follow-up consultation as well as the second treatment and the follow-up consultation, within each study group and between the respective groups.

The Wilcoxin Test was used to determine whether any significant change occurred between the initial and second treatment, between the second and the follow-up treatments and the initial and the follow-up consultation, within each study group. In each respective hypothesis conducted, the null hypothesis (Ho) stated that no significant difference existed between for example the initial and follow-up consultation. The null

hypothesis (Ho) was rejected if the P value was less than alpha; and it was concluded that there was a significant difference within the group at the alpha=0.05 level of significance.

Ho was accepted if P was greater than or equal to alpha; with the conclusion that there was no significant difference within the group at the alpha=0.05 level of significance. The P value was calculated by dividing the value of the two-tailed probability or equaling or exceeding the value of Z, by 2, and where alpha=0.05 i.e.: 95% level of significance. The Mann-Whitney Test was used to determine whether any significant differences existed between the two groups at the time of the initial, second and follow-up consultations. Each respective hypothesis test conducted was treated similarly to that described for the Wilcoxin Signed Rank Test.
Descriptive statistics incorporating mean, standard deviation and standard error were used to analyze the p-values acquired in order to further interpret the results from data collected, once in spread sheet format.

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.

The mean value was calculated by adding the sum of a set of measurements and then dividing them by the number of scores used (n) (Portney 1993: 322).

From the mean values 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 reflects the reliability of the response.

This standard deviation is the standard error of measurement (SEM) (Portney 1993: 523-524).

The results obtained from these tests were then used to discuss and draw conclusions as to the relative effect of spinal manipulation combined with "Action Potential" therapy versus spinal manipulation combined with placebo "Action Potential" therapy in the treatment of mechanical low back pain.

Chapter 4

4.0 The Results

4.1 Introduction:

This chapter concerns itself with the results obtained after statistical analysis of the data from the measurement criteria as discussed in chapter 3. This data is presented in table form with relevant comments and interpretations in order to accept or reject the null hypothesis.

4.2 The Hypotheses:

The null hypothesis is the same for both groups and is defined as follows:
Ho: There would be no statistical difference in the subjective and objective findings on analysis of the
Intra-group data, showing that this treatment was statistically insignificant.

The alternative hypothesis is again the same for both treatment groups and is defined as follows:
Ha: There would be no statistical difference in the subjective and objective findings on the analysis of the
Intra-group data, showing that this treatment protocol was statistically significant.

In order to integrate the data from the two groups, a third null hypothesis and alternative hypothesis are required.

Defined below as:
Ho: There would be no statistical difference in the subjective and objective findings on analysis of the inter-group data, showing that the two treatment groups were equally effective.

Ha: There would be a statistical difference in the subjective and objective findings on analysis of the inter-group data, showing that the two treatment groups were not equally effective.

4.3 Demographic data:

This study consisted of a sample of sixty patients, 30 receiving spinal manipulation and active "Action Potential" therapy and 30 receiving spinal manipulation and placebo "Action Potential" therapy.

Table 4.1 Age distribution of patients

Age	Manipulation and active APR	Manipulation And placebo APR	Total % of Patients
18-24	6	9	25.00
25-34	3	9	20.00
35-44	4	1	8.33
45-54	10	4	23.33
55-65	7	7	23.33

Table 4.2 Gender distribution

Gender	Manipulation and active APR	Manipulation and placebo APR	Total
Male	15	13	28
Female	15	17	32

4.4 The analysed data:

a) P-value:

The data was analyzed at the alpha=0.05 level

The decision rule was applied and states:

Reject the null hypothesis (Ho) if, p<_ alpha divided by 2.

Accept the null hypothesis (Ho) if, p>alpha divided by 2.

Now, alpha=0.05

Therefore, alpha divided by 2 =0.025

Therefore the p-value would have to be below or equal to 0.025 to eject the null hypothesis and

conclude that there is a statistically significant improvement at the alpha=5% level.

