

A DOUBLE BLINDED, PLACEBO CONTROLLED STUDY TO
DETERMINE THE INFLUENCE OF THE CLINICAL RITUAL IN
INSTRUMENT ASSISTED ADJUSTING DURING THE
MANAGEMENT OF MECHANICAL LOW BACK PAIN

BY

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Chiropractic

**I, Belinda Rose Dugmore do declare that this dissertation is representative
of my own work.**

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Date_____

DEDICATION

To my dad, Neville Dugmore, thank you for being you and having an unwavering belief in me!

You have been a pioneer in chiropractic and you have a legacy that will last beyond my lifetime.

I thank you with all my heart for all your love and support throughout my life.

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ABSTRACT

Health care practitioners have known for some time that patients benefit from specific manual intervention effects, but also from the manner in which these are presented. The latter at times having as much impact on patient health as the former. Thus the purpose of this study was to determine the effect of the clinical ritual during instrument assisted adjusting whilst managing mechanical lower back pain. The study was a randomized prospective study comprising of sixty participants aged 18-59. These individuals were randomly allocated into two groups of thirty and then further stratified to control for gender. Both Groups were diagnosed according to the Activator Methods Chiropractic Technique (AMCT), however the tension was set at maximum for group A, whilst the device was set to the minimum tension for group B.

Each patient received three treatments and one follow up visit over a two-week period. Subjective data was collected at the first, third and follow up visit. Subjective data was recorded using the Visual Analogue Scale, the Numerical Pain Rating Scale, the Roland Morris Questionnaire and the Short-form McGill Pain Questionnaire.

Outcomes were analysed through with the SPSS statistical package at a 95% level of confidence. After analysis of the collected data it was found that there was no statistical difference between the groups, but there was a non-specific trend suggesting a better outcome in the full tension activator group (Group A).

Thus, the research indicated that patients perceptions, the patient-practitioner relationship, and the assumption of an outcome of success as well as the power of placebo or non-specific effects play a large role in the managing of lower back pain in a chiropractic environment.

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DEFINITION OF TERMS

Activator Adjusting Instrument

A manually manipulatable instrument capable of providing a dynamic thrust that includes a controlled force of adjustment at a precise and specific line of drive at high speed (Fuhr,1990).

Adjustment

A manual manoeuvre specific in direction, point of contact, amplitude, and velocity intended to partly or wholly correct a subluxation.(Redwood, 1997:333).

Activator Methods Chiropractic Technique (AMCT)

A gentle low force programme that utilises specific procedures to detect spinal joint dysfunction, analyse leg length inequality and detect body mechanics problems (AMCT,n.d).

Clinical Ritual

A clinical ritual is a formalised, predetermined set of symbolic actions generally performed in a particular environment at a regular recurring interval (Encyclopaedia/ Labor law talk, n.d.).

Isolation testing

Prone observations are made of straight and flexed leg lengths while the patient's extremities are positioned so as to exacerbate muscular imbalance at specific spinal segments (Osterbauer, 1990).

Joint Dysfunction (dysfunctional segments)

Joint mechanic showing functional disturbances without structural changes (Redwood, 1997:338).

Joint Fixation (restriction)

The temporary immobilisation of a joint in a position that it may normally occupy during any phase of normal movement (Redwood, 1997:338).

Non-specific effect

Therapeutic gain/ effect in response to manual/ mechanistic elements of care giving.

Pelvic deficiency (PD) leg

The leg that appears short in performing a prone leg check (not to be confused with an anatomically short leg) (Fuhr,1983).

Placebo

The placebo effect is the measurable, observable or felt improvement in health not attributable to treatment (Kirsch,1998).

Subluxation

An alteration of alignment, movement, integrity and or physiologic function of a motion segment, while the joint surfaces remain in contact; resulting neurophysiological disturbances may be local or widespread (Redwood, 1997:343).

Syndrome

A set of symptoms that together indicate the presence of an abnormal condition.

Chapter one

1.1 Introduction

Low back pain is the most prevalent of the musculoskeletal conditions, as it affects 60-80 % of the westernized population at some point in time (Foster, 1998) (Burton and Cassidy, 1992:2), and has a lifetime prevalence reported as ranging from 11% to 84% (Walker,2000). Even though low back pain has been viewed as a largely self-limiting problem with a favourable prognosis, Frank and De Souza (2001) state that back pain may cause a loss of productivity, and in many cases in many cases industrialized societies has reached epidemic proportions. Chiropractic interventions are commonly utilised by low-back pain sufferers (Walker, 2004), of which those who attend chiropractors, 41% and 60% will present with low-back pain (Cherkin 2002).

In this context, lower back pain encompasses a large number of aetiologies, one of which has been classified as causes related to psychosocial issues, which can in some way contribute to back pain (Jamison,1998)(Up to date 2004).

This would include workplace hazards (e.g. ergonomics, heavy lifting, prolonged sitting) as well as psychological issues relating to the workplace and life-style which may contribute to the epidemic of low back pain (Up to date 2004). The placebo/ non-specific effect has been reformulated as a non-specific therapeutic intervention. The placebo, instead of being used as a control, is reconstructed as a valid, albeit non-specific treatment (DeDeyn and Hooge, 1996). Non-specific chiropractic intervention may be undertaken at the physical, chemical and psychoemotional level (Coulehan 1991). The non-specific effect may also involve the Hawthorne effect, which involves the mere fact that human beings are being studied may lead to atypical behaviour, which was interpreted by researchers as the fact that they were participating in a study would alter their perspective and responses (Mouton, 1996:152).

Health care practitioners and researchers have long since known that patients not only benefit from the specific manual therapy given from their health care providers, but also from the manner in which it's given (Cherkin and McCormack, 1989). Hence, there is a growing recognition of the close relationship between

psychological factors in back pain and disability. The strong enthusiasm and positive attitude of both patients and practitioners to chiropractic treatment may do more to reduce pain and disability than the other proposed mechanisms (Haldeman, 1993). The latter is believed to have significant effects on the patient's perception of quality of care and clinical outcome. Some authors go so far as to suggest that "the manner" surpasses the "method", in terms of its effect on satisfaction (Jamison, 1998).

The interpretations and perceptions of a patient may be some of the most important dimensions of illness behaviour (Jamison, 1999).

One such category of non-specific inventions is the clinical ritual. A clinical ritual relates to the treatment of patients according to a pre-determined set of symbolic actions, performed in a particular environment (Encyclopedia/Labor law talk, n.d). An example of the clinical ritual can be found in association with the use of the activator device and is known as the activator technique (Fuhr, 1997).

There is no scientific evidence to determine the extent that placebo treatment and patients perceptions may play whilst using the activator in a clinical ritual setting, and ultimately it's contribution to the improvement of their condition. Research in the chiropractic field enables us to expand our knowledge on the numerous facets that co-exist that ultimately contributes to improving clinical care for patients.

1.2 The Problem Statement

The Chiropractic field of practice involves a considerable amount of non-specific treatment methods, thus it is important to determine to what extent specific interventions play during treatment as well as to what extent the non-specific effect may play in the improvement or perceived improvement of patients suffering from mechanical low back pain.

1.3 The Objectives

1.3.1 The objective was to determine the effect of the activator technique in terms of subjective clinical findings.

1.3.2 The objective was to determine the effect of sham activator technique in terms of subjective clinical findings.

1.3.3 The objective was to determine the relative effect of the activator and sham activator technique in terms of subjective clinical findings.

Hypothesis :

Patients receiving treatment by means of the activator on maximum tension will show no improvement as apposed to those patients being treated with the activator on minimum tension (sham activator).

1.4 Rationale

- To establish the effect of which the chiropractic clinical ritual may play whilst using the activator instrument in the treatment of mechanical low back pain fixations
- To establish the role and effect that specific interventions have in a chiropractic setting during the treatment of mechanical low back pain.
- To determine the extent of which non-specific effects have on patients during chiropractic treatment.

1.5 Limitations of the study

The study is limited by single researcher design constraints, variation in patients and clinical interventions as applied by the activator practitioner.

1.6 Benefits of the study

Alternative techniques and tools for treatment can only add to the diversity of chiropractic care.

Determining to what extent non-specific effects may play in a chiropractic clinical setting can allow the doctor increased knowledge in the total treatment of patients by not only employing specific interventions, but incorporating non-specific methods as well, for maximum care and patient satisfaction.

1.7 Chapter layout

The rest of the thesis will be laid out in the following order. Chapter Two will consist of a review of the current literature around the topic.

Chapter Three will cover the methodology used to capture the data.

Chapter Four follows with the results obtained during the study and the statistical analysis thereof. This chapter includes figures and tables that highlight important data.

The discussion of the data follows in Chapter Five.

The conclusion and recommendations that can be drawn from this study are laid out in Chapter Six.

Chapter two

Review of related literature

2.1 Introduction

This chapter will provide a brief overview of the epidemiology of lower back pain, as well as conservative management thereof. Manipulation and mobilization will also be defined and discussed. Furthermore, instrument manipulation and the principles surrounding the use of the 'Activator Adjusting Instrument' and the Activator 'technique' will be discussed. The chapter will be concluded with a discussion on the role of the placebo effect or non-specific treatment effect during the ritual of clinical consultation.

2.2 Incidence and prevalence of lower back pain

Cassidy and Burton (1992) claim that 60-90% of any given population will suffer from low back pain and between 20-30% are suffering from low back pain at any given time. Mechanical low back pain is a major health problem among the general population in Western, industrial societies and a major cause of medical expenses, absenteeism and disablement (Van Tulder, Koes and Bouter, 1997:2128). A study done in a South African steel industry indicated multi-factorial etiologies (e.g. twisting, bending, load carriage and prolonged sitting) in idiopathic lower back problems, thus demonstrating the extent and association of occupational risk factors with the prevalence of lower back pain problems in Southern Africa (Van Vuuren, 2005).

More recent studies illustrate the magnitude and variability of the problem (Table 2.2):

Table 2.2 Prevalence and incidence of low back pain

<u>Reference</u>	<u>Population</u>	PREVALENCE		INCIDENCE
		<u>Point</u> <u>Monthly</u> <u>1-year</u>	<u>Lifetime</u>	<u>Lifetime</u>
Docrat, 1999	South Africa Indian community Coloured community		45.0 % 32.6%	78.2 % 76.6%
Walker, 1999	Non-specific	12-33 % 22-65 %	11-84%	
Van der Mulen, 1997	South Africa Formal black township		53.1%	57.6 %
Papageorgiou et al., 1995	South Manchester (UK)	35-39 %		
Kirkaldy-Willis 1988:2	Canada		60-80 %	

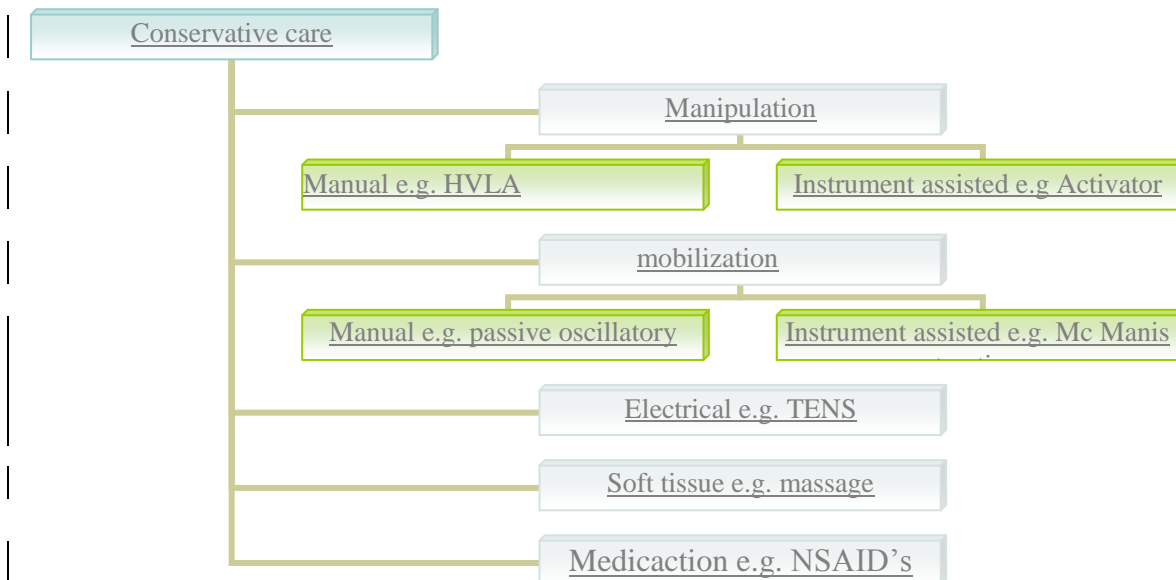
The prevalence of sacroiliac joint dysfunction in the population has been noted in the medical literature to be between 19.3% and 47.9% (Toussaint et al., 1999).

