THE EFFICACY OF ACTION POTENTIAL THERAPY, TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION AND PLACEBO IN THE TREATMENT OF OSTEOARTHRITIS OF THE KNEE

BY

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DEDICATION

I would like to dedicate this work to Vanessa Nastassja Chetty, who stood by me throughout those long and strenuous years. You are my inspiration and light at the end of the tunnel. Thank you for your constant love, understanding, patience and support. I couldn't have done it without you.

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ABSTRACT

Osteoarthritis (OA) is a disease that is localized to diarthodal joints and is characterized by degeneration of hyaline cartilage, with secondary changes in the peri-articular bone and soft tissue. OA is considered to be a sequale of traumatic and age respondent degenerative changes which result in loss of cartilage and impairment of function.

The purpose of this investigation is to evaluate the relative efficacy of Action Potential Therapy, Transcutaneous Electrical Nerve Stimulation and placebo in the treatment of Osteoarthritis of the knee. This was a prospective, randomized clinical trial consisting of sixty patients who volunteered from the greater Durban area. The patients diagnosed as having Osteoarthritis of the knee, were randomly divided into four treatment groups. Group one and two consisted of twenty patients each and group three and four consisted of ten patients each, all between the age of 40 – 65 years old.

Group one received Action Potential therapy (APT); group two received Transcutaneous Electrical Nerve Stimulation (TENS); group three received placebo APT and group four received placebo TENS.

Data capturing took place for all groups at the 1st, 2nd and 4th consultations. Subjective data was collected using the Numerical Pain Rating Scale-101; McGill Pain Questionaire and Western Ontario and MacMaster Universities Index (WOMAC). Objective data was gathered using the algometer and goniometer.

For statistical analysis parametric and non-parametric tests were used in all hypothesis

tests, due to the large sample size. All readings were considered to be continuous variables. The two sample (unpaired) t-tests was used to compare independent samples.The two sample paired t-test was used to compare related samples. All tests were conducted at α=0.05 level of significance.

Inter and intra group analysis revealed that there was no significant difference between the APT and TENS modalities in the treatment of OA of the knee.

Further studies using a larger sample per group, larger number of treatment consultations and multiple researchers are warranted, to identify changes in the measurement parameters and add to inferential validity .

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List of Abbreviations

α	- Alpha
β	- Beta
APT	- Action Potential Therapy
TENS	-Transcutaneous Electrical Nerve Stimulation
OA	- Osteoarthritis
WOMAC	- Western Ontrio and MacMaster Universities Index
Ho	- Null hypothesis
Hi	- Alternate Hypothesis
NRS	- Numerical Pain Rating Scale
Kg	- Kilograms
GAG	- Glycosaminoglycan

CHAPTER ONE

Chapter One

1.0 Introduction

1.1 The problem and its Setting

Osteoarthritis (OA) represents the most common disease in humans, that affects hands, hips, knees and the spine, with knee OA producing the most disability (Brandt 1999). The majority of individuals affected are over the age of 38 years, according to the American College of Rhuematology (Yochum and Rowe 1996:807). OA is the most common joint disease that leads to chronic disability, mobility and functional limitation (Gordon et. al . 1998:271).

Osteoarthritis presents symptomatically, with patients presenting with pains in and around the knee joint, especially during weight bearing which is relieved by rest, as well as morning stiffness of less than 30 minutes duration (Zizic et al; 1995). Martin (1994) states that the knee is the most often affected weight bearing joint and decrease in range of movement (especially flexion of the knee) is a common symptom.

According to an epidemiological study conducted by Mc Alindan et.al. (1996) up to 1% of the population in Africa is affected and OA incurs significant socio economic and psychological costs. Radiological evidence detected knee OA in as many as 30% of people over the age of 65, who presented with substantial pain and disability (Mc Alindan et al. 1996). According to Lane and Thompson (1997), OA is the most prevalent musculoskeletal condition and 70% of the US population over 65 years old demonstrate some radiographic evidence of the disease.

According to Minor and Saaford (1993), the pain assosciated with OA can arise from a number of factors i.e. inflammatory pressures; nerve compression; vascular

compression; stress on soft tissue and bone or even possible micro-trauma to muscle, however according to the authors, isolating the exact mechanism is hampered by overlapping psycho-social adaptations (Minor et al, 1993). The pain varies with changes in disease; physical activity, joint status, posture and neuromuscular function (Minor et al; 1993:197).

The prevalence of OA increases with increase in age and accounts for most of the total knee arthroplasties performed per year in the US (Mc Lindan et al; 1996:332). According to Zizic et al. (1995), due to the clinical consequences and high prevalence rate, which increases markedly with age, knee OA is a significant public health problem, especially among the elderly (Ettinger and Afable 1994:1435).

According to Ettinger aand Afable (1994), the clinical and functional status of persons with knee OA, appears to worsen gradually over time. Individuals begin to modify their activity and daily routines in response to chronic joint pain. Elderly individuals have described lack of activity to be associated with decline in health status (Klinger et al 1999). Physical disability due to musculoskeletal symptoms is a major problem and knee OA may be responsible for much suffering, disability and handicap in communities.

OA is an incurable condition, for which there exist a few effective treatments, but the symptoms of pain and disability can persist for long periods of time. Much can be done to alleviate the symptoms particularly in the early stages, but the degenerative changes of OA are irreversible (Edwards & Boucher 1991:800). According to Minor and Saaford (1993), the treatment of OA is aimed at decreasing impairment, easing pain, maintaining function and helping the patient to become an effective self manager.

Although both pharmacological and non-pharmacological therapies are promulgated for the management of OA, Byalint and Szebenyi (1997) suggest that non -.drug approaches deserve serious attention in order to manage pain, increase muscle strength and increase range of motion. The authors suggest this in the light of the definite biomechanical aspects associated with the condition which are instrumental in increasing quality of life.

Williams (1996:587) reported on the strength of clinical experience, the effectiveness of rehabilitation, patella tapering; supervised fitness walking; tidal irrigation; joint lavage; diathermy; exercise; acupunture; transcutaneous electrical nerve stimulation; topical capsaicin; low energy laser; pulsed electromagnetic fields and pharmacological preparation in the symptomatic treatment of osteoarthritis. Zizic et. al. (1995) states that the conventional non-surgical management of OA in some patients is inadequate due to lack of efficacy or adverse medical reactions and, NSAID'S have well known toxic effects in the stomach, gastro-intestinal tracts, liver and kidney.

According to Clayton (1996) a vast number of electrical modalities are being used to provide pain relief, but the most extensively investigated modality being Transcutaneous electrical nerve Stimulation. TENS is a low frequency biphasic, assymetrical square with variable frequency that produces pain relief by stimulating Aβ and Aδ fibres. Aβ fibres are stimulated by low amplitude, high frequency, short duration stimulation, while Aδ fibres are stimulated by high amplitude, low frequency currents. According to Melzack (1981) the mechanism of TENS as a form of hyper-stimulation analgesia is similar to needling and by applying TENS therapy over acupuncture points provided a powerful means of pain control . TENS is an effective, cost efficient, safe and non-invasive treatment modality that should therefore be used

in preference to more invasive and potentially harmful alternatives (Gatterman 1990 :346).

In 1992, a newer treatment modality was developed, aimed at relieving pain and disability. Action Potential Therapy (APT) has been described as a combination of direct and alternating currents, having a continuous monophasic square pulse and a constant frequency of 151Hz , that stimulates naturally occurring action potentials in the neuron (Berger 1999:11). Stimulation by APT current creates a normal action potential which apperantly restores the inherent biochemical processes in the region of pain (Berger and Matzner 1999). According to Berger (1999), if the action potential mechanism can be restored to normal, injury and disease can be affected at a cellular level and health of the organism improved or regained.

1.2 Aim and Objection of the Study

The aim of this investigation is to evaluate the relative effectiveness of Action Potential therapy, Transcutaneous Electrical Nerve Stimulation, and Placebo in terms objective and subjective patient findings in the treatment of osteoarthritis of the knee.

The first objective is to determine the relative effectiveness of Action Potential Therapy, Transcutaneous Electrical Nerve Stimulation and placebo in terms of objective patient findings.