4.4.1. The paired t-test analysis: (significant values indicated in bold)

Table 4.3

Group 1: Intra-group paired t-test assessment for the interval between consultation 1 and 2.

Variable measured	Mean	Standard Deviation	p-value
Flexion	5.767	3.002	**0.0001**
Extension	2.133	1.676	**0.0001**
Left lateral flexion	2.567	1.977	**0.0001**
Right lateral flexion	2.564	1.976	**0.0001**
Left rotation	1.567	1.736	**0.0001**
Right rotation	2.033	2.220	**0.0001**
Algometer	1.267	0.686	**0.0001**
NRS-101	-8.333	5.357	**0.0001**
Oswestry	-0.067	0.071	**0.0001**

The null-hypothesis was rejected for every one of the variables examined, indicating a significant change between the first and second consultation.

Table 4.4

Group 1: Intra-group paried t-test assessment for the interval between consultation 2 and the final consultation.

Variable measured	Mean	Standard Deviation	p-value
Flexion	3.867	2.209	**0.0001**
Extension	1.667	1.539	**0.0001**
Left lateral flexion	1.767	1.977	**0.0001**
Right lateral flexion	1.765	1.974	**0.0001**
Left rotation	2.033	2.189	**0.0001**
Right rotation	1.633	2.189	**0.0001**
Algometer	1.490	0.867	**0.0001**
NRS-101	-6.567	4.345	**0.0001**
Oswestry	-0.01	0.040	**0.0001**

Group one continued to show significant improvement between the second and final consultations for all variables measured except for the Oswestry questionnaire, where no further significant change was noted.

Table 4.5

Group 1: Intra-group paired t-test assessment for the interval between consultation 1 and the final consultation.

Variable measured	Mean	Standard Deviation	p-value
Flexion	9.633	3.378	**0.0001**
Extension	3.800	2.455	**0.0001**
Left lateral flexion	4.333	3.427	**0.0001**
Right lateral flexion	4.267	3.218	**0.0001**
Left rotation	3.600	3.450	**0.0001**
Right rotation	3.667	3.252	**0.0001**
Algometer	2.757	1.275	**0.0001**
NRS-101	-0.077	0.077	**0.0001**
Oswestry	-14.9	6.465	**0.0001**

Overall the null-hypothesis was rejected for all the variables assessed over the treatment period. The p-values were all highly significant at the 95% confidence interval level.

Table 4.4

Group 1: Intra-group paried t-test assessment for the interval between consultation 2 and the final consultation.

Variable measured	Mean	Standard Deviation	p-value
Flexion	3.867	2.209	**0.0001**
Extension	1.667	1.539	**0.0001**
Left lateral flexion	1.767	1.977	**0.0001**
Right lateral flexion	1.765	1.974	**0.0001**
Left rotation	2.033	2.189	**0.0001**
Right rotation	1.633	2.189	**0.0001**
Algometer	1.490	0.867	**0.0001**
NRS-101	-6.567	4.345	**0.0001**
Oswestry	-0.01	0.040	**0.0001**

Group one continued to show significant improvement between the second and final consultations for all variables measured except for the Oswestry questionnaire, where no further significant change was noted.

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Flexion	9.633	3.378	**0.0001**
Extension	3.800	2.455	**0.0001**
Left lateral flexion	4.333	3.427	**0.0001**
Right lateral flexion	4.267	3.218	**0.0001**
Left rotation	3.600	3.450	**0.0001**
Right rotation	3.667	3.252	**0.0001**
Algometer	2.757	1.275	**0.0001**
NRS-101	-0.077	0.077	**0.0001**
Oswestry	-14.9	6.465	**0.0001**

Overall the null-hypothesis was rejected for all the variables assessed over the treatment period. The p-values were all highly significant at the 95% confidence interval level.

Table 4.6

Group 2: Intra-group paired t-test assessment for the interval between consultation 1 and 2.