The primary source of pain arose from the sacroiliac joint in 23% of the population and from the lumbar facet for 22% (Bernard and Kirkaldy- Willis, 1987). Due to the relatively common occurrence of these lesions, this study will consider only the dysfunction of the SI joint and lumbar facet joint.

2.3 Conservative management of back pain

According to Rondberg, most people want a natural method of healing, one that utilizes the body's own abilities to promote internal healing and on-going wellness. Conservative treatment is usually considered and tried first by most individuals before options such as surgery are attempted, as fewer risks are related to this type of conservative less invasive form of treatment (Kirkaldy-Willis, 1992). Conservative care incorporates numerous interventions and methods noted in the cochrane collaboration as different ways to approach and manage lower back pain (Cochrane Library, 2006). This is where chiropractic fits in, as to date millions of people have benefited from this non-medical form of health care. Chiropractic is currently considered as having a mainstream position in the western healthcare delivery system, irrespective of whether it is regarded as complementary or alternative to the medical profession. For the continuation and expansion of the chiropractic field, numerous methods of treatment have been developed in order to make chiropractic techniques better, more efficient and perhaps even safer (Cooperstein et al, 2004). A few of these technique systems include the Thomson technique, Gonstead, Logan Basic, Pelvic blocking and instrument assisted adjusting to mention a few. This study, involves the activator adjusting instrument which results in the adjustive force to be applied by a percussive device that is in direct contact with the chosen segmental contact point of the subject. A few other techniques involving instrumented adjusting include the Torque release technique, Instrumented Upper Cervical Technique, and to a lesser extent, Chiropractic Biophysics and Spinal Biomechanics (Cooperstein, 2004).

The organogram below demonstrates how the activator fits in as a sub-category of manipulation.



2.4 Manipulation / Mobilization and instrumental thrusts

“The term dysfunction implies that at one anatomical level the components of the joint are not functioning normally” (Kirkaldy-Willis, 1992:105).

Tissue injury often occurs as a result of microtrauma that leads to inflammation, nociception and pain, all of which can reduce joint mobility and promote pathological or degenerative changes in and around a joint (Seaman and Cleveland, 1999).

Thus, the dysfunction or fixation according to Haldeman (1992: 623) is a state whereby an articulation has become temporarily immobilised in a position that it may normally occupy during any phase of physiological movement. This dysfunction is what chiropractors address in their management of patients who present with pain and discomfort.

2.4.1 Definition of manipulation and mobilization

Gatterman describes chiropractic adjustments as 'a passive manual maneuver in which specifically directed forces are applied to vertebral and extra-vertebral articulations of the body, with the object of restoring mobility to restricted areas' (Gatterman, 1990). Manipulation has two uses, firstly to relieve pain resulting from joint dysfunction and secondly to restore the range of motion to a joint whose function is impaired (Mennel, 1990, Panzer 1995:424).

During mobilization, the adjustive force is applied singularly or repetitively within or at the end range of a joint's physiological range of motion, without imparting a thrust or impulse. Mobilization procedures may include blocking procedures and flexion-distraction procedures, differing only in that mobilization is purely manual, rather than mechanically assisted (Cooperstein et al, 2004).

2.4.2 Comparative effects of manual and instrumental thrusts

The difference between manual and instrumental thrusts with respect to their application seems to be from the differences in mechanical properties (force and speed), as well as the lack or occurrence of the cavitation sound. The 'cracking' sound often heard with a joint manipulation, is also known as the 'audible release' (Brodeur, 1995), which is seldom heard with instrumental thrusts (Osterbauer and Fuhr, 1990). The clinical significance of the cavitation sound is still uncertain. Herzog et al. (1995) when comparing slow and fast manipulations to the thoracic spine indicate that it was the speed of the manipulation and not the cavitation sound that evoked the electromyographical (EMG) activation that influenced the outcome. Brodeur (1995), when reviewing the cavitation states that the cavitation mechanism provides a means of producing the necessary forces on the ligaments to initiate the desired reflexes. He then goes on to mention that drop mechanisms, Activator adjusting instruments and other tools might also provide a means to produce the same result because of their high velocity, that could stimulate the same mechanoreceptors as the cavitation adjustment. Hence, the effects of an adjustment may not be from the cavitation process itself, but merely that the forces that are produced during the process or from the process may be similar to those produced from higher speed interventions such as from instrumental thrusts (Brodeur, 1995).

To summarise: Chiropractic manipulation is considered as a manual maneuver applied by the hand with contact maintained to a specific point and a high-velocity, low-amplitude dynamic-thrust is then delivered in a precise direction.

2.4.3 Instrument assisted manipulation

This study involves the use of instrument manipulation, namely, the activator.

The use of instruments to adjust the spine dates back to the origins of the profession (Fuhr et al.1997). Development of the “Activator Adjusting Instrument” began in 1967 when Fuhr and Lee found repetitive use of the thumb toggle technique led to extreme fatigue, muscle strain and frequent elbow injuries.

Hence, they sought an instrument that would reduce stress on the clinician as well as control the speed, force and direction of thrusts (Osterbauer et al. 1995).

Instrumental thrusts are generally accepted to be clinically safer and less traumatic than manual thrusts. The reasons being that instrumental thrusts are low-force and delivered in a neutral prone position, so there is no torque or stretching of ligament or joint capsule (Kleynhans 1980: 364,369, Fuhr 1995).

It is Slosberg’s (1998) opinion that the manner in which impulses are delivered (i.e. no torque) may also eliminate the elements of fear, discomfort and resistance that may accompany a manual adjustment, thus improving patient perception. The activator instrument would seem to deliver a more controlled force to a specific contact point (Fuhr and Smith 1986, Byfield 1991) than a manual thrust.

To summarise: The activator adjusting instrument provides a manually manipulatable adjusting device, designed to generate reproducible and controlled force, displacement, acceleration, and specific line of correction to the fixated segment. The activator thus attempts to eliminate variability inherent in manual adjusting.

2.4.4 The Activator and Activator Methods Chiropractic Technique (AMCT)

“The AMCT seeks to conduct a systemic analysis of basic body biomechanics, with the understanding that disturbed mechanics leads to disturbed function“(Cooperstein et al, 2004). Numerous biomechanical assessment procedures have been utilised by the chiropractic profession for its diagnostic and therapeutic decisions. One such measure is the assessment of leg length inequality (LLI), which is thought to provide valuable information about the status of the lumbar spine and sacroiliac joints, which is of central importance to Activator Methods Chiropractic Technique (Fuhr et al.,

1997). Leg length inequality (LLI) has been implicated in numerous musculoskeletal conditions, and is usually categorized as anatomic or functional. Anatomic leg length inequality results from congenital or acquired deformities and represents actual or 'true' bony asymmetry (Giles, 1981). Functional contributions to LLI are physiologic responses to altered mechanics along the kinetic chain, sometimes resulting in the appearance of a short leg (Mannello, 1992). The activator method uses the prone leg check as an approach to diagnose and determine if a leg length inequality exists

and then uses pressure testing by the doctor to certain areas as well as particular hand /arm movements by the patient to determine where the fixated joint exists. The activator is then applied to the appropriate area and a number of high-velocity, low-amplitude thrusts are delivered (Fuhr, 1997).

2.4.5 Contra-indications to treatment

Slosberg (1998) states that he is not aware of any contra-indications to care that are specific to AMCT that are any different to chiropractic care in general. The percussive instrument is thought to however lower the risk of iatrogenic post-manipulative injuries that may occur. He also states that "the activator technique, because of its controlled force and displacement, is widely considered to be safe, non-traumatic method of chiropractic care" (Slosberg, 1998).

2.4.6 Studies involving the activator adjusting instrument

A review was done which included a case study in which Osterbauer and Fuhr (1992), found that a sciatica patient improved within one month of care using instrument manipulation, after three months of failed medical care. Another study done by Osterbauer and De Boer, et al (1993) found significant decrease in the Visual Analogue Scale and Oswestry scores following treatment using instrument manipulation for sacroiliac joint syndrome. They also noticed a reduction in the number of pain provocation tests applied to the research subjects.

Numerous other conditions have also been treated using the activator as a stand alone intervention, one of which involves the relative effectiveness of the activator when compared to manual manipulation in the treatment of cervical spine dysfunction. The study states that both interventions had benefits in improving the facet joint dysfunction (Wood, 2001). Another study involving acute facet syndrome of the lumbar spine, compared manual adjusting to instrument assisted adjusting and

concluded that both groups displayed statistically significant improvement (Gillespie, 2003).

2.5 The placebo effect and non-specific effects

“The placebo effect in general practice is the power of the doctor alone to make the patient feel better, irrespective of medications. It is one of the most important factors in the consultation, yet generally it is neglected, unrecognised and untaught ” (Thomas, 1994).

2.5.1 Defining placebo

In Latin, a pure placebo, meaning: ‘ I will please’, may be defined as a treatment or intervention which is believed to lack any specific treatment effect, or scientific mechanism of action.

The use of the term “placebo” has been described by Kienle as an imitation of a therapy. The term is also applied to all modifications of self-healing properties, to complementary therapies, and to all psychological therapies. This research relates to an imitation of therapy. It is this concept of placebo effects for which there are such tremendous claims of therapeutic effects from 30% to 100% (Kienle et al., 1996).

Hrobjartsson (1996) states that placebo effects can result simply from contact with doctors or other health care providers and puts it “ Any therapeutic meeting between a conscious patient and a doctor has the potential of initiating a placebo effect” (Hrobjartsson, 1996). Thus, the placebo effect can be described as the measurable, observable or felt improvement in health not attributable to treatment. Some believe the placebo effect is psychological due to belief in the treatment or to a subjective feeling of improvement (Kirsch 1998). He believes that the critical factors is the patient’s belief and hopes about a treatment, combined with suggestibility that may have a biochemical effect, i.e. the sensory experience and thoughts can affect neurochemistry, hence the body’s neurochemical system, which include the hormonal and immune system. Thus, he states that a person’s hopeful attitude and beliefs may be what’s important to their physical well - being and recovery from injury and illness. He summarises by suggesting that it may be that the placebo effect is not a matter of mind over molecules, but mind over behaviour (Kirsch, 1998).

The management approach of chiropractic interventions can either have specific (active) effects, e.g. spinal manipulation to restore joint motion, releasing muscle

spasm and altering neurophysiological effects, or it can provide the greatest non-specific effects. Non-specific effects are often used interchangeably with placebo effects, and are the benefits felt by the patient because of the nature of the healing encounter, such as the magic potency of pills, the reassurance of the laying on of the hands, the definitive 'pop' of the chiropractic adjustment and the presence of the confident health practitioner (Barker 1985).

Numerous psychological triggers have been identified which can affect the non-specific component during treatment. The nature of chiropractic practice is very physical and social which would make use of the wellness triggers, which may enhance non-specific outcomes in the healing encounter, but to what extent is unknown (Jamison, 1998). The wellness triggers can be put into categories, i.e. a healing setting, a healing ritual, a positive outcome expectation, and a positive efficacy expectation (Jamison, 1998).

Analysis of the reasons for a patient's improvement must not only be limited to specific and non-specific treatment effects but natural regression should also be considered. During any period of treatment there is a natural tendency to get better, thus natural remission may also play a role (McDonald et al., 1983).

Contributing to this concept which needs to be considered, is that fluctuations of symptoms and natural improvement of a disease are special forms of a regression to the mean, which always has to be considered when observations are started with values strongly deviating from the norm. He suggests that many patients tend to consult physicians or get help when their symptoms are at their worst, hence in these situations symptoms will rather improve than deteriorate (McDonald, 1983).