The second objective is to determine the relative effectiveness of Action potential Therapy, Transcutaneous Electrical Nerve Stimulation, and placebo in terms of subjective patient findings.

1.3 Motivation and Benefits of this Study

According to Ettinger and Afabe (1994), more strategies are needed to prevent and retard physical disability from OA of the knee. More data are needed to evaluate the role of conservative treatment modalities (including electrical therapies) in the management of knee OA (Puett et al 1994). Puett et al also proposes that alternatives to NSAID'S be established, or safer interventions be developed. According to Martin (1994:1443), a better understanding of this highly prevalent disorder is required and in so doing be able to diagnose this condition early, allowing us to deal more effectively with this condition. According to Brandt (1995), recent studies argue for a change in the treatment of patients with OA. The treatment program should emphasize on conservative measures (i.e. non-pharmacological), and only when this approach is not a alternative, should NSAID'S be prescribed. Traditionally, NSAID'S have been the treatment of choice, since it is believed that pain in OA is due to inflammation. However, NSAID'S are expensive and not forgetting its gastro-

intestinal toxicity, especially in elderly patients with OA. Thus alternative treatment options should be initiated (Lane and Thompson 1997:265).

The degenerative process in OA of the knee is irreversible, but the rate of change can be modified (Yochum & Rowe 1996:803). According to Zizic et al (1995:1760), new interventions are required to stimulate cartilage repair and retard degeneration.

Given the pervalance and disabling effects of OA of the knee, more scientific knowledge and treatment strategies are required to prove advantageous to both patients and practitioners (Williams 1996:586). Each patient, based on severity of the degeneration, becomes an optimum recipient for a particular treatment protocol, be it pharmacological or non-pharmacological.

Electro therapy is proving to a popular non-pharmacological interventions. The use of TENS (Clayton 1996) and Action Potential Therapy (Berger 1999) to produce pain relief and reduce disability, in musculoskeletal conditions is encouraging. This study will attempt to compare the relative effectiveness of Action Potential Therapy and Transcutaneous Electrical Nerve Stimulation in the treatment of OA of the knee.

CHAPTER TWO

Chapter Two

2.0 Review of Related Literature

2.1 Introduction

The following is an overview of the related literature concerned with the basic clinical etiological and epidemiological aspects of osteoarthritis of the knee. The theoretic basis for the action and effects of Action Potential Therapy (APT) and Transcutaneous Electrical Nerve stimulation (TENS) are also discussed.

2.2 Osteoarthritis Synonyms

Osteoarthritis (OA) is also known by the terms osteoarthrosis, degenerative arthritis, degenerative arthrosis and degenerative joint disease (Yochum & Rowe 1996:802). The descriptive terminology of "degenerative joint disease", more accurately depicts the primary process (Martin 1994:1429), and is presently a more popular name. However the author notes that the term OA is well recognised and easily understood among the majority of the population.

2.3 Incidence, prevalence and gender distribution

Osteoarthritis is the leading cause of disability in the United states. It is the most common joint disorder affecting over 25 million Americans, resulting in impaired mobility and lower extremity physical dysfunction. Population surveys indicate that 10 – 13% of men and women aged 65 years and older have symptomatic knee OA and nearly one third have radiographic findings (Nevitt & Lane 1999:632). Felson et.al. (1995:1500) performed the Framingham osteoarthritis study, aimed at determining the incidence of radiographic knee OA and symptomatic OA, as well as determining the

rate of progression of pre-existing radiographic OA, in a population sample of elderly persons. The rate of incident disease were 1,7 times higher in women than in men (95% confidence interval [C.I.] 1.0-2.7) and progressive disease occurred more commonly in women (relative risk = 1.4; 95% confidence interval – 0.8-2.5). Among women, approximately 2% per year developed symptomatic knee OA and 4% per year experienced progressive knee OA. They concluded that OA was more common in women than in men and the new onset of OA frequented more in elderly person (Felson et.al. 1995:1500).

A study performed by Oliveria et.al. (1995:1134), to quantify the incidence of symptomatic hand, hip and knee OA among members of a health maintenance organisation in Central Massachusets, found that the incidence of OA among women ranged from a low of 0/100 000 persons per year for those aged 70-79, the age –sex standardlized incidence rates for knee OA was 240/100 000 persons per year(95% C.I. 218,262). They concluded that OA incidence increased with age and women had higher rates than men, especially after the age of 50. The incidence of knee OA was twice that of hand and hip OA. The annual incidence of Clinical knee OA was > 1%/year in women aged 70-89 (Oliveria et.al. 1995:1134). Although it is suspected that OA is signifficantly represented in South Africa, the exact incidence and prevalence has not been studied at a national level (Modi : 2001/05).

2.4 Osteoarthritis

2.4.1 Definition

OA is defined as a progressive, non-inflammatory disease characterized by degenerative pathologic changes in the articular cartilage and its related components

(Yochum & Rowe 1996:802). Calliet (1991:190) considers OA to be a sequelea of traumatic and age dependent degenerative changes which results in a loss of cartilage and impairment of function.

According to Martin (1994:1429) OA is a slowly, progressive mono-articular disorder of unknown cause and obscure pathogenesis. Osteoarthritis occurs later in life; principally affecting the hands and large weight bearing joints and OA is characterized clinically by pain, deformity, enlargement of the joints and limitation of motion. Pathologically, the disease is characterized by focal erosive lesions, cartilage destruction, subchondral sclerosis, cyst formation and large osteophytes at the margin of the joints.

2.4.2 Classification of OA

OA is usually classified into 2 groups: primary (idiopathic) and secondary. According to Martin (1994:1429) generally, the secondary group is based on having an identifiable disorder, underlying inflammatory condition or crystalline disease.

Yochum & Rowe (1996:802) state that a classification system based on etiology is commonly encountered. Primary (idiopathic) joint disease is where no proven factor or groups of factors is directly attributable to the arthropathy, although numerous factors have been hypothesized. Secondary degenerative joint disease conversely, applied where a known factor or event has caused the resultant degenerative changes.

2.4.3 Anatomy

The knee is probably the most complicated joint in the human body. It is intricate because it comprises of two structurally and functionally different yet interrelated

joints: the tibiofemoral and patellofemoral joints (Calliet : 1991:1).

The knee joint is a diarthroidal joint which is a load bearing unit that consists of two or more skeletal surfaces, the subchondral bone is covered with hyaline (articular) cartilage and united by a fibrous capsule (Walker and Helewa 1996:20).

Calliet continued that the tibiofemoral joint is formed by the distal end of the femur and the proximal surface of the tibia. The distal aspect of the femur has two surfaces, which are converse, assymetrical, saddle-shaped condylar surfaces that are coated with cartilage. They are separated by a deep v-shaped notch, the intracondylar fossa. These femoral articular surfaces correspond to similar articular surfaces of the apposing tibial condyles. Cartilage covers a small anterior curvature and the entire posterior surface of the inferior and posterior portion of the femoral condyles.

The tibia is located on the medial side of the leg and has a large proximal end because of its medial and lateral condyles, articulate with the large condyles of the femur. The superior surface of the tibia is flat, forming a tibial plateau consisting of the medial and lateral tibial condyles and an inter condylar eminence. The eminence of the tibia fits into the inter condylar fossa between the femoral condyles (Moore and Dalley 1999:512). The tibial condyles are concave articular surfaces and are shallower than the convex femoral condyles. These opposing articular surfaces are assymetrical because of this difference in curvature. The medial tibial plateau faces outward, both face superiorly with the intercondylar eminence. The opposing articluar surfaces of the femoral condyles and the tibial plateau are incongruent and thus, even though they are directly opposed and are in contact, they do not constitute a stable joint (Calliet 1991:2).

Anteriorly, the femoral condyles merge at a shallow depression, known as the patellar surface, where they articlulate with the patella surface (Moore and Dalley 1999:509). The patella is a sessamoid bone contained "within" the quadriceps tendon, has assymetrical facets on its inferior surface that are separated by a central incongruous manner with the femoral condyles, which are coated with hyaline cartilage (Calliet 1991:144).