Variable measured	Mean	Standard Deviation	p-value
Flexion	2.200	1.157	**0.0001**
Extension	0.966	1.189	**0.0001**
Left lateral flexion	1.967	1.790	**0.0001**
Right lateral flexion	1.333	1.373	**0.0001**
Left rotation	1.033	1.377	**0.0003**
Right rotation	0.700	1.022	**0.0008**
Algometer	0.610	0.579	**0.0001**
NRS-101	-5.500	3.442	**0.0001**
Oswestry	-0.030	0.466	**0.0014**

All variables assessed showed a significant change during the interval between visit one and two. Therefore, the null-hypothesis was rejected at the 95% level of significance.

Table 4.7

Group 2: Intra-group paired t-test assessment for the final interval between consultation 2 and the final consultation.

Variable measured	Mean	Standard Deviation	p-value
Flexion	1.533	1.961	**0.0002**
Extension	0.600	1.037	**0.0036**
Left lateral flexion	0.667	1.493	**0.0208**
Right lateral flexion	1.333	1.373	**0.0001**
Left rotation	0.400	1.003	**0.0372**
Right rotation	0.300	0.915	0.0831
Algometer	0.163	0.154	**0.0001**
NRS-101	-4.733	4.518	**0.0001**
Oswestry	-0.023	0.050	**0.0169**

The null hypothesis was accepted for the right rotation variable, but was accepted for the rest of the variables.

Table 4.8

Group 2: Intra-group paired t-test assessment for the interval between consultation 1 and the final consultation.

Variable measured	Mean	Standard Deviation	p-value
Flexion	3.733	2.258	**0.0001**
Extension	1.566	1.524	**0.0001**
Left lateral flexion	2.633	2.414	**0.0001**
Right lateral flexion	2.100	2.171	**0.0001**
Left rotation	1.433	1.695	**0.0001**
Right rotation	1.000	1.287	**0.0002**
Algometer	0.773	0.525	**0.0001**
NRS-101	-10.233	5.722	**0.0001**
Oswestry	-0.053	0.051	**0.0001**

The overall within- group assessment indicated a highly significant change in all the variables assessed. The null-hypothesis is therefore rejected.

4.4.2 The unpaired t-test analysis:

Table 4.9

Inter-group unpaired t-test assessment at consultation 1.

Variable measured	Mean	Standard Deviation	Standard error	p-value (two-tailed)	p-value (one-tailed)
Flexion	5.767	3.002	0.548	**0.0001**	0.00005
Extension	0.967	1.188	0.217	**0.0025**	0.00125
Left lateral flexion	1.967	1.790	0.327	0.2229	0.11145
Right lateral flexion	1.967	2.125	0.388	0.1765	0.08825
Left rotation	2.033	2.220	0.405	**0.0047**	0.00235
Right rotation	2.033	2.467	0.420	**0.0068**	0.0034
Algometer	0.610	0.579	0.106	**0.0002**	0.0001
Oswestry	-0.066	0.071	0.013	**0.022**	0.011
NRS-101	-8.333	0.077	0.014	0.1734	0.0867

At the time of the first assessment there was no significant difference between the groups for left lateral flexion, right lateral flexion and the NRS-101. However, a significant difference was noted, for the other variables measured.

Table 4.10

Inter-group unpaired t-test assessment at the second consultation.

Variable measured	Mean	Standard Deviation	Standard error	p-value (two-tailed)	p-value (one-tailed)
Flexion	11.533	1.960	0.358	**0.0001**	0.00005
Extension	1.653	1.510	0.276	**0.0027**	0.00135
Left lateral flexion	0.666	1.493	0.273	**0.0181**	0.00905
Right lateral flexion	0.766	1.960	0.358	0.1909	0.09545
Left rotation	1.633	2.009	0.380	**0.0030**	0.0015
Right rotation	1.633	2.189	0.399	**0.0038**	0.0019
Algometer	1.490	0.867	0.158	**0.0010**	0.0005
Oswestry	-0.023	0.050	0.009	0.2620	0.131
NRS-101	-4.733	4.518	0.825	0.1146	0.0573

At the time of the second consultation, the null-hypothesis was accepted for right lateral flexion, the Oswestry questionnaire and the NRS-101. However, the null-hypothesis was rejected for the other variables tested.