2.5.2 The Clinical ritual in manual therapy

A clinical ritual relates to the treatment of patients according to a pre-determined set of symbolic actions, performed in a particular environment (Encyclopedia / Labor law talk, n.d). An example of the clinical ritual relating to manual therapy can be found in association with the use of the activator device and is known as the activator technique (as discussed in 2.4.4) (Fuhr, 1997).

The clinical ritual may contain elements that strengthen the non-specific effect.

Vernon states that the interaction between physician and the patient can be extremely influential in terms of patient outcomes, and in some cases the patient and

provider expectations and interactions may be more important than the actual treatment (Vernon, 1991). Roberts (1993) evaluated the hypothesis that the power of non-specific effect may account for as much as two thirds of successful treatment outcomes when both the healer and the patient believe in the efficacy of a treatment, and concluded that under conditions of heightened expectations, the power of non-specific effects far exceeds that commonly reported in the literature (Roberts et al, 1993). Many patients have negative experiences with practitioners, for either their hurried manner, insensitivity, lack of responsiveness, failure to explain the problem or treatment or, unwillingness to involve the patient (Young et al, 1995). Thus it stands to reason that the non-specific therapy should be an inherent component of every clinical encounter. Failure to recognise, maintain and enhance the particular elements of non-specific intervention in chiropractic care may ultimately impoverish the profession according to Jamison (Jamison, 1998).

The clinical ritual in this research involves practitioner-patient interaction, diagnostic provocative maneuvers and leg checks by the doctor to determine fixations, as well as active participation from the patient to perform certain movements and subsequent application of low force adjustments by means of the activator. Hence, the clinical ritual will be repeated in precisely the same manner at every visit. This will enable a greater understanding of the extent of the clinical ritual and it's relationship with non-specific effects that occur in the chiropractic clinical setting.

2.6 Conclusion

The activator in accordance with the activator methods chiropractic technique has a strong clinical ritual associated with it, and therefore it may not be appropriate to try and isolate specific and non-specific effects from one another as both appear to be important and interactive either to enhance or minimise the other. The clinical environment as well as the patient-practitioner interaction all appears to influence the patient's perception and the overall outcome of the patient's condition, thus forming an integral part of effective chiropractic care. Patient care and the management thereof have developed greatly in recent years. The trend of medicine moving toward a more holistic approach, including regard for patient's perceptions, can only improve the therapeutic encounter (Bolton, 1999).

Therefore it can be deduced that both specific and non-specific effects, can have a distinct advantage of not being isolated from each other as chiropractic is very strong in both spheres, hence this will allow us to appreciate clinical effect.

Hence the aim of this research was to determine the extent of influence that non-specific effects may have during the clinical ritual, whilst implementing instrument assisted adjusting during the management of mechanical lower back pain.

Chapter three

Materials and Methods

3.1 Introduction

This chapter gives details of the methods employed in data collection as well as the statistical methods used for the interpretation of the data. This includes a detailed description of the design, primary and secondary data, the subjects and intervention used.

The object of the study was to determine the effect of the clinical ritual during treatment using the activator methods chiropractic technique for patients suffering from mechanical low back pain, in order to determine the extent of which non-specific effects may play in the chiropractic environment.

3.2 The data

Both primary and secondary data were used in this study. The nature of the data is discussed below.

3.2.1 The primary data

Primary data was collected directly from the patient using the following: Information gathered from the case history (Appendix A), and a physical examination (Appendix B), as well as:

- 1) The Visual Analogue Scale (Fejer et al, 2005) (Duncan, 1989) was used (Appendix H) at the first visit only, to measure the patient's perception of their pain level, of which a minimum score of 5 was needed to partake in the study. The cut-point on the VAS was set at 5. Although the establishment of cut-points is still in its infancy, patients had to have a VAS rating of 5 or greater to be included in the study. This allows for greater group/sample homogeneity (Mouton, 1996).

- 2) The patient's perception of their disability was obtained through the use of the Roland Morris Back Pain Questionnaire (Stratford et al., 1998) (Appendix J), in order to determine if the patients perceived functionality regarding their lower back was improving or not during and after the treatment.
- 3) The numerical pain rating scale (McCaffery et al., 1999) (Appendix I), was used to determine the patients current level of pain in order to establish if their level is decreasing or not over the duration of the treatment. Grading pain intensity scales into simple categories provides useful information for both clinicians and epidemiologists, and methods to classify pain severity for numerical rating scales have been recommended (Fejer et al. 2005).
- 4) The patient's subjective level of current pain type was obtained through the use of the Short -form McGill pain questionnaire, which included their present pain intensity (PPI) (Melzack, 1987) (Appendix K).
- 5) Diagnosis of presenting fixations in the lumbar-sacral area using the Activator Methods Chiropractic Technique (Fuhr, 1997) (Appendix N).

3.2.2 The secondary data

The secondary data was obtained from scientific journal articles, published reports and textbooks containing the relevant information, as well as the internet (using relevant search engines).

3.2.3 Criteria governing the admissibility of the data

The only subjective data admissible was obtained from the Visual Analogue Scale (visit one only), the Numerical Pain Rating Scale (first, third and fourth visits), the Roland Morris Back Pain Questionnaire (first, third and fourth visits) and the Short-form McGill Pain Questionnaire, which included their present pain intensity (first, third and fourth visits), which were completed by the patients under the supervision of the researcher. The data i.e. specific fixations found in the lumbar-sacral area, was obtained from the diagnosis using the Activator Methods Chiropractic Technique, which was obtained by the technician and documented by the researcher.

3.3 Subject selection

Subjects were recruited by means of adverts (appendix M), which were placed at local sports clubs, pharmacies, and health shops around the Port Elizabeth area. Word of mouth proved to be successful. It was advertised that free treatment would be available to any members of the public between the ages of 18-59 suffering from low back pain that correlated with the research criteria. Although there was a wide range in age i.e. (18-59), the aim was to observe the ritual and not necessarily the intervention effect.

3.3.1 Sampling procedure

A) Sample size

The sample size consisted of two selected groups of 30($n=30$) patients each, making the total of 60 ($n=60$).

B) Sample allocation and characteristics

The patients were accepted either from telephonic or walk-in encounters, who were then screened (i.e. case history, physical examination and lumbar regional examination). The candidates who qualified according to the research criteria were allocated into two groups by their choice of letter (A or B), by the researcher.

The sampling allocation used was done by means of stratified sampling according to gender parameters. The sample was then allocated randomly after it was stratified.

The groups were formed as follows:

	Treatment group	Placebo group
Male	15	15
Female	15	15

3.4 Inclusion and exclusion criteria

3.4.1 Inclusion criteria

- a) The patients were between the ages of 18-59 years, so as to avoid the possibility of fibrous ankylosis in the sacroiliac joint after the sixth decade (Kirkaldy-Willis 1992). The placebo effect is not age related and therefore, age homogeneity was not a primary concern in this study.
- b) Patients had to test positive for either lumbar facet syndrome or sacro-iliac syndrome (i.e. mechanical low back pain) (Kirkaldy-Willis 1992).
- c) Patients already taking anti-inflammatories were included, following a 3-day washout period (Seth 1999), in order to obtain a more accurate set of results.
- d) Patients had to obtain a score of between 5-10 on the VAS questionnaire, to establish a significant level of pain or discomfort that is to be treated so as to narrow the range of pain levels in order to obtain a more refined set of results.
- e) All candidates to the study had to be “naïve” to the treatment and exposure to AMCT. This would include any patients who have received activator treatment in the last 3-6 months, so as to ensure the maximal naivety of the participating patients, and to ensure that the placebo treatment was not perceived as a sham (Mouton, 1996).
- f) An informed consent form had to be signed by the patient.

3.4.2 Exclusion criteria

- a) Patients who were pregnant (due to hormone induced ligament laxity and possible resultant instability of the sacroiliac joint) (Vleeming et al., 1990).
- b) If they had any hip pathology or recent surgery (Kirkaldy-Willis 1992).
- c) Any patients with destructive lesions of the lumbar spine, gross instability, cauda equina syndrome, large abdominal aortic aneurysm or visceral referred pain (Kirkaldy-Willis 1992).
- d) Contra -indications for the activator would be infections of the skin/dermatitis, as placement is directly on the skin (Fuhr et al., 1997).
- e) Patients with underlying systemic/organic pathology, which could cause their underlying low back pain (Davidson 2002).
- f) Any patient with objective neurological deficit (Davidson 2002).
- g) Any patient requiring an x-ray or other form of specialised diagnostic testing other than clinical examination.

3.5 Patient allocation

Following the case history, physical and regional examinations, and providing the patients qualified according to the research criteria, the participant needed to agree to participate in the study and subsequently read a letter of information (Appendix E), which gave a detailed outline of the study. Once this was completed they were required to sign an informed consent form (Appendix F).

The sample population consisted of sixty patients, selected for the study according to the aforementioned criteria.

3.5.1 Random allocation

A system of randomized allocation was used in order to divide the subjects into two equal groups, which were then further sub-divided into two groups of 15 according to gender. Sixty pieces of paper with either an A or B were placed into an envelope and patients were asked to draw a letter. Patients drawing letter A were placed into the treatment group with the tension of activator on maximum, and those choosing letter B were placed into the placebo group (tension of activator on zero).

3.6 Blinding

The patients were blinded as to whether they were in the treatment group or the placebo group. The technician assisting in the treatment process was also blinded as to whether the patients were improving or not, so as to try and remove any treatment bias possibly given by the technician during each session. Increased areas of blinding add to a more objective outcome that ultimately aims to increase the validity of results, especially as this study has a large non-specific aspect to it. The technician was not blinded to which group the participants were in when performing the clinical, as the technician would be able to establish which setting the activator was on.

3.7 Intervention

According to Fuhr, fixations are detected primarily by the leg check procedure, and addressed with a mechanical percussive tool (Activator Adjusting Instrument) (Fuhr,1997). It is a hand held, manually assisted, spring-activated device, which delivers a maximum of 0.3 J of energy under controlled conditions (Osterbauer, 1992) (See appendix Q for a diagram). Thus, the activator is capable of providing a dynamic thrust that includes a controlled force of adjustment at a precise and specific line of drive at high speed (Fuhr, 1990).

GROUP A: Activator Adjusting Instrument (tension on maximum)

Patients in group A received adjustments instrumentally by means of the Activator Adjusting Instrument according to the AMCT (3.7.1).

Dysfunctional segments were identified by means of the AMCT (Appendix N), which was at the discretion of the technician.

Group B: Activator Adjusting Instrument (tension on zero)

Patients in group B received adjustments instrumentally by means of the Activator Adjusting Instrument according to the AMCT (3.7.1), except the tension of the activator was on zero. Dysfunctional segments were identified by means of the AMCT (Appendix N), which was at the discretion of the technician.

3.7.1 Adjustment protocol according to AMCT

The AMCT aims to conduct a systemic analysis of basic body mechanics, under the general belief that disturbed mechanics leads to disturbed function (Cooperstein,1997). The measurement of relative leg length constitutes the primary AMCT- specific diagnostic procedure. Relative leg lengths may change in response to isolation testing, i.e. turning the head, placing the hands on the lower back or raising the hip, providing prima facie evidence of a fixation. The relative leg length differentials, provide evidence of pelvic torsion and associated lumbopelvic dysfunction (Cooperstein, 1997). Cooperstein also states that isolation testing is the primary screen for fixation detection, in that changes in relative leg length in response to provocative positioning of the extremities are thought to indicate segmental dysfunction. Suspected segments would then be systematically subjected to pressure testing and palpation as confirming procedures (Cooperstein, 1997).

Fixation	Adjustment
Lumbar 5-	Contact mammillary process on side indicated by short- long rule-loss of direction is anterior-superior
Lumbar 4-	Contact mammillary process on side indicated by short-long rule -loss of direction is anterior –superior
Lumbar 3-	Contact mammillary process on side indicated by short-long rule-loss of direction is anterior-superior
Lumbar 2-	Contact mammillary process on side indicated by short-long rule-loss of direction is anterior-superior
Lumbar 1-	Contact maxillary process on side indicated by short long-rule-LOD is anterior-superior
Contact points for left AS (anterior- superior) and left PI (posterior-inferior) Appendix: O	
Contact points for right AS (anterior-superior) and right PI (posterior-inferior) Appendix: P	

3.8 Methods of measurement

3.8.1 Subjective measurements

Subjective measurements were obtained using the Visual Analogue Scale, (Appendix H), the Numerical Pain Rating Scale (Appendix I) and the Roland Morris low back pain questionnaire (Appendix J), and the McGill Pain questionnaire (Appendix K).