Articlular Cartilage

Hyaline articluar cartilage covering the subchondial bone plate functions to distribute and transmit loads and shear forces to the underlying bone protecting the underlying bone and permitting synovial joints to have a wide range of almost frictional movement. It is aneural largely avasular and only sparsely cellular: it is up to 80% water. Cells called chondrocytes are responsible for the synthesis of the proteoglycans and collagen fibres that comprise the cartilage matrix. Proteoglycans and glycosaminoglycans are hydrophilic (water-loving) and play an important role in regulating the movement of water within the matrix, thereby influencing the mechanical and lubricant properties of cartilage. Articular cartilage, bone, fibrous capsule, tendons and ligaments are all comprised of a high proportion of collagen, constituting the extracellular matrix of these tissues. Articular cartilage differs from bone, capsule, tendon and ligament in that it chiefly comprises of type II collagen as opposed to type 1 in other tissues (Walker & Helewa 1996:21).

Joint Capsule

Surrounding the external aspect of the joint is the fibrous joint capsule attaching at the margins of the articular cartilage (Bergman 1993:663). The capsule is a type of

regular white connective tissue similar to that of tendons and ligaments (Walker & Helewa 1996:25). The capsule is redundant and essentially acts to contain the nutrient synovial fluid, but the capsule adds little support to the joints stability (Calliet 1991:13). The extent of redundancy in the fibrous capsule and its associate synovial tissue, or lack thereof, has important consequence to the mobility of the joint, especially when involved in an inflammatory process (Walker & Helewa 1996:25).

Synovial Membrane

The synovial membrane borders the joint cavity and covers all intra-articular structures except for load bearing surfaces of the joint. It consists of vascular fibrous tissue and superficial branching synovial cells. Synovial fluid nourishes articular structures and provides joint lubrication. It has a very low coeffeicient of friction, as it is non-Newtonian, i.e. the faster the joint moves the less viscious the fluid becomes. Fluid becomes Newtonian (like water), when less viscous, in inflammatory conditions (Golding 1989:3). Bergman continues to state that the fluid film lubrication may be:

a) Hydrodynamic : a thick synovial film separates articular cartilage; the surfaces are at an angle to each other, a gap is produced and fluid drawn into the gap produces a pressure that separates the surface.
b) Fluid film lubrication : the cartilage is separated by fluid film.
c) Hydrostatic lubrication : pressure on cartilage causes interstitial fluid to keep-out, to be re-imbibed when pressure becomes normal.
d) Boosted lubrication : under loads, the plasma dialysate portion of synovial fluid is squeezed out to form trapped pools in undulations which act as reservoirs and hyalurcic acid – protein complexes form a sturdy skin over rough areas.

Menisci:

Menisci are curved, wedge shaped fibrocartilagenous pieces of tissue located on the periphery of the tibiofemoral joint, which are connected to each other and the joint capsule (Calliet 1991:9). This serves to deepen the articular surface of the tibial plateau which provides additional stability to the joint. The medial Menisci is C-shaped and broader posteriorly than anteriorly. Its anterior horn attaches to the anterior intercondyler area of the tibia, anterior to the attachment of the anterior cruciate ligament. Its posterior horn attaches to the posterior intercondyler area, anterior to the attachment of the posterior cruciate ligament. The medial meniscis firmly adheres to the deep surface of the tibial collateral ligament.

The lateral meniscis is nearly circular and smaller and more freely movable than the medial meniscis. The tendon of the popliteus separates the lateral meniscus from the fibular collateral ligament. A strong tendinous slip, the posterior meniscofemoral ligament joins the lateral menisci to the posterior cruciate ligament and medial femoral condyle (Moore and Dalley 1996:621).

Knee Ligaments

Internal to the joint are the cruciate ligaments, arranged in opposing directions, providing anterior to posterior as well as medial to lateral stability to the knee. They also prevent excessive medial rotation of the tibia and help to maintain contact between the articular surfaces of the tibia and femur. The anterior cruciate ligament resists anterior displacement of the tibia and checks extensive movement. In contrast, the posterior cruciate ligament checks posterior displacement of the tibia and resists internal rotation of the tibia. The collatral ligaments provide medial and lateral

stability and support for the knee while also preventing excessive external rotation of the tibia (Bergman et.al._1993:659).

Bursae: Most tendons run parallel to the bones and pull lengthwise across the knee joint during knee movement, thus providing twelve or more bursae.

Subcutaneous bursae – prepatella and infra-patella bursae are also at the convex surface of the joint because the slkin must be able to move freely during movements of the knee (Moore and Dalley 1999:626). Bursae facilitate gliding and provide a low friction movement of one tissue over another (Walker & Helewa 1996:26).

Vascular Supply

The knee joint is supplied by five branches of the popliteal artery. The femoral artery originates from the illiac artery, in the femoral triangle of the groin and descends anteriorly into the profundus femoral artery, which branches further into four perforating arteries of which the popliteal artery is one. The popliteal artery has five branches in the area of the knee joint: the middle and inferior genicular branches supply the menisci, which are mostly avascular. Only the outer one third of the meniscus has any significant blood supply and its this vascularity that plays a major part in the recovery from any injury that may be sustained by the meniscus (Calliet 1991:11).

2.4.4 Biomechanics of the Knee

The main movement of the knee consist of flexion and extension. The knee joint has to maintain a wide range of motion while maintaining stability. The knee has to react

to rotational forces as well as absorb shock and then prepare for propulsion. Because the opposing articulating surfaces of the femoral condyles and the tibial plateau are incongruent or assymetrical (Calliet 1991:6), these movements are a combination of roll, slide and spin movements (Bergman et.al. 1993:666). The spin of the articulating joint surfaces combined with rotation, results in a slide movement as the knee moves from extension to flexion (Calliet 1991:6).

The sagital plane range of motion consists of approximately 10° of hypertension to 145° of flexion. Achievement of the closed pack position negates rotation, adduction, and abduction (Varus and Valgus). However, up to 45° each of internal and external rotation are available when the knee is at 60 or more degrees of flexion (Soderberg 1997:273).

The tibiofemoral joint is markedly incongruent in the position of flexion, but becomes progressively more congruent as the knees extend (Hertling & Kessler 1996:320). Hertling and Kessler (1996:320) continued that the fibrocartilagenous menisci reduces joint surface incongruency. The anterior segments of the menisci are somewhat mobile, whereas the posterior horns are comparatively fixed, thus as the knee extends, and the contacting surfaces of the femoral condyles increase, the anterior aspect of the menisci glide forward. Conversely as the knees flex, the anterior segments of the menisci recede to conform to the smaller surface area of the contacting femoral condyles. By reducing joint surface incongruency, the menisci help distribute the compressive stresses to the joint surface of the knee (Hertling & Kessler 1996:320).

The Menisci also aid in the lubrication and nutrition of the joint and coupled with their shock-absorption capabilities, help to decrease cartilage wear

(Bergman et.al. 1993:664).

During the flexion and extension of the knee, the patella moves vertically as much as 8cm in the intercondylar groove. While flexion is accomplished, the patella and patella tendon are displaced posteriorly. During rotation of the knee, the patella is displaced laterally during internal rotation of the tibia and medially during lateral rotation of the tibia (Soderberg 1997:272).

Joint play is an accessory motion, necessary for normal active and passive range of motion, and represents the amount of capsular laxity within a joint. Joint play should not be confused with end feel (end play), which is the assessment of resistance, supplied at the end of passive range of motion and tests intergrity of the capsular and ligamentous fibres (Gatterman 1990:98)

2.5.5 Etiology of Osteoarthritis

The etiology of primary osteoarthritis is not known, however many biomechanical,inflammatory and immunologic factors have been considered. These explanations are placed in two broad catergories viz: normal forces acting on abnormal cartilage with an inadequate healing response or an excessive force acting on normal cartilage. Several factors have been found to play a role in the initiation or perpetuation of osteoarthritis. These include aging, alteration in matrix structure of articular cartilage, alterations in the activity of articular cartilage chondrocytes, alterations in the chemical mediators in synovial fluid, trauma and poorly understood immune response. Whether it be abnormal stresses or abnormal cartilage that starts the process of osteoarthritis, the biochemical changes that occur in early osteoarthritis lead to continued cartilage degradation and an advancing of the disease process. The

repair process can only keep up with the continued cartilage breakdown for a short time. The degradative process continues and there is a complete breakdown in the weight bearing capabilities of articular cartilage. End stage disease results with loss of cartilage, in bone on bone weight bearing and severe disability and pain (Martin 1994:1433).