Table 4.11

Inter-group unpaired t-test assessment at the final consultation.

Variable measured	Mean	Standard Deviation	Standard error	p-value (two-tailed)	p-value (one-tailed)
Flexion	1.633	3.378	0.617	**0.0001**	0.00005
Extension	3.800	2.455	0.448	**0.0001**	0.0005
Left lateral flexion	2.633	2.414	0.441	**0.0303**	0.01515
Right lateral flexion	3.400	3.286	0.600	0.0766	0.0383
Left rotation	3.666	3.150	0.292	**0.0002**	0.0001
Right rotation	3.666	3.252	0.594	**0.0002**	0.0001
Algometer	2.757	1.275	0.234	**0.0001**	0.00005
Oswestry	-0.077	0.077	0.014	0.1734	0.0867
NRS-101	-10.233	5.722	1.045	**0.0044**	0.0022

At the final consultation, there was a significant difference between all the variables tested except for right lateral flexion and the Oswestry questionnaire.

Chapter 5

5.0 Discussion

5.1 Introduction:

This chapter will discuss the results of the objective and subjective clinical findings as gathered from the range of motion, algometer as well as the Oswestry Low Back Disability Questionnaire and Numerical Pain Rating scale- 101, respectively.

5.2 Intra-group comparisons:

Group one (experimental group) showed a progressive, significant improvement in all variables tested over the treatment intervals, except for the Oswestry questionnaire, at the second measurement interval (table 4.4). This was attributed to the large negative change that took place during the first measurement interval. Patients often had no significant disability at the second treatment.

Group two (control group) also presented with a uniform, significant change in the variables tested, however right rotation did not significantly change within the group for the second measurement interval (table 4.7).

If one compares that standard deviations for group 1, for the objective measures over the first and second assessment periods, the values do narrow, indicating a greater proficiency in measurement on the part of the examiner. However, this trend was not supported by the results from group 2.

The standard deviation for the NRS-101 measurement showed the greater variation in both groups. For group one the standard deviation narrowed progressively, indicating a greater level of conformity in the values expressed by patients, whilst the opposite was

true for group two, where the standard deviation for the first to final treatment interval was 5.722 (table 4.8).

One must also keep in mind possible instrument error, which was not tested for. However, this would have been a constant error throughout the study.

5.3 Inter-group comparisons: (tables 4.9-4.11)

At the first consultation there was a number of significant differences in the baseline characteristics of the two groups. There was a significant difference between the groups with respect to flexion, extension, left rotation, right rotation as well as the objective pain measurement (algometer). There was also a significant difference in the amount of subjective disability suffered (Oswestry). The standard error was low, whilst the standard deviation was more or less centered around the mean.

At the second consultation all the objective measurements, except for the right lateral flexion were significant. This indicated a greater improvement within the experimental group with respect to mobility as well as pain threshold. There was no significant difference between the subjective measures at this point. As both groups were recovering well at this point, the lack of difference could be ascribed to the lack of disability and pain patients were experiencing subjectively by the second consultation. However, the NRS-101 measurement had a much higher standard deviation at the second visit, which indicated a greater spread of pain values experienced by the patients.

At the final consultation there was a significant difference between the two groups in all but two areas, namely right lateral flexion (0.0766) and the Oswestry questionnaire. These results indicate that the experimental group improved significantly beyond the control in almost every facet investigated. It is important to note that the left lateral flexion values as well as the NRS-101 values were not significantly different initially, but were so by the end of the study (a significance was almost established with right lateral

flexion.) This indicates a positive change from the baseline, as opposed to change due to variance. This is further confirmed by the one-tailed version of the t-tests performed .