3.8.1.1 Visual Analogue Scale (VAS)

The VAS was used to determine a current pain intensity level. The VAS is one of the most frequently used measurement scales (Duncan et al., 1989). All candidates had to score a minimum of a 5 out of 10 /50-100, done only at the first visit in order to qualify for the study. Grading pain intensity scales into simple categories provides useful information for both clinicians and epidemiologists and methods to classify pain severity for numerical rating scales have been recommended (Fejer et al. 2005). The cut point for this study was a minimum of 5 out of 10 as this allow for greater sample homogeneity (Mouton, 19960).

3.8.1.2 Numerical Pain Rating Scale- 101

The Numerical Pain Rating Scale has been selected due to its advantages over other measures. It is extremely easy to administer and score, and has 101 response scores and is thus more accepted by clinicians and researchers (McCaffery et al., 1999). The patients were instructed to record their pain intensity on the scale. Zero was pain free and one hundred was pain at its worst. Measurements were taken at the first, third and fourth visits.

3.8.1.3 Roland Morris Questionnaire

The Roland Morris Questionnaire has been used due to its simplicity for the patient regarding questions concerning their functional ability, with respect to their low back pain (Stratford et al., 1989).

The appropriate boxes were marked on the questionnaire, and this was administered on the first, third and fourth visits.

3.8.1.4 Short-form McGill Pain Questionnaire

According to Melzack, "It is the most widely used measuring test for pain providing valuable information on the sensory, affective and evaluation dimensions of pain experience". This form of measurement is of the patient's perception of their pain intensity and quality. This allows for a sensory dimension of pain. The form is made up of fifteen descriptive words which are rated on an intensity scale: 0=no pain, 1=mild, 2=moderate and 3=severe. Present pain intensity was also rated and circled by the participant on the form, ranging from 0=no pain; 1=mild; 2=discomforting; 3=horrible; 4=excruciating. The sheet once completed is scored and then converted into a percentage (Melzack, 1987:197).

3.9 Statistical methods of satisfying objectives

3.9.1 Intra-group tests, namely independent t-tests and Pearson's correlation were used for objectives one and two.

3.9.2 Inter-group tests, namely repeated measures ANOVA, were used for objective three.

3.10 Statistical Analysis

3.10.1 Treatment Of The Data

3.10.1.1 Subjective Data

The subjective data was treated as follows:

Questionnaires that the patients filled out were screened to ensure that they had been filled out correctly. Raw data from the questionnaires were converted into percentages where necessary and recorded separately for each group.

The data was analyzed using a 5% significance level.

3.11 Statistical procedure

Following consultation with a research statistician, statistical analysis was conducted on the subjective data using the SPSS Version 11.5 statistical software programme (manufactured by SPSS Inc., 444N. Michigan Ave, Chicago, Illinois, 60611, USA).

The results of the demographic profiles of the participants **are** presented in the form of graphs and tables.

Inferential statistical evaluation was aimed at measuring any significant changes occurring between the initial and third consultations, and the follow up consultation, as well as between the two groups.

Thus, parametric testing was used to analyze the VAS, NRS, Roland Morris and Short-Form McGill Questionnaires. The analysis determines any significant changes between the first, third and follow up consultations. Treatment effect was analysed by repeated measures ANOVA since repeated data was collected over three time points. Pearson's correlation was done intra-group to assess correlations between changes in outcome measures over time.

A two-tailed p value of <0.05 was considered as statistically significant.

Chapter four

The results

4.1 Introduction

This study was made up of 60 patients, ranging between 18-59 years of age, equally divided into 2 groups of 30 and further divided into four groups of 15 according to gender, to control for this variable.

Group A was treated by means of the activator according to the AMCT with the activator on maximum tension and group B, the placebo group was also treated by means of the activator according to the AMCT but with the tension on zero.

Statistical analyses of the patient's pain and discomfort levels were carried out to assess the extent of the non-specific effects that occur between the two groups. Both inter and intra group comparisons were drawn.

4.2 Criteria governing the admissibility of the data

The data used in this study was obtained from the following information:

Patient demographics - Age

- Number of pelvic fixations
- Number of lumbar fixations

Visual Analogue Scale (VAS)

Numerical Pain Rating Scale-101 (NRS)

Roland Morris Pain Questionnaire (RMQ)

Short-form McGill Pain Questionnaire (SM)

Fixations diagnosed according to AMCT

4.3 Results

4.3.1 Demographics

Demographics and baseline outcomes were compared between the two randomized groups to ensure that they were equal at the outset.

4.3.1.1 Age

Age of participants was significantly different between the treatment groups ($p=0.016$, Table 1). The placebo group was older than the treatment group (mean age of placebo group = 35.97, mean age of treatment group = 29.53). Since this factor may have influenced the outcomes measured, it was controlled for in subsequent analysis of the effect of the treatment. Age was entered in the ANOVA model as a covariate.

Table 1: Comparison of mean age of participants between treatment groups using an unpaired-t-test

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	t	p value
AGE	Full tension activator	30	29.53	8.529	1.557	-2.478	0.016
	Placebo	30	35.97	11.379	2.078		

4.3.1.2 Number of pelvic fixations

Table 2 shows that there was no evidence of a treatment effect for number of pelvic fixations ($p=0.464$) over the intervention period, however, Figure 1 shows that the number of fixations decreased at a faster rate in the activator group than the placebo group.

Table 2: Within and between subjects effects for number of pelvic fixations (n=60)

Effect	Statistic	p value
Time	Wilk's lambda=0.977	0.522
Group	F=0.056	0.814
Time* group	Wilk's lambda=0.972	0.464

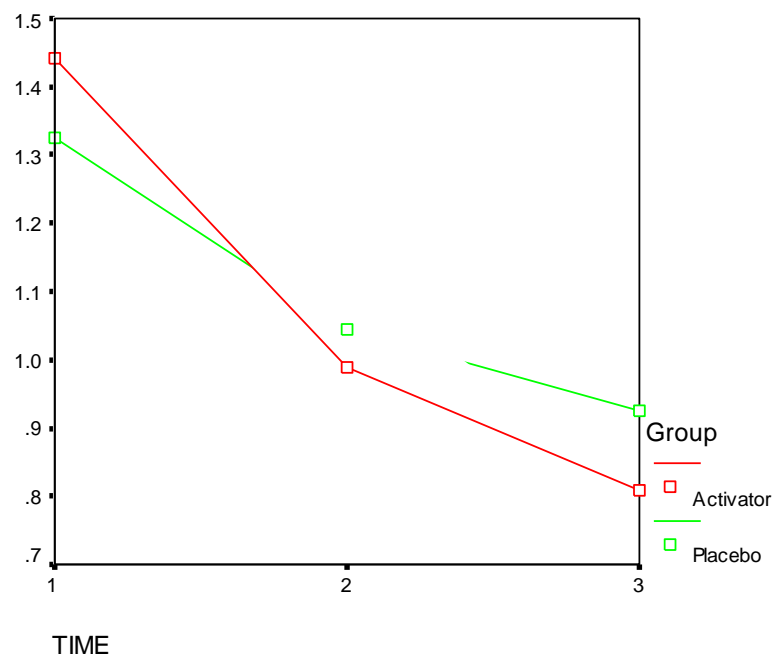


Figure 1: Profile plot of mean number of pelvic fixations by group over time

4.3.1.3 Number of lumbar fixations

Table 3 shows that there was no evidence of a treatment effect for number of lumbar fixations ($p=0.905$) over the intervention period, however, there was a significant difference between the two groups at all time points ($p=0.018$) in terms of the number of fixations identified. If one examines Figure 2, the rate of decrease over time in the two groups is parallel. Thus, the treatment did not have an effect on decreasing the number of lumbar fixations over and above the placebo effect.

Table 3: Within and between subjects effects for number of lumbar fixations (n=60)

Effect	Statistic	p value
Time	Wilk's lambda=0.978	0.547
Group	F=5.956	0.018
Time* group	Wilk's lambda=0.996	0.905

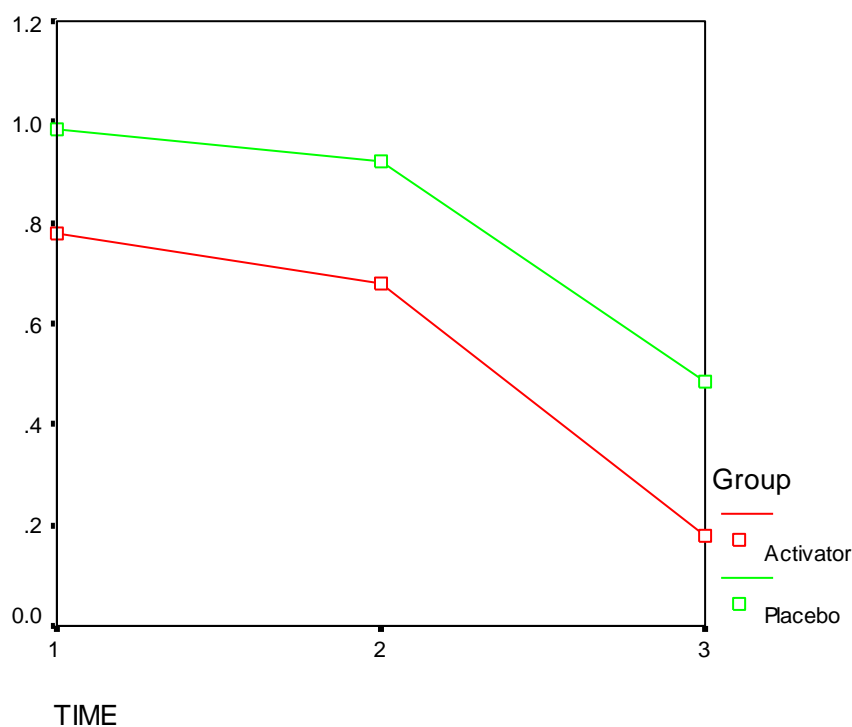


Figure 2: Profile plot of mean number of lumbar fixations by group over time

4.4 Inferential statistics

4.4.1 VAS

The VAS was only done at the first visit in order to ascertain whether the patient was able to partake in the study, i.e. they had to have a level of pain rating between 5-10. Table 4 shows the comparison between the treatment groups of the mean VAS score at baseline. This is an indicator of severity of pain at baseline, and should ideally be identical in both groups. However, a significant difference was found ($p=0.004$) between the groups with the placebo group having a higher mean VAS score and thus more pain than the treatment group. Thus VAS was also controlled for in the further analysis of the treatment effect. The VAS was entered into the ANOVA model as a covariate.

Table 4: Comparison of mean visual analogue scale score between treatment groups using unpaired-t-test

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	t	p value
VAS	Full tension activator	30	5.33	.758	.138	-3.043	0.004
	Placebo	30	6.07	1.081	.197		

4.4.2 NRS

Table 5 shows that there was a significant difference in NRS score between the two groups at baseline ($p=0.013$), with the placebo group having a higher score (mean = 6) than the treatment group (mean = 5.33). This is consistent with the difference in VAS scores between the groups. There were no other significant differences in baseline outcome measurements between the groups. The repeated measures ANOVA procedure corrects for any baseline differences between groups.