Causes of secondary OA include the following (Edwards and Bochier 1991:799):

1. Developmental factors
2. Trauma
3. Metabolic
4. Endocrine
5. Inflammatory
6. Aseptic necrosis
7. Neurapathic factors.

2.4.6 Risk factors, Mechanisms and Pathophysiology:

OA has been classified as primary (idiopathic) or secondary, that is, a process related to infection, trauma, inflammation, metabolism or aging (Calliet 1991:191). Primary OA is termed when there is no causative factor (Hertling and Kessler 1996:363), although it is often hereditary (Golding 1989). Genetic studies suggest that genetic factors may account for 40-60% of the disease (Hart et.al. 1999:17).

Golding (1989:144) states that both sexes are affected, but primarly degenerative arthritis is more common in women, especially after menopause. He continued that previous fracture or dislocation as well as accumulated microtrauma (Occupational

OA; obesity; Occupational Trauma) could also predispose joints to develop osteoarthritis. Secondary OA may follow previous joint disease such as inflammatory joint disease (rheumatoid arthritic, gout); endocrine disorders (acromegaly, diabetic neuropathy, hypothyroidism); metabolic disorders (haemochromatosis, ochronosis, chondrocalcinosis, gout, Wilsons disease), Pagets disease of the bone, developmental disorders (Perthes disease of hip; slipped femoral epiphysis); neuropathic joints, avascular necrosis and haemophyllic arthritis. Climatic factors play a role as more frequent symptoms are seen in populations exposed to cold air and damp weather (Golding 1989:144).

2.4.6.1 Risk Factors.

Although factors with strong positive predictive values are not exactly identifiable, the following have been implicated in accelerated progression of the disorder.

1. **Age and Sex predisposition**

Knee OA prevalence increases with age and is more common in women than in men, especially after the age of 50 (Felson & Radin 1994:181). According to Hart et.al. (1999:121) 3% of middle aged women will develop knee osteophytes and joint space narrowing each year and a 2 fold risk is seen in elder women than with women 20 years younger. It was concluded that 3% of middleaged women would develop radiographic OA each year. Clinical studies have described a "Menopausal arthritis",and observations suggest that oestrogen deficiency may play a role in the development of OA in women (Felson et.al. 1995: 917).

2. Obesity

Obesity is a risk factor for the development and progression of knee OA and one study reported that weight loss was associated with a slower rate of development of symptomatic knee OA in women (Lane and Thompson 1997:285). In a study performed by Spector et.al. (1995:565), obesity was the most important factor related to incident disease and 47% of women in the top body mass index (BMI) tertile developing knee OA, compared with 10% in the lowest tertile. Greater body mass index in young men aged 20-29 years is associated with an increased risk of subsequent OA (Gelber et.al. 1999:542). In addition, obesity may increase the risk of OA, because adiposity is associated with abnormal levels of hormones and growth factors, greater bone mineral density and other metabolic intermediaries (Nevitt & Lane 1999:632).

3. Structural Malalignment

Various malalignments increases medial tibiofemoral compartment load and valgus malalignment increases lateral compartments load (Sharma et.al. 2000:568). A study by Sharma et.al. (2000), showed that B.M.I was related to OA severity in those with varus knees, but not those with Valgus knees. OA of the knee correlates with decreased tibial torsion as well as femoral anteversion (Eckhoff et.al. 1994:608).

4. Genetics

A study by Spector and collegues (Cited by Hochberg 1996:1498) reported the results of a twin study that showed a strong genetic predisposition to both hand and knee OA. In this study of 130 monozygotic and 120 dizygotic female twin pairs, between 39 and 59% of the variance of hand and knee OA, could be explained by genetic factors

after adjusting for age and weight (Hochberg 1996:1498).

5. Race

There exists an interesting difference in both the prevalence and pattern of joint involvement. For example, interphalangeal joint OA and especially hip OA are much less common in South African blacks than in South African whites. It is not known whether these differences are due to joint usage related to lifestyle or occupation (Brandt 1995:1059).

6. Gender

The increase in prevalence of OA with age, companded by the greater life expectancy among women, results in OA being twice as prevalent among women as among men aged 55 years or older. These gender differences are most prominent when OA affects the knee (7,3% of women and 4,1% of men age 55 through 64 years; 18% of women and 8,3% of men aged 65 through 74 years). For all grades of radiographic severity of OA, more women than men report knee pain, among those over age 60 years, women are twice as likely as men to have symptomatic OA (Brandt 1995:1059).

7. Level of Activity

According to McAlindan et.al. (1999:151), heavy physical activity is an important risk factor for the development of knee OA, in elderly, especially among obese individuals. However, Hannan et.al. (1993:704) found that habitual physical activity does not increase the risk. Cooper et.al. (1994:90) performed a study to determine the risk factors of occupational physical activities and found the risk of knee OA

increases in jobs that entailed prolonged or repeated knee bending, kneeling or combined knee bending with mechanical loading. The highest incidence of OA in sporting activities was found to be in soccer players and weight lifters (Kujala et.al. 1995:539).

8. Metabolic factors

A study by Hart et.al. (1995:1118) found that hypertension, hypercholestemia and high blood glucose levels are associated with both unilateral and bilateral knee OA, independent of obesity, and supports the concept that OA has an important systemic and metabolic component in its aetiology

9. Mechanical Derangment

Signifficant knee injury produces a risk factor for the development of medial tibiofemoral joint (TFJ) OA (Cooper et.al. 1994:307). Surgical removal of a menisci following knee injury also represents a significant risk factor for radiographic TFJ OA (Roos et.al. 1998:687). Varus-Valgus laxity may increase the risk of knee OA and cynically contribute to its progression (Sharma et.al. 1999:861). However the possible etiological and risk factors have questionable positive predictive values which are reflected by the wide range of management protocols.

2.4.6.2 Mechanisms

According to Manek and Lane (2000:1795) biomechanical and biochemical forces are involved in cartilage destruction, which is at the core of osteoarthritis. Cytokinines and growth factor are thought to play a role in the pathophysiology of the disorder. Interleuken 1 and tumour necrosis factor B may function to activate enzymes that are

involved in proteolytic digestion of cartilage. Growth factors, such as tissue growth factor B and insulin growth factor may play a role in the body's attempts to repair cartilage through cartilage synthesis. When catabolism exceeds cartilage synthesis, OA develops. Collagenolytic enzymes are thought to contribute to the breakdown of cartilage (Manek and Lane 2000:1795).

Changes in the articular cartilage trigger a cycle leading to the progression of degenerative joint disease (Hertling & Kessler 1996:44). Cartilage damage may occur after a single traumatic incident, causing a tension or compression strain, sufficient to interfere with the structural integrity of cartilage. More common is cartilage wearing from fatigue, due to it being aneural; any other muscloskeletal tissue is relatively immune to fatigue because protective reflex inhibition occurs with abnormal stress. This inhibitory response requires intact innervation. Cartilage is also susceptible to injury because it is also avascular. It lacks normal inflammation and repair response that would replace damaged parts of tissue. Hyaline articular cartilage partly makes up for the fact that it is aneural and avascular by its considerable ability to deform when loaded in compression (Hertling & Kessler 1996:44).

The breakdown mechanism of hyaline cartilage involve multiple factors and an imbalance between extracellular matrix degradation and synthesis. Repetitive impulse loading is considered to be a major factor. The type of load and the manner of loading is more important than the actual load on the joint surface. The more rapid the loading the higher the tensile and shear rates and the greater the potential for damage (Walker & Helewa 1996:32)

Cartilage, albeit resilent, because of its viscoelastic properties, is too thin to be an

effective shock absorber. Articular cartilage tends to deform causing resultant tension at its periphery. A constant clinical finding is the presence of cartilage degeneration in the load bearing areas, implying that compression and shear play a vital role in degeneration. Although loads borne by the joint come from weight bearing, most of the forces on joints result from muscular ccontraction about the joints. The muscles acting across the knee joint are alternatively used for acceleration and doceleration, which places compressive stress and impact on the knee. The cartilage absorbs some of these forces, but the subchondral bone probably absorbs most of it (Calliet 1991:194).