Furthermore, on intra-group assessment (table 4.7), no significant change occurred within the control group, where as a highly significant change had taken place at the same time within the experimental group. This strengthens the argument for a greater degree of improvement within the experimental group.

However, no significant change occurred within the Oswestry questionnaire values at the final consultation. One could argue that the reason for this seems to lie in that both groups decreased dramatically in their disability between the first and second consultations (tables 4.3 & 4.6), which meant that the levels of disability did not alter a great deal from then on to the final consultation.

5.4 Study Limitations:

From the statistical analysis of this study it is inferred that a significant difference exists between the results achieved from the treatment group as opposed to the placebo group. Both treatment groups improved, however the added clinical effect of the A.P.R. treatment group (group 1) allowed patients to improve to a greater extent overall, as well as during the second treatment interval where the control group was exposed to placebo A.P.R. therapy.
Having stated the above, the following factors should be considered for future studies of this nature:

5.4.1 Blinding:

According to Koes et al. (1995) there is consensus that outcome measures should be valid, precise and sensitive for measuring small, but clinically relevant changes. There is, however, debate as to whether the assessment should be left up to the patient or

conducted by a blinded observer who, based on physical examination, decides on the extent of clinical changes.
The authors believe that both of these should be considered, depending on the specific questions that need answering. This may, however, not be necessary as the clinical significance may not be revealed by statistical analysis of the objective or subjective data used.
We cannot be sure that the clinical phenomenon under consideration is being correctly measured and as a result the statistical outcome may not reveal the true impact of the treatment protocols used.

5.4.2 Double-Blinding:

To achieve a gold standard within a clinical trial, according to Pocok (1993:32), double blinding must be utilised to prove a therapy effective. Assendfelt et al. (1992) stated that for a pragmatic study, where another treatment group is used as a
Reference, blinding is problematic and patient naiveté has to be used as substitute. In this study this was attempted by not allowing patients who had received either of the treatment modalities within the preceeding 3 months of the study. This, it was felt, would minimise the risk of the results being influenced, in either direction, through preconceived ideas on the part of the patient.
However, an attempt was still made at double blinding, by randomly assigning patients to either a placebo or active A.P.R. device. Furthermore, as the units were simply marked "a,b,c or d", the researcher was at least initially blinded as to the true nature of the four units used. However, observer bias could have become a factor towards the end of the study as some unblinding of the researcher occurred (Assendfelt et al. (1992).

It is therefore the opinion of the author, that although a pragmatic study design, such as this, will always be of a quasi-experimental nature, a good attempt was made at assuring blinded outcome.

5.4.3 Homogeneity:

According to Koes et al. (1995), the greater the number of comparable baseline characteristics between study subjects, the better the resulting study design. However, this poses the researcher with a challenge, as it is not always possible to have test subjects with a high homogeneity in terms of age, sex, occupation, etc., that can be compared to maximise the method quality, whilst at the same time not falling into the trap of selection bias.

The studies clinical setting and time constraints prevented achieving this. However, when considering the demographic data it can be seen that the two groups were very similar in baseline characteristics. Consequently, this possible bias did not play a significant role even though it was not specifically controlled for.

5.5 Outcome commentary:

Patients in both groups received a manual intervention at the first consultation. Spinal manipulative therapy carries with it a significant clinical effect size. Combine this with a placebo modality, and significant intra-group movements within the control group were to be expected (Di Fabio 1992). This was indeed noted in that when the control group improved it did so at the first consultation and overall (see tables 4.6, 4.7 and 4.8).
It is therefore important that significant inter-group differences were noted for measured pain as well as five of the six ranges of motion were significantly changed at the end of the treatment protocol.

This indicates that the combination of spinal manipulative therapy and active action potential therapy enabled patients to improve to a greater extent at the end of the set treatment period, when compared to the same spinal manipulative procedure combined with a placebo treatment.