Table 5: Comparison of mean baseline outcome measurements between treatment groups using an unpaired-t-test

	Group	N	Mean	Std. Deviation	Std. Error Mean	t	p value
NRS	Full tension activator	30	5.33	.758	.138	-2.567	0.013
	Placebo	30	6.00	1.203	.220		
RMQ	Full tension activator	30	4.00	3.667	.670	-1.639	0.107
	Placebo	30	5.57	3.739	.683		
SM	Full tension activator	30	7.77	5.870	1.072	0.985	0.330
	Placebo	30	6.60	2.762	.504		
Present pain intensity (PPI)	Full tension activator	30	2.03	.320	.058	-1.163	0.250
	Placebo	30	2.13	.346	.063		
Number of pelvic fixations	Full tension activator	30	1.43	.504	.092	0.787	0.434
	Placebo	30	1.33	.479	.088		
Number of lumbar fixations	Full tension activator	30	.80	.610	.111	-1.054	0.296
	Placebo	30	.97	.615	.112		

Table 6 shows that there was no significant time or group main effects, but the time*group interaction (treatment effect) was statistically significant. This means that the effects over time were different according to treatment group. If one examines Figure 3, the profile plot shows that while both groups decreased in mean NRS over time, the rate of decrease was steeper in the activator group. Thus for NRS, whilst controlling for age and VAS, a significant treatment benefit for the activator group was found.

Table 6: Within and between subjects effects for NRS (n=60)

Effect	Statistic	p value
Time	Wilk's lambda=0.928	0.127
Group	F=2.855	0.097
Time* group	Wilk's lambda=0.896	0.048

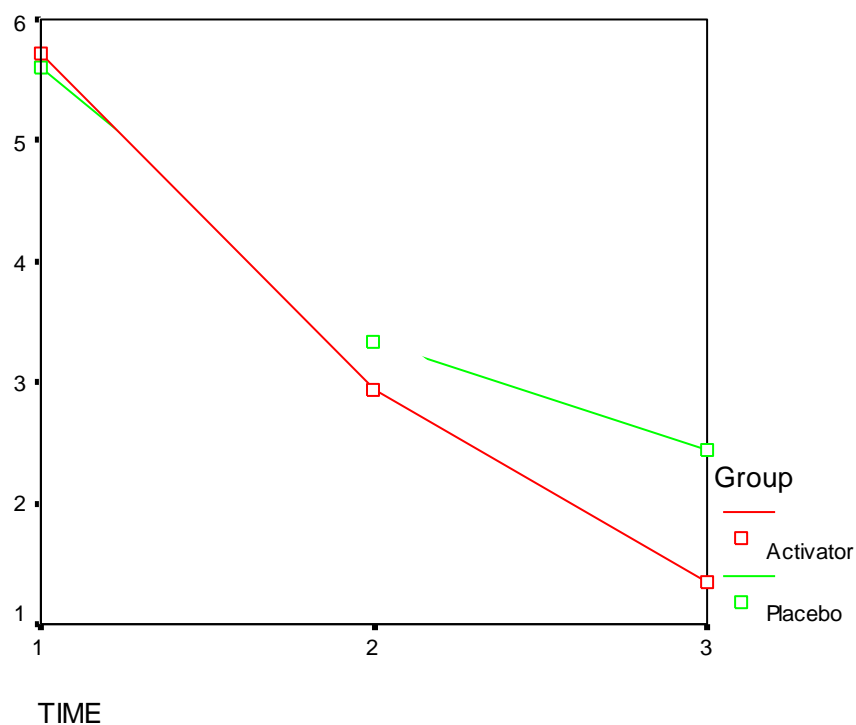


Figure 3: Profile plot of mean NRS by group over time

4.4.3 RMQ Score

RMQ score showed no evidence of a differential treatment effect ($p=0.855$). There was also no significant improvement in either group over time ($p=0.911$). Figure 4 shows that the groups did show a decrease in score over the three time points, but the slopes of the two lines were similar.

Table 7: Within and between subjects effects for RMQ (n=60)

Effect	Statistic	p value
Time	Wilk's lambda=0.997	0.911
Group	F=2.003	0.163
Time* group	Wilk's lambda=0.994	0.855

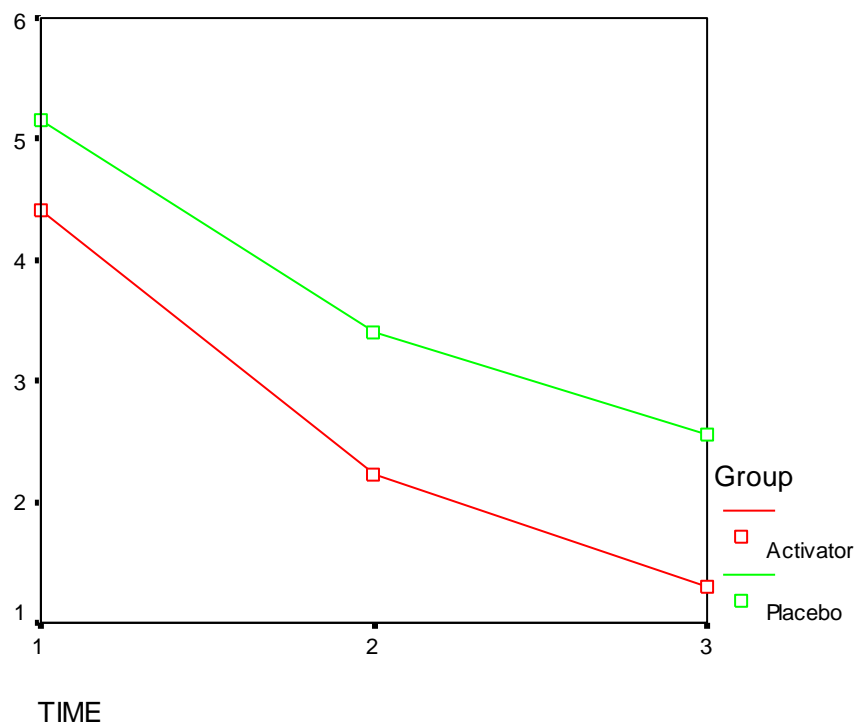


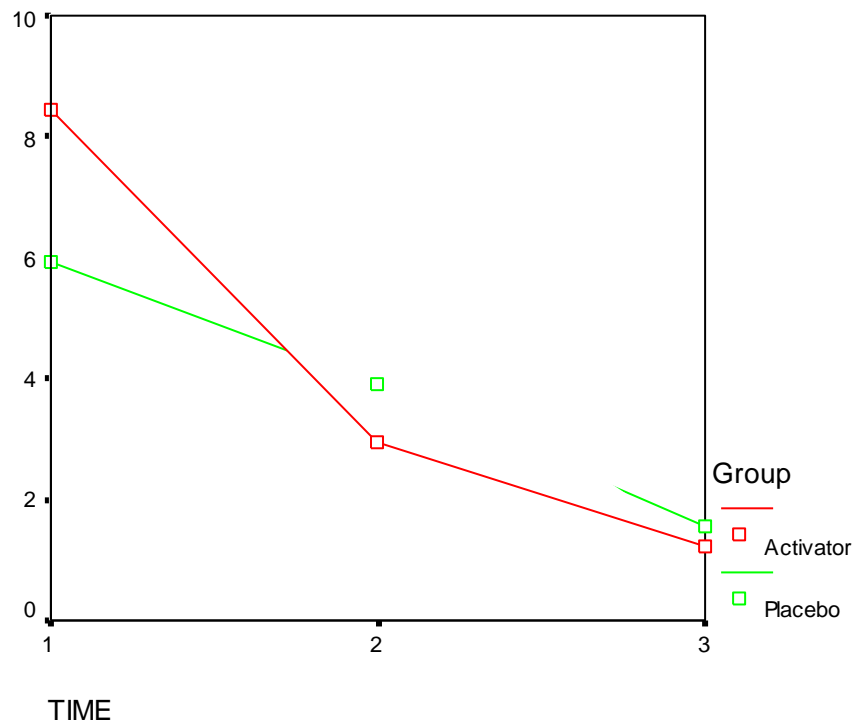
Figure 4: Profile plot of mean RMQ score by group over time

4.4.4 Short Form McGill Score (SM)

SM score was a composite score composed of summing the scores of all the items in the SM questionnaire. For SM score there was a marginally non-significant treatment effect ($p=0.085$). Figure 5 showed a faster rate of decrease over time in the activator group, while the decrease in the placebo group was linear and steady.

Table 8: Within and between subjects effects for SM score (n=60)

Effect	Statistic	p value
Time	Wilk's lambda=0.996	0.896
Group	F=0.302	0.585
Time* group	Wilk's lambda=0.914	0.085

**Figure 5: Profile plot of mean SM score by group over time**

4.4.5 Present pain intensity (PPI)

PPI score changed significantly over time in both groups ($p < 0.001$) but the rate of change was the same in both groups ($p = 0.294$), thus there was no statistical evidence of a treatment effect. However, Figure 6 shows a trend towards a slightly steeper rate of descent in the activator group than in the placebo group.

Table 9: Within and between subjects effects for PPI score (n=60)

Effect	Statistic	p value
Time	Wilk's lambda=0.772	<0.001
Group	F=1.713	0.196
Time* group	Wilk's lambda=0.956	0.294

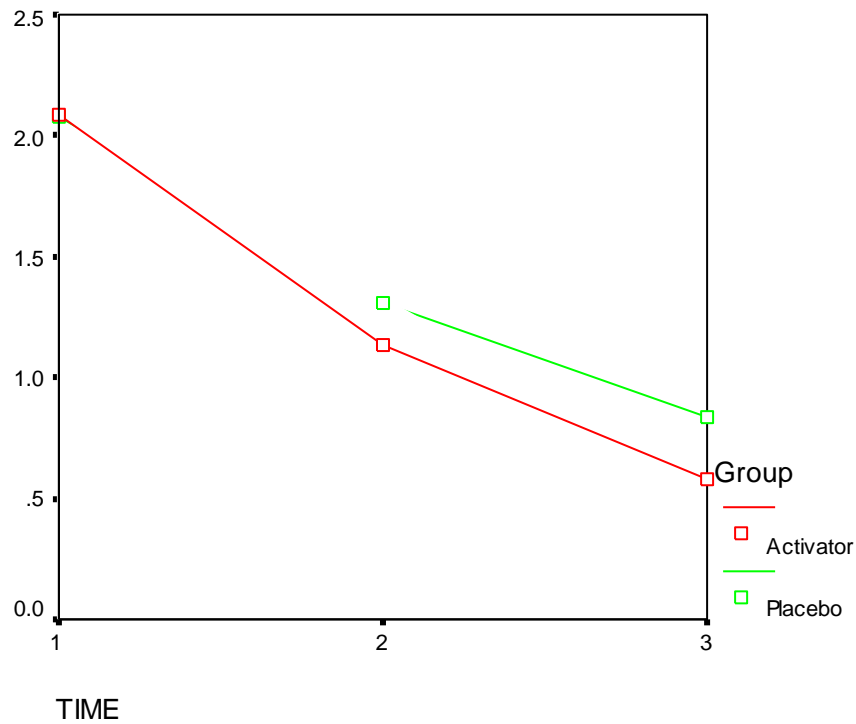


Figure 6: Profile plot of mean PPI score by group over time

4.5 Correlation in changes in outcomes

4.5.1 Activator group

Intra-group correlation analysis in the activator group revealed that not many of the outcome measurements were correlated together. Only the change in NRS and PPI showed a weak positive correlation ($r=0.437$, $p=0.016$), as well as a moderate positive correlation between RMQ and SM ($r=0.760$, $p<0.01$). Change in number of lumbar and pelvic fixations were weakly negatively correlated ($r=-0.448$, $p=0.013$), thus as the one increased, the other decreased.

Table 10: Pearson's correlation between changes in outcome measurements in the activator group

		Change in NRS	Change in RMQ	Change in SM	Change in PPI	Change in no. of pelvic fixations	Change in no. of lumbar fixations
Change in NRS	Pearson Correlation	1	.054	.027	.437(*)	.054	.251
	Sig. (2-tailed)	.	.777	.888	.016	.776	.180
	N	30	30	30	30	30	30
Change in RMQ	Pearson Correlation	.054	1	.760(**)	.243	-.283	.072
	Sig. (2-tailed)	.777	.	.000	.196	.129	.707
	N	30	30	30	30	30	30
Change in SM	Pearson Correlation	.027	.760(**)	1	.221	-.291	.060
	Sig. (2-tailed)	.888	.000	.	.240	.119	.752
	N	30	30	30	30	30	30
Change in PPI	Pearson Correlation	.437(*)	.243	.221	1	.024	.198
	Sig. (2-tailed)	.016	.196	.240	.	.900	.294
	N	30	30	30	30	30	30
Change in no. of pelvic fixations	Pearson Correlation	.054	-.283	-.291	.024	1	-.448(*)
	Sig. (2-tailed)	.776	.129	.119	.900	.	.013
	N	30	30	30	30	30	30
Change in no. of lumbar fixations	Pearson Correlation	.251	.072	.060	.198	-.448(*)	1
	Sig. (2-tailed)	.180	.707	.752	.294	.013	.
	N	30	30	30	30	30	30

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

4.5.2 Placebo group

Slightly more of the outcomes were positively correlated in the placebo group. NRS was weakly correlated with change in RMQ, SM and PPI, as was RMQ and PPI, all with correlation coefficients less than 0.5. There was a moderate positive correlation between RMQ and SM ($r=0.644$, $p<0.001$).