2.4.6.3 Pathophysiology of OA

Osteoarthritis is marked by fissuring, pitting and erosions on the surface of the articular cartilage. The cartilage softens as a result of decreased proteoglycan content. The cartilage then thins with overall fraying and fibrillation of the cartilage and roughening with ulceration occuring on the surface. Cartilage damage leads to breakdown and enzyme release leading to further cartilage loss. Bone changes include subchondral sclerosis and marginal osteophyte formation. The bone marrow below the subchondral bone undergoes degeneration and cyst formation, while the joint capsule undergoes thickening and the synovial tissue becomes inflamed. As the weight bearing continues in this abnormal situation, the damage continues and the cartilage destruction advances, leading to pain and disability (Martin 1994:1433).

The pathogenesis of the disease is well marked by cartilage breakdown, as is the role of the clustered fixed negative charges in the glycosamino glycans (GAG) in cartilage, in absorbing compressive stresses. In the development of OA, the concentration of GAG is decreased, therefore the ability of cartilage to absorb

compressive stresses is impaired and more pressure is transmitted to the underlying bone where pain receptors are present (especially in the periosteum). (Troch et.al. 1994:1910).

2.4.7 Clinical Features

Pain:

This is a major complaint (Hertling & Kessler 1996:364) which can vary from mild to severe and could be due to many causes such as: worn internal structures,tense popliteal cysts, medial ligament strain, trabecular fractures, tender fat pads, synovitus, capsular contraction, loose bodies, super added crystal deposition (Golding 1989:148).

According to Hertling and Kessler (1996:364) the pain could have muscular, capsular or perhaps venous origin. They went on to state that the pain is aggravated by activity or weight bearing, but may also be aggravated by rest, especially if the knee is kept in one position for a prolonged time. Pain associated with OA of the knee will often be worse on activities involving climbing and prolonged standing. The patellafemoral compartment undergoes major compressive forces when the body is raised from a kneeling or squatting position and on climbing stairs and hills. The patellafemoral joint reaction (PFJR) force during walking is 0,5 times body weight (BW), but doing deep knee bends (squatting) it raises to 7,6 times BW, and during stair climbing or descending, can reach a levelof 3.3 times BW [7 times greater than when walking]. (Scuderi 1995:30) Abnormal anatomic and biomechanical relationship between the patella and the femoral condyles can predispose the knee to chondromelacia and ultimately osteoarthritic changes (Calliet 1991:149).

Stiffness:

According to Hertling and Kessler (1996:364), morning stiffness is a common complaint, which is relived after motion, but the knee becomes painful again, once the weight bearing tolerance of the joint is exceeded by prolonged standing or walking. Moderate stiffness can be aggravated by rest, which is a form of elastic (as opposed to frictional or viscous) stiffness in which the patient complains of difficulty in getting going after sitting for a while (Golding 1989:148).

Inflammation and Swelling:

Synovial swelling or eflusions occur in episodes of acute OA (Golding 1989:148). According to Walker & Helewa (1996:30), the typical protective reaction of the body to injury, pathologic insult and microbes is one of inflammation. The classic inflammatory process, as seen in wound repair, is characterized by redness, swelling, heat and pain. The process involves increased vascular permeability, vasodilation, cell proliferation, neovascularization and fibroplasias. The ability of a tissue to exhibit the classic inflammatory response is strongly related to its vascularity. Hence in arthritis, synovial lining tissues invariably demonstrate a degree of inflammation, while hayaline articular cartilage being avascular does not. Similarly, strong fibrous, less vascular structures such as tendons and ligaments demonstrate a poor inflammatory process (Walker & Helewa 1996:305).

Limitation of Movement:

The range of movement of the knee may be decreased by capsular fibrosis, osteophytes, irregularity of articular surfaces or impaction of loose bodies. Fine or

course crepitus may occur on motion (Golding 1989:148).

Muscle Wasting:

According to Brandt et.al. (1999:2431), weakness of the quadriceps muscle is common and it is generally believed to be the result of disuse atrophy, due to a decrease in loading of the limb, because of pain.

Deformity:

Malalignment may result from irregularities of articular surfaces (Golding 1989:149). Degenerative change in the medial compartment are associated with a varus deformity, and those in the lateral compartment are associated with valgus deformities (Hertling & Kessler 1996:363).

Instability:

According to Hertling and Kessler (1996:36) episodes of giving way occurs secondarily to muscle wasting, transient severe pain or secondarily to minor trauma which may be the result of impingement of degenerated menisci, the pressure of loose bodies or a misstep.

2.4.8 Radiographic Evidence

Many people over the age of 65 have some radiographic evidence of OA, although many do not have symptoms (Oliveria et.al. 1995:1134). McAlindan et.al. (1993:258) elaborates that by the age 65 years, 30% of men and 40% of women have radiographic changes of knee OA. Traditionally, the severity of OA has been assessed using a system which scores radiographic features believed to be

characteristic of the disorder.

There are eight essential roentgen signs of degenerative joint disease: asymmetric distribution, non-uniform loss of joint space; osteophytes, subchondral sclerosis, subchondral cysts, intrarticular loose bodies, intraarticular deformity, and joint sublaxation. These roentgen signs closely parallel the underlying pathogenetic sequence involving the joint components. All signs will not necessarily be present in every case of degenerative joint disease (Yochum & Rowe 1996:804).

Mc Alindan et.al. (1993:258) propose an alternate hypothesis that radiographic features reflect outcome and tell us little about the disease process, or more provocatively that the radiopathological changes believed to constitute OA, do not represent a disease entity and are not a cause of disability.

A recent study by Lanyon et.al. (1998:595), evaluated radiographic features of OA to determine which is more closely associated with knee pain and hence might be used as a radiographic definition of OA in the community. They concluded that among men and women, osteophytes are the radiographic feature that associates best with knee pain. Their results showed that joint space loss is not a feature of assymtomatic aging. This finding that joint space does not necessarily decrease with age among assyptomatic subjects is in keeping with the concept that OA is a part of aging or "wear and tear" (Lanyon et.al. 1998:595).

Although reasonable basis for correlating radiographic findings with clinical signs and symptoms exists, radiographic findings are not indicative of symptoms produced by the patient.

2.5 Treatment

Treatment of OA is aimed at decreasing impairment, easing pain and maintaining function (Minor and Saaford 1993: 197). Currently, management of osteoarthritis of the knee includes both pharmacological and non-pharmacological therapies. According to Bÿalint and Szebenyi (1997) non-pharmacological management is very important in the treatment of osteoarthritisof the knee, in helping to relieve pain, increase muscle strength and improve range of motion, without the significant side-effects introduced by prolonged drug therapy.

Each health profession approaches pain management with its own objectives and clinical tools. The objective of physical therapists, in regard to a person with osteoarthritis are to relieve pain, maintain function and to make the person an effective self manager. (Minor and Saaford 1993: 197).

According to Lane and Thompson (1997:25s), education about OA for the patient and their families, should be the first non-pharmacological therapy. The patient should also be instructed on the principle of joint protection. Brandt (1995:1061) advises patients with OA of the hip and knee to seek alternatives to prolonged standing, kneeling and squatting. Another non-pharmacological option for treatment of OA of the knee are assistance devices, such as using a cane in the hand contralateral to the affected knee to help reduce the compression force on the affected knee (Lane and Thompson 1997 : 28s); use of crutches or a walker; orthotics support (eg. Wedged insoles for varus or valgus deformities) and rest periods during the day may be beneficial (Brandt 1995 : 1061)

Although there is no evidence supporting weight loss as a means of slowing the

progression of OA of the knee, a physician should encourage an overweight patient with OA of the knee to lose weight especially if the patient is under consideration for knee arthroplasty (Lane and Thompson 1997 : 28s). Several lines of evidence exists to support the use of exercise training for knee OA. Patients with knee OA have deficits in physical capacity that may affect their ability to walk and transfer. Muscle strength, aerobic capacity and joint range of motion are all decreased in patients with knee OA. Therapeutic exercises has positive health benefits in older patients, inducing improved mental and physical health. Numerous studies have shown that regular exercise can improve a patients work capacity and muscle strength. Aerobic and resistance training appear to be safer and effective even in older patients. Resistance training of the quadriceps muscle increases strength , decreases knee pain and improves physical functioning in patients with OA of the knee, whereas studies of aerobic training have shown significant improvement in measured aerobic capacity, walking time and physical functioning (Ettinger and Afable 1994 :1437). The management of OA should be comprehensive. Non-pharmacological treatment programs are as important as, and often more important than drug therapy. Pharmacological therapy can be expensive and result in gastro-intestinal toxicity in elderly patients with OA (Lane and Thompson 1997 : 26s).