Chapter 6

6.0 Recommendations and Conclusions

6.1 Recommendations:

The author feels that to fully investigate the effectiveness of spinal manipulative therapy and A.P.R. therapy in the treatment of mechanical low back pain of the lumbar spine, sacro-iliac joint or a combination of both greater time and financial freedom would be necessary.

The following improvements are suggested:

Homogeneity:

Stricter inclusion and exclusion criteria with regards to using matched pairs with respect to age, sex, race and history of complaint, would greatly enhance the strength of the study.

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.

Crossing Over (counter-balancing):

This feature could be considered within the two treatment groups whereby patients that are not showing strong improvement are switched to opposite treatment to see if there is any improvement.

6.3 Conclusions:

The statistical analysis of the results revealed statistically significant improvements within the treatment group receiving spinal manipulation and active action potential therapy both objectively and subjectively, after the treatment period.
The group receiving placebo action potential therapy in conjunction to the spinal manipulation also showed significant improvements within the group, however these were to a lesser degree that the treatment group receiving active action potential therapy.

When statistical analysis was used to compare the two groups significant differences were noted. Although both treatment groups responded favourably there was a significantly greater improvement noted in the group receiving active action potential therapy as opposed to the group receiving a placebo in terms of both subjective and objective measures.
The results of this study therefore indicate that a clear trend could be established for the use of active action potential therapy in conjunction with spinal manipulative therapy in the conservative management of mechanical low back pain, in particular that of the lumbar spine and the sacro-iliac joint.

From a practical point of view the author recommends the following:
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 it would require for significant objective and subjective improvement, would be the optimum treatment frequency.

Due to the lack of treatment protocols as opposed to single therapy options for the treatment of mechanical low back pain, there is a responsibility on the part of every practitioner to address the problem. An effective system of constant re-evaluation must be utilised in order to effectively and clinically monitor the patients' response. It is this author's opinion that in uncomplicated mechanical low back pain, patients should show a significant improvement to the treatments given within four visits from the initial

consultation. If this is not the case, diagnostic and treatment adjustments should be considered.

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TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

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

FOR CLINICIAN'S USE ONLY
Initial visit clinician:_____Signature:_____

Case History:

Examination:
Previous: Current:

X-Ray Studies:
Previous: Current:

Clinical Path. lab:
Previous: Current:

Case Status:

PTT: Conditional: Signed Off: Final Sign out:

Recommendations:

Intern's Case History

1. Source of History:

2. Chief Complaint: (patient's own words)

3. Present Illness:

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

4. Other Complaints:

5. Past Medical History:

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

6. Current health status and life-style:

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

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient:_____File#: _____Date:_____
Clinician:_____Signature:_____
Intern:_____Signature:_____

1. VITALS

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

2. GENERAL EXAMINATION

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

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

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

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

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

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

Percussion: - borders of heart

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

4. RESPIRATORY EXAMINATION

1) Is this patient in **Respiratory Distress** ?

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

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

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

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

5. ABDOMINAL EXAMINATION

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

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

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

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

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

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

b. Motor - Masseter:
- Jaw lateral movement:

c. Reflexes - Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

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

b. Taste - Anterior two-thirds of tongue:

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

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

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

XII Inspection of tongue (deviation):

Motor System:

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

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

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

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

Sensory System:

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

b. Joint position sense
- Finger:
- Toe:

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

Cerebellar function:

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

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

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

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

9. **BREAST EXAMINATION:**

Summon female chaperon.