Table 11: Pearson's correlation between changes in outcome measurements in the placebo group

		Change in NRS	Change in RMQ	Change in SM	Change in PPI	Change in no. of pelvic fixations	Change in no. of lumbar fixations
Change in NRS	Pearson Correlation	1	.469(**)	.484(**)	.380(*)	-.053	.279
	Sig. (2- tailed)	.	.009	.007	.038	.781	.135
	N	30	30	30	30	30	30
Change in RMQ	Pearson Correlation	.469(**)	1	.644(**)	.398(*)	-.008	.007
	Sig. (2- tailed)	.009	.	.000	.029	.966	.972
	N	30	30	30	30	30	30
Change in SM	Pearson Correlation	.484(**)	.644(**)	1	.175	.016	-.189
	Sig. (2- tailed)	.007	.000	.	.355	.934	.317
	N	30	30	30	30	30	30
Change in PPI	Pearson Correlation	.380(*)	.398(*)	.175	1	-.284	.155
	Sig. (2- tailed)	.038	.029	.355	.	.129	.415
	N	30	30	30	30	30	30
Change in no. of pelvic fixations	Pearson Correlation	-.053	-.008	.016	-.284	1	-.071
	Sig. (2- tailed)	.781	.966	.934	.129	.	.709
	N	30	30	30	30	30	30
Change in no. of lumbar fixations	Pearson Correlation	.279	.007	-.189	.155	-.071	1
	Sig. (2- tailed)	.135	.972	.317	.415	.709	.
	N	30	30	30	30	30	30

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

Chapter five

Discussion

5.1 Introduction

The aim of this chapter is to discuss the subjective findings in a simple and clear manner. The results will be divided into demographics, inferential statistics and correlation in changes in outcomes.

5.2 Criteria governing the data

The demographical statistics consisted of age, number of pelvic fixations and number of lumbar fixations. The subjective data consisted of the Visual Analogue Scale, the Numerical Pain Rating Scale-101, the Roland Morris Questionnaire, and the Short-form McGill Pain Questionnaire (which included the present pain intensity).

5.3 Results

5.3.1 Demographics

5.3.1.1 Age

There was a significant difference between the groups, the placebo group having a higher age group than the treatment group. The clinical and natural history progression between the two groups may have been different, due to the age differences, favoring the activator group. This factor may have influenced the outcomes measured, so it was controlled for in subsequent analysis of the effect of the treatment. Hence it was entered in the ANOVA model as a covariate.

5.3.1.2 Number of pelvic fixations

Fig 1 indicates that the number of pelvic fixations in the full tension activator group decreased more rapidly from the 1st to the 3rd visit when compared to the placebo group, even though the number of pelvic fixations in the placebo group also decreased. This difference could be due to the fact that there was a trend in the full-tension activator group participants to have a longer period of lower back pain than the placebo group (gathered from case history notes). Thus natural history could have had some sort of influence as back pain, tends to improve spontaneously with time (Whitney, 1992). Thus there was a non -specific trend towards a beneficial effect of the activator for decreasing the number of pelvic fixations. There was no correlation found between pelvic fixations and pain.

5.3.1.3 Number of lumbar fixations

Fig 2 indicates that there is a decrease in lumbar fixations over time, however there is no overlapping of the 2 groups, thus the groups remain steadily parallel. The full tension activator group did start at a slightly lower amount of fixations presenting as apposed to the placebo group, thus baseline differences may have persisted. The rate of decrease over time in the two groups is parallel, and both groups only showed a steeper decline after the 3rd visit. Thus, the treatment did not have an effect on decreasing the number of lumbar fixations over and above the placebo effect. Fixations are not necessarily indicative of clinical severity i.e. the number of fixations do not predict the progression of the clinical condition or account for the symptoms that may or may not be present (Schafer et al., 1990:28). There is only a very weak positive correlation between lumbar fixations and pain present.

5.4 Inferential statistics

5.4.1 VAS (Visual Analogue Scale)

In a study by Osterbauer and De Boer, et al. (1993) they found a significant decrease in the VAS score following treatment using instrument manipulation for sacroiliac syndrome. The VAS score to participate in the study had to be a minimum 5 at the initial visit. The participants in the placebo group were found to have a higher

severity of pain at their initial treatment and therefore more pain to start with than the actual treatment group. This could contribute to the fact that even though the placebo group continued to get better, they did so at a slower rate than the actual treatment group, thus possibly contributing to the difference in response between the groups. Refer to Table 4.

5.4.2 NRS (Numerical Pain Rating Scale)

Measurement of pain is essential, as the alleviation of pain is what patients expect from treatment (Bolton, 1994). Table 5 shows that there was a significant difference between the two groups pain rating to start with i.e. the placebo group having a higher rate initially. This may contribute to the difference in response between the groups. The older the person, the greater the tendency to have more chronic problems, furthermore, chronic patients become sensitized after awhile and have a heightened experience of pain, this is sometimes termed generalised hyperalgesia (Badke, 2006).

Fig 3 shows that although both group's pain decreases over time, the full tension activator group's rate of decrease was more significant and had a steeper decline. Thus there would be more benefits shown for the full tension group. However, there was a significant difference between the two groups concerning their numerical pain rating at the beginning of their treatment i.e. the actual group (tension on maximum) started at a lower level. The ANOVA model controls for this difference.

5.4.3 RMQ (Roland Morris Questionnaire)

Fig 4 shows that there was no evidence that there was a more significant improvement between groups even though there was a decrease over time in both groups, especially between the 1st and 2nd visits. The placebo group did, however, start at a slightly higher level (indicating more functional discomfort) than the actual treatment group. The RMQ describes the patient's functionality, so even though the pain intensity may have been decreasing, it may have been at a greater extent when compared to their functional ability. Thus, there was no evidence of a treatment effect for RMQ. It may also have been that the group of patients didn't have any functionality problems looking at the clinical entity being studied.

5.4.4 SM (Short-form McGill Questionnaire)

In Fig 5 the full tension activator group showed a rapid decline in the description of their pain over time, especially between visits 1 and 2, as compared to the placebo group who followed a steadier decrease. The treatment group did start at a higher rate (sum of all scores) than the placebo group, which may account for the steeper decline. Therefore, for the SM score there was a marginally non-significant treatment effect - shown. The McGill questionnaire attempts to measure subjective pain experience. In this study it supports the acute versus chronic issue, because the treatment group was perhaps more acute and therefore their pain experience was one of it disappearing quickly. Treatments that are applied aggressively and at an early stage of the condition have the best chance of success with LBP patients (Liebenson, 1992).

5.4.5 PPI (Present Pain Intensity)

Figure 6 shows that both groups pain intensity decreased significantly from the 1st to the 4th visit. Both groups initial pain level started from the same minimum, but the full tension activator group's level dropped at a slightly higher rate. This may be due to mechanical improvement in the lumbar-sacral joints as apposed to the placebo group whose pain intensity may be decreasing due to behavioural changes and not necessarily biomechanical changes (Clark, 1994). This therefore shows no significant statistical treatment effect but it does show that the full tension activator does have a non-significant trend towards a beneficial treatment effect.

5.5 Correlation between changes in outcomes

5.5.1 Activator group (Full tension)

5.5.1.1 NRS

The NRS and PPI showed a weak positive correlation possibly due to the fact that both scales report pain intensity. In a study comparing six methods of measuring clinical pain intensity, Jensen et al. (1986) found the NRS-101 to be the superior measure, this result was also concluded in a study on a comparison of three pain scales, of which the NRS was found to be the most responsive due to the ease of use and scoring by means of 11 points (Bolton et al., 1998).

5.5.1.2 RMQ and SM

There was a moderate correlation between the RMQ and SM. This may be due to the functionality of the lumbar-sacral areas in the groups improving which could relate to the evaluation of pain as the SM is sensitive to clinical therapies (Melzack, 1987).

5.5.1.3 Lumbar-pelvic fixations

The number of lumbar and pelvic fixations was weakly negatively correlated, which means that as the one decreased, the other increased. Thus, as the pelvic fixations decreased and achieved more mobility the number of lumbar fixations didn't improve. Hesch (1997: 535) suggested that the sacroiliac joint was part of an integrated system and presumably did not function in an isolated fashion; hence hypomobility in the SI joints could result in over-stress of related structures, such as the lumbar area, which could contribute to dysfunction.

5.5.2 Placebo group

5.5.2.1 NRS

The NRS was weakly correlated with a change in the RMQ, SM and PPI. This may be due to the decrease in pain perception (NRS), which may enable the patient to alter their functional ability due to the influence of the mind-body relationship (Kirsch, 1998). Not only the patient's perception should be considered in effecting the results, but 'polite' answers given by the patient in order to 'please' the doctor (Roberts, 1995). This may demonstrate the power of the placebo effect as discussed in chapter two.

5.5.2.2 RMQ

The RMQ was correlated to PPI. This may be due to the patient improving in their functional capabilities, which could be directly related to their pain intensity decreasing as they perceive their state to be improving. There was also a moderate correlation between the SM. The same principle of the power of placebo may apply here (Kirsch, 1998). If the patient's functional level improves then the evaluation of pain used to describe their discomfort may also change.

Another phenomenon should also be considered; this is called experimental subordination, which means that the subject says what is expected of them and not necessarily what they actually experience (Kiene, 1996). These factors need to be considered when comparing the results.

5.6 Comparison of results

In terms of inferential statistics the actual activator group was marginally significantly better than the placebo group for NRS measurements. However, for most of the other outcomes measured, there was a non-significant trend suggesting better outcome in the activator group, which could not be verified statistically. Thus, for 4 out of 6 outcomes there were possible beneficial effects of the activator and for the other 2 outcomes the activator was no worse or better than the placebo effect.

5.7 Summary

After statistical analysis and its interpretation regarding the effect of the clinical ritual during instrument manipulation, it was found that some marginal differences did occur favouring the full tension activator group. However, for most of the other outcomes measured there was only a non-significant trend suggesting better outcome in the full tension activator group, which could not be verified statistically. Thus, there was a decrease in pain in the full-tension activator group, but this does not constitute a clinically significant effect, given the poor correlation with the other outcomes. The relationship between statistical and clinical significance is often debated. Ideally, statistics are used to determine clinical significance and thus the intervention's effectiveness. However, a test that has been employed and its results used in statistical analysis, may or may not measure the clinical phenomenon i.e. the very thing it measures or claims to measure may or may not have a clinical impact. It is for this reason that we must be very careful in assuming that statistical and clinical significance is related. To summarise a relevant quote from Crighton (1993:14) "By stating a treatment difference we consider to be of clinical importance we ensure that statistically significant equates to clinically important."

In summary, both groups responded to the treatment and experienced some degree of relief from lower back pain. No studies are found to demonstrate the effect of a clinical ritual during instrument manipulation in the management of mechanical lower back pain. This study would therefore act as a base-line study for further research in this field.

Chapter six

Conclusions and recommendations

6.1 Conclusion

The results of this study showed a significant improvement in both groups. Group A (full tension activator) did however show a greater overall improvement as compared to Group B (placebo group). For most of the outcomes, there was a non-specific trend suggesting better outcome in the activator group (A), which could not be verified statistically. This study thus proves the power of the placebo effect and how it can influence patient's health and their feeling of well-being.

The lack of long-term follow up prevents any comment on the long-term effects of the protocols, as the natural regression of the low back discomfort/pain would need to be taken into consideration.