According to Brandt (1995 :1061), a patient with OA of the knee needs to modify the types of activity performed, reduce the intensities and frequency of activities, change attitudes in response to health restrictions, seeking help and restructuring the physical enviroment in order to cope and stabilize the declining health.

2.6 Transcutaneous Electrical Nerve Stimulation (TENS)

One of the most extensively investigated modalities to provide pain relief is Transcutaneous electrical nerve stimulation (TENS). TENS is a low frequency, biphasic , assymetrical square wave with a variable frequency ranging from 0 to 600Hz, that produces pain relief by stimulatin Aβ fibres and Aδ nerve fibres. Aβ fibres are stimulated by low amplitude, high frequency, short duration stimulation, while Ag nerve fibres are stimulated by high amplitude and low frequency currents (Clayton 1996).

Melzack and Wall (1982) found in a controlled clinical trial, that high frequency (70Hz) stimulation was more effective in pain relief than low frequency (3Hz) in patients suffering of rheumatoid arthritis. According to Melzack (1982), the optimal frequencies and intensities of TENS for each kind of pain is not known, however it is known that continuous stimulation produces a gradual rise in pain threshold at the spinal cord cells, producing optimal relief. (There are no other recent studies that stipulate a specific intensity or frequency for a particular pain). Clayton (1988:105) states the most commonly used parameters for pain control by TENS is a frequency between 100-150Hz, an intensity of between 12-30mA over daily 40 minute time period.

2.6.1 The use of TENS in the treatment of OA knee

According to Melzack (1982), TENS could be used for brief periods of time at moderate to high intensity to stimulate specific areas of the nervous system to bring about reflex inhibition. TENS selectively stimulates the large, fast A-beta fibres, preventing the smaller slower conducting, non myelineteal nerve fibres, which carry

noxious (painful) stimulation from conveying their message to the spinal cord. This is called presyneptic inhibition. Both the large and small afferent nerve fibres converge on the substantia Gelatinosa (Forster and Palastanga 1985:1003).

According to the gate control theory (Melzack 1982), these noxious impulses will be blocked at the spinal cord level by the input received from TENS via the large, type Aβ afferent nerve fibres. A frequency of 100Hz appears to be most conducive in producing this effect (Graff – Radford et.al. 1988).

It would be logical to assume therefore that the theraputic effect of TENS would not be lasting. If this was the case, it would follow that treatment of symptomatic pain in the knee would be a waste of time, as the actual cause of the pain was not being dealt with, and the pain would therefore be recurring. However, according to Melzack (1982), prolonged pain relief can be obtained by TENS in terms of two hypothesis.

1) There are reverborating neural circuits which underlie "memories" of the earlier injury (OA of the knee). These circuits are facilitated by low level inputs received from the pathological structures. These circuits are disrupted for long periods of time, or even permanently, by electrical stimulation as is the case with TENS.

2) When the pain that the patient is so accustomed to, is blocked, even for a short period of time, the patient resumes normal motor activity. The resulting normal proprioceptive input may prevent the resumption of the abnormal reverberating neural circuits which underlie the pain.

In a study conducted by Lindsay et.al. (1990) of 73 private physiotherapy practices in Austrailia, more clinics owned a TENS unit than any other electrical modality.

Unfortunately clinical trials to establish guidelines for most effective usage of electrotherapy modulation is lacking (Lindsay et.al. 1990).

2.6.2 Treatment Duration

There are no definite guidelines as to the most effective length of stimulation. Graff – Radford et.al. (1988) chose treatment duration of 10 minutes. Walsh et.al. (1995) applied TENS for 15 minutes per session, but they seemed to consider the combination of the stimulation parameters (intensity and frequency) to be of greater importance than treatment duration. Grimmer (1993) applied TENS for 30 minutes duration in her investigation on the effects of TENS on painful osteoarthritic knees. All three studies produced positive results, therefore, until definite guidelines are established, the treatment duration relies upon examiner discretion.

2.6.3 Electrode Placements

The effectiveness of the TENS for pain control is critically dependent on the correct electrode placement (Lindsay et.al. 1990), however guidelines in this regard are vague. A suggestion by Forster and Palastangs (1985:105) are placement directly over the area of greatest pain intensity.

Robinson (1996) advocated placing the electrodes directly over the painful area, in the treatment of soft tissue inflammatory conditions. In a controlled study of the effect of TENS on painful osteoarthritic knees, Grimmer (1993), achieved positive results by positioning the electrodes over the appropriate acupuncture points to maximise intermenisci opiate response. In this study, the electrode placement was constant. The variable was the choice of either burst mode or high rate TENS.

The fact that TENS indirectly modulates the transmission of impulses through nerve fibres by stimulating the A beta fibres, shows that there exists physiological evidence to support electrode placement over the painful area, although controlled studies to this effect, could not be found.

2.7 ACTION POTENTIAL THERAPY (APT)

2.7.1 Introduction

In 1992, a newer treatment modality was developed in South Africa. It was aimed at helping to relieve pain and prevent disability. It has been used by both laymen and health professionals since 1994 (Berger 1999:11).

Action Potential Therapy has been described as a combination of direct and alternating currents, having a continuous monopausic square pulse, and a constant frequency of 151Hz, that can theoretically stimulate the naturally occurring action potential found in a neuron (Berger 1999:115).

2.7.2 Action Potential

Nervous signals are transmitted by Action Potentials. Both nerves and muscles are excitable, which means that they are able to produce an action potential after adequate stimulation (Guyton 1992:47s). The action potential is divided into 3 successive phases namely:

Resting stage:

This is resting membrane potential. The membrane is polarized, which means that there is a very large negative membrane potential. This is the stage before the action

potential occurs.

Depolarization Stage:

Nerve fibres membranes consist of voltage activated ion channels, that are sensitive to voltage changes across the membrane. When the voltage reaches a critical point, the gates open allowing specific ions to pass through the channels. The membrane becomes permeable to sodium ions, which flow through the channels to the axon. The nerve fibre depolarises moving away from its depolarised state of 90mV, with the potential reaching the zero level. In large fibres, the membrane potential may overshoot beyond the zero level, with a momentary reversal in polarity.

Repolarization Stage:

After a few 10 000ths of a second, the sodium channels begin to close with the potassium channels opening. The diflusion of potassium ions externally re-establishes the normal negative resting potential of the nerve fibre. That is the nerve is repolarized (Guyton 1992:47).

2.7.3 Action Potential Current Therapy (APT)

APT is said to stimulate or mimic the naturally occurring action potentials in a neuron (Berger 1999:285). According to Shipton (1999:314), a weakened transmission of action potential or even cessation of activity along a neuron may occur when a pathological process such as inflammtion or damage to a schwann cell causes a blockage along the path of the action potential. If the action potential mechanism can be restored to normal, injury and disease can be affected at a cellular level and health of the organism improved or regained. This is the alleged action of APT (Berger 1999:31).

According to Berger (1999:31) depolarisation takes place, when a neuron is

stimulated by APT, because the APT device has a supposedly stronger voltage, than the normal current required to produce the action potentials. Stimulation by APT creates a normal action potential, which apparently restores the inherent biochemical processes in the region (Berger and Matzner 1999:32).