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

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

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

PATIENT: _____

FILE #: _____ DATE: _____

INTERN/RESIDENT: _____

SUPERVISING CLINICIAN: _____

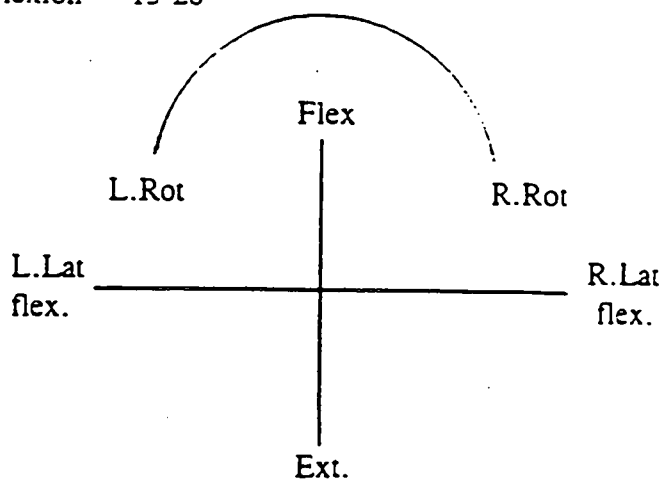
STANDING:

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

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

RANGE OF MOTION

Forward Flexion = 40-60°(15cm from floor)
Extension = 20-35°
L/R Rotation = 3-18°
L/R Lateral Flexion = 15-20°



SUPINE:

Skin
Hair
Nails
Palpate Abdomen/groin
Pulses (abdomen)

Observe abdomen
Fasciculations
Abdominal Reflexes

Pulses (extremities)
SLR
Bowstring
Plantar Reflex
Circumference (thigh, calf)
Leg Length:
- actual
- apparent

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

LATERAL RECUMBENT

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

NON ORGANIC SIGNS

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

GAIT

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

PRONE

Gluteal skyline
Skin rolling
Iliac crest compression
Facet joint challenge
S-I tenderness
Erichson's Test
Pheasant's Test
Myotome:
- Glut. Max

Active MF Trigger Pts:
- QL
- Glut. Med
- Glut. Min
- Glut. Max
- Piriformis
- Hamstrings
- TFL

NEUROLOGICAL EXAMINATION

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

Tripod
Kemp's Test

MOTION PALPATION and JOINT PLAY:

LEFT: Upper Thoracics:
Lumbar Spine:
Sacroiliac Joint:

RIGHT: Upper Thoracics:
Lumbar Spine:
Sacroiliac Joint:

Basic Exam: Hip
Case History:

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

Observ/Palpation:

Basic Exam: Thoracic Spine
Case History:

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

Observ/Palpation:

APPENDIX A

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject*) *Delete whichever is not applicable.

TITLE OF RESEARCH PROJECT:

_____

_____

NAME OF SUPERVISOR:

_____

NAME OF RESEARCH STUDENT:

_____

PLEASE CIRCLE THE APPROPRIATE ANSWER

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

PATIENT/SUBJECT* Name _____ Signature_____
(in block letters)

PARENT/GUARDIAN* Name _____ Signature _____
(in block letters)

WITNESS Name _____ Signature _____
(in block letters)

RESEARCH STUDENT Name_____ Signature _____
(in block letters)

ADDENDUM E

OSWESTRY BACK DISABILITY INDEX

Patient Name:___ ___ ___ File no.:_____ Date:____

This questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage ever 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 s in any one section could relate to you, but please just mark the box which most closely describes your problem.

Section 1 - Pain Intensity

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

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

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

Section 3 - Lifting

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

Section 4 - Walking

- ☐ Pain does not prevent me walking any distance.
- ☐ Pain prevents me walking more than 1 mile (2.2km).
- ☐ Pain prevents me walking more than ½ mile (1.1km).
- ☐ Pain prevents me walking more than 1/4 mile (0.5km).
- ☐ I can only walk using a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 - Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than ½ hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6 - Standing

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

Section 7 - Sex life

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

Section 8 - Social life

- ☐ My social life is normal and gives no extra pain.
- ☐ My social life is normal but increases the degree of pai
- ☐ Pain has no significant effect on my social life apart fr limiting my more energetic interests, for example danc
- ☐ Pain has restricted my social life and I do not go out as
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

Section 9 - Sleeping

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

Section 10 - Traveling

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

Adapted from Fairbanks (1980)

Numerical Rating Scale - 101 Questionnaire

Date: _____

Patient name: _____

File 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 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 the 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 the number.

_____