Based on the findings of this study, it is suggested that for successful management of mechanical low back pain in a chiropractic setting, specific effects and non-specific effects should not be separated from each other, in order to enhance treatment. This would include the chiropractor being confident, enthusiastic, and having enough information and advice to provide the patient with an expectation of success. This coupling of the specific and non-specific effects will provide the patient with the greatest care and relief from discomfort in trying to combat low back pain

6.2 Recommendations

6.1.1 Homogeneity

More closely defined parameters with regard to using matched pairs with regards to age, race and occupation would greatly enhance the strength of the study.

Psychological stresses, environmental stresses and the duration of the complaint are prognostic factors that can modify the effect of manipulation (Assendeft et al., 1992).

It is therefore recommended that future studies include stratification to ensure homogeneity within two groups. This would improve comparability of baseline patient characteristics.

6.1.2 Follow- up consultations

Long-term follow-up consultations (around 1 month and then 6 months) should be incorporated into the study. This would address general efficacy of the protocols used and determine the long- term effects of the placebo group treatment.

6.1.3 Epidemiological studies

Studies involving point prevalence and lifetime incidence around the greater Port Elizabeth area would enhance the reporting of mechanical lower back pain and allow for stratification of subjects presenting with this condition. More research into similar categorizing techniques as described by Langworth and Breen (1997) is needed.

6.1.4 Pain rating scales

In future studies it is suggested that both the NRS and PPI are not necessarily needed to ascertain improved levels of pain. The NRS is sufficient at determining any significant changes in pain levels (Fejer, 2005).

6.1.5 Duration of the complaint

Treatments that are applied aggressively and at an early stage of the condition have the best chance of success with LBP patients (Liebenson,1992). It is therefore recommended that future studies separate acute and chronic conditions in order to eliminate the differences on the amount of treatment needed by each of these conditions.

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APPENDIX A

DURBAN INSTITUTE OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient: _____ Date _____
File # : _____ Age: _____

Sex : _____ Occupation: _____

Intern : _____
Signature

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: _____ Signature : _____

Case History:

Examination:

Previous:

Current:

X-Ray Studies:

Previous:

Current:

Clinical Path. lab:

Previous:

Current:

CASE STATUS:

PTT:

Signature:

Date:

CONDITIONAL:

Reason for Conditional:

Signature:

Date:

Conditions met in Visit No:

Signed into PTT:

Date:

Case Summary signed off:

Date:

Intern's Case History:**1. Source of History:****2. Chief Complaint : (patient's own words):****3. Present Illness:**

	Complaint 1	Complaint 2
< Location		
< Onset : Initial:		
Recent:		
< Cause:		
< Duration		
< Frequency		
< Pain (Character)		
< Progression		
< Aggravating Factors		
< Relieving Factors		
< Associated S & S		
< Previous Occurrences		
< Past Treatment		
< 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 incl. x rays
- < Environmental Hazards (Home, School, Work)
- < Exercise and Leisure
- < Sleep Patterns
- < Diet
- < Current Medication
- Analgesics/week:
- < Tobacco
- < Alcohol
- < Social Drugs

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

APPENDIX B

Durban Institute of Technology PHYSICAL EXAMINATION: SENIOR					
Patient name: _____ File no.: _____ Date: _____					
Student: _____ Signature: _____					
VITALS:					
Pulse rate:				Respiratory rate:	
Blood pressure:	R	L	Medication if hypertensive:		
Temperature:				Height:	
Weight:	Any recent change? Y / N		If Yes: How much gain/loss	Over what period	
GENERAL EXAMINATION:					
General Impression					
Skin					
Jaundice					
Pallor					
Clubbing					
Cyanosis (Central/Peripheral)					
Oedema					
Lymph nodes	Head and neck				
	Axillary				
	Epitrochlear				
	Inguinal				
Pulses					
Urinalysis					
SYSTEM SPECIFIC EXAMINATION:					
CARDIOVASCULAR EXAMINATION					
RESPIRATORY EXAMINATION					
ABDOMINAL EXAMINATION					
NEUROLOGICAL EXAMINATION					
COMMENTS					
<div style="display: flex; justify-content: space-between;"> Clinician: Signature : </div>					

APPENDIX C

REGIONAL EXAMINATION - LUMBAR SPINE AND PELVIS

Patient: _____ File#: _____ Date: __/__/__

Intern/Resident: _____ Clinician: _____

STANDING:

Posture– scoliosis, antalgia, kyphosis
Body Type
Skin
Scars
Discolouration

Minor's Sign
Muscle Tone
Spinous Percussion
Schober's Test (6cm)
Bony and Soft Tissue Contours

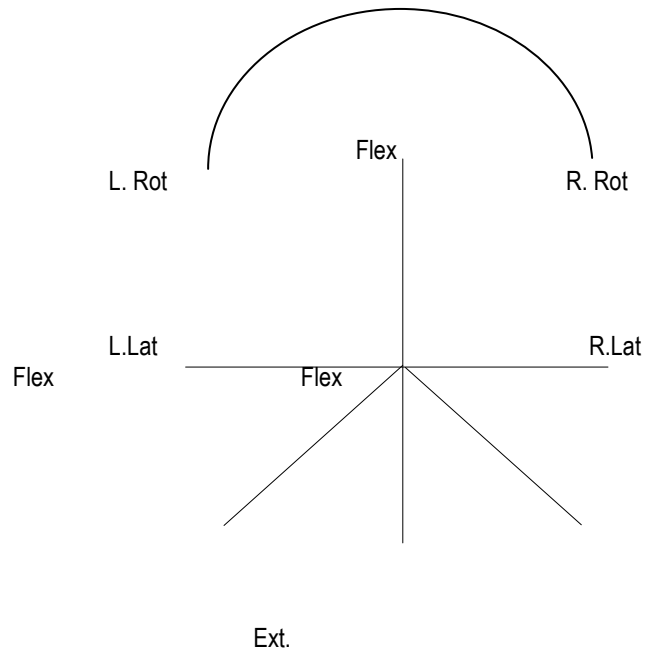
GAIT:

Normal walking
Toe walking
Heel walking
Half squat

ROM:

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

Extension = 20-35°
L/R Rotation = 3-18°
L/R Lateral Flexion = 15-20°



Which movt. reproduces the pain or is the worst?

- Location of pain
- Supported Adams: Relief? (SI)
Aggravates? (disc, muscle strain)

SUPINE:

Observe abdomen (hair, skin, nails)
Palpate abdomen/groin
Pulses - abdominal
- lower extremity
Abdominal reflexes

SLR		Degree	LBP?	Location	Leg pain	Buttock	Thigh	Calf	Heel	Foot	Braggard
	L										
	R										

	L	R
Bowstring		
Sciatic notch		
Circumference (thigh and calf)		
Leg length: actual -		

apparent -		
Patrick FABERE: pos\neg – location of pain?		
Gaenslen's Test		
Gluteus max stretch		
Piriformis test (hypertonicity?)		
Thomas test: hip \ psoas? \ rectus femoris?		
Psoas Test		

SITTING:

Spinous Percussion

Valsalva

Lhermitte

TRIPOD SI, +, ++		Degree	LBP?	Location	Leg pain	Buttock	Thigh	Calf	Heel	Foot	Braggard
	<u>L</u>										
	<u>R</u>										

Slump 7 test	<u>L</u>										
	<u>R</u>										

LATERAL RECUMBENT:

L

R

Ober's		
Femoral n. stretch		
SI Compression		

PRONE:

L

R

Gluteal skyline		
Skin rolling		
Iliac crest compression		
Facet joint challenge		
SI tenderness		
SI compression		
Erichson's		
Pheasant's		

<i>MF tp's</i>	Latent	Active	Radiation
QL			
Paraspinal			
Glut Max			
Glut Med			

Glut Min			
Piriformis			
Hamstring			
TFL			
Iliopsoas			
Rectus Abdominis			
Ext/Int Oblique muscles			

NON ORGANIC SIGNS:

Pin point pain

Axial compression

Trunk rotation

Burn's Bench test

Flip Test

Hoover's test

Ankle dorsiflexion test

Repeat Pin point test

Plantar reflex

level	Tender?	Dermatomes		DTR		
		L	R		L	R
T12				Patellar		
L1				Achilles		
L2						
L3				Proprioception		
L4						
L5						
S1						
S2						
S3						

Action	Muscles	L	R	
Lateral Flexion spine	Muscle QL			
Hip flexion	Psoas, Rectus femoris			5+ Full strength
Hip extension	Hamstring, glutes			4+ Weakness
Hip internal rotat	Glutmed, min;TFL, adductors			3+ Weak against grav
Hip external rotat	Gluteus max, Piriformis			2+ Weak w/o gravity
Hip abduction	TFL, Glut med and minimus			1+ Fascic w/o gross movt
Hip adduction	Adductors			0 No movement
Knee flexion	Hamstring,			
Knee extension	Quad			W - wasting
Ankle plantarflex	Gastroc, soleus			
Ankle dorsiflexion	Tibialis anterior			
Inversion	Tibialis anterior			
Eversion	Peroneus longus			
Great toe extens	EHL			

Passive : Medial rotation :

A) Supine (neutral)	If reduced	- hard \ soft end feel
B) Supine (hip flexed):		- Trochanteric bursa

APPENDIX D

Patient Name:		File #:	Page:
Date:	Visit:	Intern:	Signature:
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		Intern Rating <input style="width: 40px; height: 20px;" type="text"/>	A:
O:		P:	
		E:	
Special attention to:		Next appointment:	
Date:	Visit:	Intern:	Signature:
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		Intern Rating <input style="width: 40px; height: 20px;" type="text"/>	A:
O:		P:	
		E:	
Special attention to:		Next appointment:	
Date:	Visit:	Intern:	Signature
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst			
O:		P:	
		E:	
Special attention to:		Next appointment:	

Patient Name:		File #:	Page:
Date:	Visit:	Intern:	Signature:
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		Intern Rating <input style="width: 40px; height: 20px;" type="text"/>	A:
O:		P:	
		E:	
Special attention to:		Next appointment:	
Date:	Visit:	Intern:	Signature:
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		Intern Rating <input style="width: 40px; height: 20px;" type="text"/>	A:
O:		P:	
		E:	
Special attention to:		Next appointment:	
Date:	Visit:	Intern:	Signature
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		Intern Rating <input style="width: 40px; height: 20px;" type="text"/>	A:
O:		P:	
		E:	
Special attention to:		Next appointment:	

APPENDIX E

LETTER OF INFORMATION

Dear Patient,

Welcome to my study,

The purpose of the study is to assess the influence of the clinical ritual and its outcomes on the patient who is experiencing lower back pain. Two groups will be formed, of which one will make up a placebo group.

RESEARCHER: Belinda Dugmore (0732778748)

Supervisors are: Dr. C. Myburgh (031 2042923)

Research ethics committee secretary: Mr. V. Singh (031 204 2701)

PROCEDURE

A full case history, physical examination and lower back regional exam will be performed. The informed consent form will be signed and the questionnaires completed. Treatment will be given at the initial consultation followed by two treatments thereafter within a two- week period. There will then be a follow up consultation after last treatment to take final measurements. Please note that to participate in the study, the following is required from you:

1. Inclusion and exclusion criteria will have been fulfilled at the telephonic interview –INCLUSION CRITERIA:

- patient's must be between the ages of 18-60 years
- patient's on medication must continue on the same dosage throughout the research or if coming off, need to complete a 3-day washout

EXCLUSION CRITERIA:

- pregnancy
- recent surgery /hip pathology
- skin infections in the lower back region

2. A consent form must be completed prior to commencement of the examination.

Between visits please continue your daily routine as usual. Please answer all questions as truthfully and as accurately as possible as this will ensure accuracy of the outcome of the study.

VENUE

The study will be done at the Mount Croix Chiropractic Clinic, in Port Elizabeth.

ADDITIONAL TREATMENT

Those participants involved in the placebo group will be granted two free treatments by Belinda to be used within one month of their finishing the research.

CONFIDENTIALITY

Please be assured that all information and findings will be kept strictly confidential. Access is restricted to the researcher, the research supervisor and the ethics committee chair. All data recordings, analysis and reporting will be coded.