Berger (1999:33-34) lists the following physiological effects of APT:

1. Breakdown of biochemical waste from uric acid, inflammtion and exess fluid in the treated area.
2. Increased melatonin levels, which induces relief from anxiety and has beneficial effects on muscle spasm.
    a. Increase in leu-enkephalin, which modulates pain.
    b. Improves circulation resulting in increased transportation of antibodies, hormones and neuro-transmitters to the area being treated.
    c. Improved circulation also has positive effects on lymph drainage in the area.

2.7.4 Comparison between APT and TENS

Pulses produced by TENS are balanced biphasic pulses, whereas APT unit produces a monophasic current, with an exponential decay, with a negative balance between the polarities, therefore facilitating depolarisation of the nerve. The effect of TENS is obtained by stimulation of large, low threshold sensory nerve fibres (Berger 1999:17-20). According to the gate control theory by Melzack and Wall (1988:98) this would inhibit cells which transmit injury signals. According to Berger (1999:17), stimulation by APT current creates a normal action potential, which restores the inherent biochemical processes in the region, whereas TENS produces pain suppression by means of the gate control theory.

2.7.5 Clinical Trials on Action Potential Therapy

Various trials were conducted at South African universities to evaluate the effectiveness of Action Potential therapy. The outcome proved promising results. Oodendeal et.al. (1999), undertook a randomised patient blinded, placebo controlled study of the pain control unit, Department of Aneathesiaology, University of Orange Free State, Bloemfontein. The study population consisted of 76 osteoporotic patients, with chronic backache. Each patient received 6 treatments with one day, interval between each treatment. Each treatment lasted 32 minutes (16 minutes followed by a 3 minute interval followed by another 16 minutes). Clinically the results of the effect of the treatment concluded to be successful. Berger (1999), undertook a randomised, single blinded, placebo controlled study involving 99 patients with osteoarthritis of the knee conducted at the pain relief and research unit, Department of Anaesthesiaology, Baragwanath Chris Hani Hosiptal, University of Witwatersrand. Although the study reported the superior effectiveness of Action Potential therapy, the methodology jeopardises the inferential validity of the study.

2.7.6 Contra-indications of APT (According to manufacture guidelines)

- Patient with any electrical medical devices
- Patients predisposed to thrombolytic episodes
- Patients with epilepsy
- Abdominal area of pregnant women
- Vacinity of malignant tumour
- Directly over eyes
- Children under 12 years and persons with body mass less than 15 kilograms

- directly over broken and damaged skin
- each individual has different surface (skin) resistance, therefore the intensity of the current perceived by each individual may vary accordingly.

2.8 Summary

The review of the literature reveals that OA is a very prominent condition with many conservative factors involved in its pathogenesis. OA of the knee is a non-fatal condition, but is responsible for much pain, suffering and disability. OA requires a comprehensive treatment regime, which may consist of a progression of treatment modalities.

The goal of the treatment will be to slow down the arthritic process and improve the patients quality of life.

Various studies, using different treatment protocol proved successful. The use of electrical devices (i.e. TENS and Action Potential Therapy by Berger (1999)) to treat the symptoms of osteoarthritis of the knee, produced superior effectiveness, however, the study methology jeopardises the inferential validity of the study.

Berger applied TENS and APT to patients for 6 treatments over a period of 2 weeks, however the settings on both modalities were not constant (i.e. TENS frequency 200Hz; intensity 4mA; time 20 minutes, whilst APT frequency has 151Hz fixed; and the intensity based on patient comfort, time 8 – 16 minutes). APT and TENS are low frequency currents and to prove the relative difference between these modalities, an equal and constant frequency, intensity and time should have been used. Another short coming, was the sample size that is not large enough to provide a valid outcome. Berger used a sample size of 17 patients in each group to evaluate its difference.

Therefore, although an appreciable difference in the mechanical characteristics of the 2 modalities exist, due to the flawed research conducted to date, a paucity of evidence exists in order to answer the question whether there is a significant difference in the APT and TENS as treatment modalities to relieve pain.

CHAPTER THREE

Chapter Three

3.0 Materials and Method

3.1 Introduction

This chapter deals with the details of the research study undertaken. This includes a detailed description of the design, primary and secondary data, the subjects and intervention used. An overview of each questionnaire and the validity of each measurement parameter are discussed. Statistical procedures for the assessment of the data are also discussed.

Design Type : A prospective randomised clinical trial analyzing objective and subjective clinical outcomes.

3.2 The Subjects (Population group)

The subjects consisted of volunteers from the population of Durban.

3.2.1 Selection of Subjects

Patients were obtained by purposive sampling, using advertisements posted in the Technikon Natal Chiropractic Day Clinic, on local community notice boards, and in the local newspaper, inviting free participation in a clinical trial for people with osteoarthritis of the knee. The advertisement called on people having painful knees for at least six months previously to respond. Any patient presenting to the clinic with knee pain, for longer than six months duration, was also considered a candidate for the study. No restrictions were placed on the patients sex, racial group, occupation,

income bracket or area of residence.

Upon reply, each subject was telephonically interviewed so as to explain the conditions of the study and as an initial screening process with questions pertaining to the history and progression of their complaint, to eliminate those patients obviously falling outside the range of the study. Patients were immediately excluded if they were below the age of 40 or over the age of 65 years (DJD is an age related disorder and therefore a greater chance of finding it in the above mentioned age group is likely. However, in order to attain an homogenous sample a lower and upper age was set), pregnant or potentially pregnant females or breastfeeding mothers (The likelihood of finding a pregnant or potentially pregnant patient at this age is remote, but if found to be so, the patient was excluded to prevent the side-effects of x-ray as each patient had to be x-rayed to confirm the diagnosis of OA of the knee).

Sixty patients were consecutively selected from those that responded. After agreeing to participate, an initial consultation was scheduled for the prospective participant at which a case history (Appendix A), a relevant physical examination (Appendix B) and a full knee regional examination (Appendix C) was scheduled.

3.2.2 Allocation of Subjects

As patients were examined and found suitable, they were asked to complete an informed consent form (Appendix D). Random assignment was used to allocate each patient to either the APT; TENS or placebo group. As the total size of the population was 60 patients, numbers 1- 20 was assigned to the APT group; number 21-40 to the TENS group, number 41-50 to the placebo APT group and numbers 51-60 to the placebo TENS group (patients were divided into the four groups to compare the

relative effectiveness of each modality). As the patients met the inclusion criteria and were accepted into the study, they were asked to draw a number from a box with their eyes closed. After drawing a number, the piece of paper was discarded, and the process was repeated until all 60 patients were allocated in the four groups.

3.2.3 Inclusion and Exclusion Criteria

The criteria were as follows:

1. Patients between the age of 40 and 65 years.
2. Only patients diagnosed by the researcher as having OA of the knee were involved in the study. The diagnosis was confirmed by the consulting clinician in accordance with the treatment protocol. A diagnosis of OA was made using the following criteria (Yochum and Rowe 1996:856).
    - Knee joint pain in one or both knees
    - Decreased range of motion
    - Pain in the involved knee that is aggravated by activity and relieved by rest
    - Morning stiffness upon rising or stiffness after disuse
    - Joint crepitus
    - Bony enlargements
    - Varus deformity
    - Radiographic evidence.
3. Weight bearing A.P., lateral and skyline radiographs were taken to confirm the diagnosis and rule out any other pathology. The evidence of radiographic OA, should include:

- Narrowing of joint space of either the medial or lateral compartments on a standing AP Radiograph
- Subchondral bony sclerosis
- Osteophyte formation
- Evidence of genu varus or valgus deformity

However not all of the above citeria need to be present in order to make a diagnosis (Yochum and Rowe 1996:803).

4. **Blinding procedure** : Patients randomised to the placebo group had to be "naïve" to their treatment. If they were not, they were automatically excluded from the study. If a patient became aware that placebo treatment was being administered they could be biased in the subjective rating of their condition.

5. Patients were instructed not to change their everyday routine, and compliance was ensured by the researcher at each consultation.

6. Patients receiving any other form of treatment or altered their lifestyle signifficantly in the duration of the study would be excluded.