RISKS AND BENEFITS

There are no risks associated with the use of the activator adjusting instrument,as the patient is lying on their stomach which prevents stretching/ twisting of the supporting paraspinal ligaments and joint capsules. The benefits are thought to be that of reduction of pain, altered muscle spasm, localized sympathetic activity and increased mobility.

COSTS

Treatment is free of charge to patients partaking in the research study.

TREATMENT TABLE

DATE	WEEK	VISIT	GROUP A	GROUP B
	1	1	Case hx, Physical, Regional, M 1 TX Y	Case hx, Physical, Regional, M 1 Tx Z
		2	TXY	TXZ
	2	3	M 1 Tx Y	M 1 Tx Z
		4	M1	M1

KEY for table

- (M1) MEASUREMENT 1 - Measurements taken
- (TxY) TREATMENT Y - Activator adjusting instrument
- (TxZ) TREATMENT Z - Activator adjusting instrument

Thank you for participating in the study.

Belinda Dugmore (intern)

APPENDIX F



INFORMED CONSENT FORM

(To be completed by patient / subject)

Date

:

Title of research project

: A double blinded study to determine the influence of the clinical ritual in instrument assisted adjusting during the management of chronic mechanical low back pain.

Name of supervisor

: Dr. C. Myburgh

Tel ?

: (031) 204 29 23

Name of research student

: Belinda R. Dugmore

Tel ?

: 073 277 87 48

Please circle the appropriate answer

YES / NO

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

Please ensure that the researcher completes each section with you

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

Please Print in block letters:

Patient /Subject Name: _____ Signature: _____

Parent/ Guardian: _____ Signature: _____

Witness Name: _____ Signature: _____

Research Student Name: _____ Signature: _____

APPENDIX G

DETAILS AND CLINICAL OUTCOMES FORM

PATIENT NAME:_____ FILE NO:_____

Group A / B

Male / Female

Occupation _____

Age _____

Visual Analogue Scale: Visit 1_____

Numerical Pain Rating Scale : Visit 1 _____

Visit 3_____

Visit 4 _____

Roland Morris Questionnaire : Visit 1 _____

Visit 3 _____

Visit 4 _____

Fixations:

VISIT R-AS L-PI L-AS R-PI L1 L2 L3 L4 L5

1													
2													
3													
4													

APPENDIX H

VISUAL ANALOG SCALE

Date: _____ File no.: _____ Visit no: _____

Patient name: _____

Please rate your overall pain level on the following Visual Analog Scale by placing a mark in the block which best matches your pain level.

No pain

0

1

2

3

4

5

6

7

8

9

10

Worst possible pain

APPENDIX I

Numerical Rating Scale - 101 Questionnaire

Date: _____ File no: _____ Visit no: _____

Patient name: _____

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

Please write only **one** number.

0 _____ 100

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

Please write only **one** number.

0 _____ 100

APPENDIX J

ROLAND-MORRIS LOW BACK PAIN AND DISABILITY QUESTIONNAIRE

When your back hurts you may find it difficult to do some of the things you normally do. Mark only the sentences that describe today.

1. ☐ I stay at home most of the time because of my back.
2. ☐ I change position frequently to try and get my back comfortable.
3. ☐ I walk more slowly than usual because of my back.
4. ☐ Because of my back, I am not doing any jobs that I usually do around the house.
5. ☐ Because of my back, I use a handrail to get upstairs.
6. ☐ Because of my back, I lie down to rest more often.
7. ☐ Because of my back, I have to hold on to something to get out of an easy chair.
8. ☐ Because of my back, I try to get other people to do things for me.
9. ☐ I get dressed more slowly than usual because of my back.
10. ☐ I stand up only for short periods of time because of my back.
11. ☐ Because of my back, I try not to bend or kneel down.
12. ☐ I find it difficult to get out of a chair because of my back.
13. ☐ My back is painful almost all of the time.
14. ☐ I find it difficult to turn over in bed because of my back.
15. ☐ My appetite is not very good because of my back.
16. ☐ I have trouble putting on my socks (or stockings) because of pain in my back.
17. ☐ I walk only short distances because of my back pain.
18. ☐ I sleep less well because of my back.
19. ☐ Because of back pain, I get dressed with help from someone else.
20. ☐ I sit down for most of the day because of my back.
21. ☐ I avoid heavy jobs around the house because of my back.
22. ☐ Because of back pain, I am more irritable and bad tempered with people than usual.
23. ☐ Because of my back, I go up stairs more slowly than usual.
24. ☐ I stay in bed most of the time because of my back.

From Roland M, Morris R. A study of the natural history of back pain: Part I: Development of a reliable and sensitive measure of disability in low-back 1983;8:141-144

The original 24 item Roland-Morris Questionnaire is displayed. The RM-18 deletes items 2, 15, 17, 19, 20, and 24 without affecting its quality

APPENDIX K

Short-form McGill Pain Questionnaire (SF-MPQ)

Ronald Melzack (1984)

Date: _____ File no.: _____ Visit no: _____

Patient name: _____

		NONE 0	MILD 1	MODERATE 2	SEVERE 3
1.	Throbbing				
2.	Shooting				
3.	Stabbing				
4.	Sharp				
5.	Cramping				
6.	Gnawing				
7.	Hot-Burning				
8.	Aching				
9.	Heavy				
10.	Tender				
11.	Splitting				
12.	Tiring-Exhausting				
13.	Sickening				
14.	Fearful				
15.	Punishing-Cruel				

Please rate your overall pain level on the following line by placing a mark on the line which best matches your pain level.

No pain

Worst possible pain

PPI (Present Pain Intensity) – Please rate your PPI (Circle the appropriate number):

- 0 No pain
- 1 Mild
- 2 Discomforting
- 3 Horrible
- 4 Excruciating

APPENDIX L



DR. CANDICE DUGMORE Bsc (MBK) D.C. (USA)

Mount Croix Chiropractic

Pr No. 0094242

2 Gipson Road, Mount Croix
Port Elizabeth, 6001
Tel: +27 41 3730862
Fax: +27 41 3733259

01 September 2005

Dear Belinda

This is to confirm that I will partake in your research as a technician and co-supervisor. I am aware that there will be two groups formulated, of which 1 is a placebo group and that you will be offering two free treatments to the appropriate candidates of that group post participation.

I look forward to working with you.

Yours sincerely

Dr Candice Dugmore BSc (MBK) D C (USA) (Life College)

APPENDIX M

DO YOU SUFFER FROM

LOWER BACK PAIN?

Are you between the ages of 18-60 years?

FREE TREATMENT

**Is available for participants
who would like to partake in my research study.**

If you require more information, please call

BELINDA

for an appointment

0732778748

APPENDIX N

Test and adjustments for AMCT basic scan protocol

<u>SUBLUXATION</u>	<u>TEST</u>	<u>ADJUSTMENT</u>
<u>PELVIS</u>		
AS Ilium	Pressure test crest of ilium	Step One: Contact base of sacrum on side opposite PD- LOD is anterior-inferior Step two: Contact crest of ilium- LOD is inferior-medial Step three: Contact ischial tuberosity- LOD is anterior-inferior
PI Ilium	Pressure test under sacrotuberous Ligament-posterior, superior, and Lateral	Step one: Contact spine of ischium-LOD is posterior superior and lateral Step two: Contact sacrotuberous Ligament-LOD is posterior, Superior, and lateral Step three: Contact lateral aspect Of ilium- LOD is anterior-superior
<u>LUMBAR</u>		
Fifth Lumbar (L5)	Instruct patient to place Forearm on side of PD on Low back with palm up	Contact mammillary process on side indicated by short-long rule-LOD is anterior-superior
Fourth Lumbar (L4)	Instruct patient to place forearm On side opposite PD on low back With palm up	Contact mammillary process on side indicated by short-long rule-LOD is anterior-superior
Third Lumbar (L3)	Instruct patient to lift hip on side Of PD off the table	Contact mammillary process on side indicated by short long rule -LOD is anterior-superior
Second Lumbar (L2)	Instruct patient to place both forearms On low back with palms up	Contact mammillary process on side indicated by short-long rule -LOD is anterior-superior
First Lumbar (L1)	Instruct patient to raise and place the Forearm of the PD side on the table, Superior and lateral and next to head. Forearm on side opposite PD is kept On low back	Contact mammillary process on side indicated by the short-long Rule-LOD is anterior-superior

APPENDIX O

Schematic of Pelvis

(in the prone position)

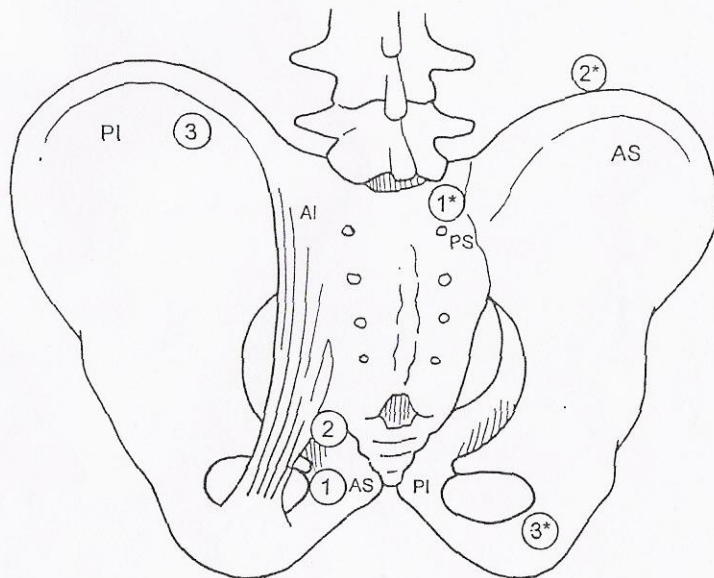
Left Side PD

Contact Points for PI Ilium

1. Spine of Ischium
LOD: Post-Sup-Lat
2. Under Sacrotuberous Ligament
toward S.I. Joint
LOD: Post-Sup-Lat
3. Iliac Fossa
LOD: Ant-Sup

Contact Points for AS Ilium

- 1.* Posterior Base of Sacrum
 $\frac{1}{2}$ " lateral to 1st Sacral Tubercle
LOD: Ant-Inf
- 2.* Crest of Ilium
LOD: Inf-Med
- 3.* Ischial Tuberosity
LOD: Ant-Inf



APPENDIX P

Schematic of Pelvis

(in the prone position)

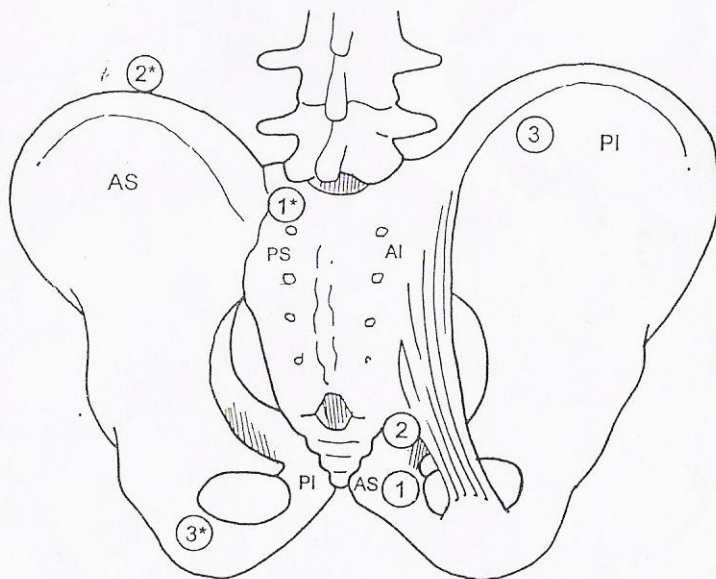
Right Side PD

Contact Points for AS Ilium

- 1.* Posterior Base of Sacrum
½" lateral to 1st Sacral Tubercle
LOD: Ant-Inf
- 2.* Crest of Ilium
LOD: Inf-Med
- 3.* Ischial Tuberosity
LOD: Ant-Inf

Contact Points for PI Ilium

1. Spine of Ischium
LOD: Post-Sup-Lat
2. Under Sacrotuberous Ligament
toward S.I. Joint
LOD: Post-Sup-Lat
3. Iliac Fossa
LOD: Ant-Sup



APPENDIX Q