7. Patients will be excluded if they present with or if they show any indication that they have any of the following:

- Grade 3 ligamentous instability of the knee.
- Neoplastic disease / Malignancy
- Infective Arthritides
- Haematological disease
- Systemic arthritis: Rheumatoid or Psoriatric arthritis
- Osteomyelitis
- Extremely acutely painful knees

- Septic arthritis
- Broken or fragile skin or dermatoses or infection of the application site.
- Implanted electrical devices (e.g. Pacemaker)
- Epilepsy

3.2.4 Ethics

The ethical procedures were instituted according to Technikon Natal guidelines. All patients information was treated as confidential. Each patient upon acceptance into the study was required to complete and sign an informed consent form (Appendix D). Patients were free to withdraw from the study at any time.

3.3 The Data

This consists of primary and secondary data.

3.3.1 The Primary Data

The primary data consists of:

- The case history; relevant parts of the physical examination; and radiographic findings of the patients used in this study.
- Knee ranges of motion measured with a goniometer
- Pain threshold measured with an algometer
- Patients perception of their worst and least levels of pain intensity using the Numerical Pain rating scale (N.R.S –101)
- Patients perception of their disability using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

3.3.2 The Secondary Data

This consisted of documents and relevant literature obtained from various sources containing applicable, information relating to this study. Information was acquired from journals; books; and medical search engines on the internet (Medline, Mantis, Medscape).

3.4 Assessments

The subjective data was collected on the 1st and 4th evaluation, and the objective data was collected on the 1st, 2nd and 4th evaluation.

These were performed at the beginning of the consultation prior to any examination or treatment.

3.4.1 Subjective measurements

Subjective information was obtained using the NRS-101 (Jensen et al. 1988) [Appendix E] and WOMAC (Bellany et al. 1988) [Appendix F]

3.4.1.1 The Numerical Pain rating Scale-101 (NRS-101)

The NRS-101 (Appendix E) is a questionnaire used to access the patients perceived level of pain intensity.

The patient is presented with two lines, each marked with "O" at one end, "100" at the other. The patient is informed that "O" represents "no pain" and "100" represents "pain as bad as it could be". On the first line, the patient is asked to identify the number which best represents the level of pain they are experiencing when the pain is

at its worst. On the second line, they are asked to identify the number that best represents the level of pain when it is at it's least. The average between these two figures was then taken as the percentage intensity of pain they were experiencing (Jensen et.al. 1986)

Jenson, Karoly and Braver (1986) established its validity and reliability when providing subjective information about pain levels. This scale is extremely simple to administer and score, and can be administered either in written or verbal form. The authors also believe that this is the most practical and superior index (Jensen et al. 1986:117-125).

3.4.1.2 Western Ontario and MacMaster Universities Scale (WOMAC)

The WOMAC Osteoarthritis index consists of 24 questions, each corresponding to a five point (None, slight, moderate, severe, extreme) likert scale. The index utilizes pain (5 items), stiffness (2 items) and physical function (17 items) subscales. WOMAC offers 2 main advantages over other previously utilized scales, the first is that it has been shown to offer superior efficiency as compared to other traditional measures in assessing the efficiency of antirheumatic drugs, and secondly it probes patient relevant outcomes of clinical importance as opposed to traditional measures which often lack patient relevance. This index has been shown to be reliable, valid and responsive multi-dimensional outcome measure for evaluation of patients with OA of hips or knee (Bellany et al. 1988). The other commonly used index for evaluating OA of the hip or knee is the Lequesne index, in spite of the simplicity of this index, little data exists on its validity and reliability (Hart et al. 1995).
On completion of the index, the values for each subsection were added to attain scores for the consultation.

3.4.1.3 The Short Form McGill Pain Questionnaire:

The short form McGill pain Questionnaire provides valuable information on the patients sensory, affective and evaluative dimensions of pain experiences in a limited time frame. It was derived from the standard McGill Pain Questionnaire for more rapid acquisition of data. The questionnaire consists of is representative words (descriptors) which are rated on an intensity scale as o = none, 1 = mild, 2 = moderate or 3 = severe (Melzack, 1987). On completion of the questionnaire, the points were added to form a final score for that consultation.

3.4.2 Objective measurements

Objective measurements were obtained using a goniometer (Appendix G) for knee range of motion and an algometer (Appendix H) for pain threshold readings.

3.4.2.1 The Goniometer

The goniometer was used to measure the knee range of motion. Readings were taken at full extension and at full flexion.

The procedure for assessing knee ROM was as follows;

- The patient was asked to lie supine on the examination table
- The centre binding ring of the goniometer was placed over the central aspect of the lateral femoral candyle.
- One arm of the goniometer was extended to line with the lateral mallelous of the ankle, while the other arm was extended to line up with the trochanteric notch of the femur.

- The patient was asked to fully extend the knee, and the angle was measured and recorded.
- The patient was asked to fully flex the knee and again the reading was recorded.

3.4.2.2 The Algometer

The algometer readings were used to quantify any changes in the patients pressure pain threshold (pain sensitivity). Pressure algometers have been successfully employed for the assessment of general sensitivity of pain, and has been used to evaluate arthritis, tendonitis, inflammation, and fibrositis. Fischer (1986:838) states that the activity of arthritis can be quantified by pressure threshold measurement, and that changes in the patients pressure threshold under standard clinical conditions can be regarded as reliable data.

Measurements were taken over the "most painful" point in the involved knee. Force readings were recorded in kilograms per square centimetre. The higher the reading, the less tenderness is present. Improvement is shown by a higher threshold (Fischer 1986:836-838).

The procedure for accessing the pain threshold was as follows;

- The algometer dial was reset to zero
- The disk was placed over the "most painful" area perpendicular to the skin and pressure was applied at the rate of one kilogram per second.
- The patient was instructed, through vocal feedback, when the sensation changed from pressure to pain / discomfort, at which point the pressure was released and the reading was recorded.

3.5 Intervention

The patients were treated with their randomly selected intervention. Each patient accepted into the study underwent a total of 3 treatments over a period of 7 days. The treatment time was 16 minutes with the TENS; APR; Placebo TENS or Placebo APR being administered.

3.6 The location of Data

The primary data was obtained from the McGill Pain Questionaire, the NRS-101, the WOMAC index, the algometer readings and goniometer readings. Data was collected at the first visit pre-treatment one, on the second visit pre-treatment two and on the fourth consultation (evaluation visit). All consultations took place at the Technikon Natal Chiropractic Day Clinic.

The secondary data was obtained from journals and text books.

3.7 Statistical Analysis

The SPSS statistical package as supplied by SPSS Inc. marketing Department, 444 North Michigan Avenue, Chicago, Illinois, 60611) was utilized for data analysis. The statistical evaluation was aimed at measuring any significant changes between and within the initial and second consultations, the initial and fourth consultations, as well as the second and fourth consultations between the different study groups.

3.7.1 Comparison between Independent Samples

The Mann-Whitney U-Test (non-parametric test) was used to determine whether any significant difference occurred between the three groups, for categorical as well as

continuous variables. In each test, the null hypothesis states that there is no difference between the groups, with respect to the variables in charge, at the $\alpha = 0,05$ level of significance. The alternate hypothesis states that there is a difference.

{Ho : There is no difference between the groups}

{H1 : There is a difference between the groups}

Decision Rule: The null hypothesis is rejected at the α level of significance if $p < \alpha$, where p is the SPSS reported value (p – value). Otherwise, the null hypothesis is accepted at the same level.

3.7.2 Comparison between related samples (Wilcoxon Signed Ranks Test)

The Wilcoxon Signed Ranks Test (non-parametric test) was used to determine whether any significant change occurred between:

- The initial and second consultation
- The second and fourth consultation and
- the initial and fourth consultation, within each study group

The variables listed were the NRS-101, the McGill Short Form pain Questionnaire and the WOMAC index as well as the algometer and goniometer readings.

In each test, the null hypothesis states that there is no improvement between the related samples being compared, at the $\alpha = 0,05$ level of significance. The alternate hypothesis states that there is an improvement.

{Ho : There is no improvement between consultations}

{H1 : There is an improvement between consultations}

For one-tailed test the decision rule is :

1. Reject Ho if the p - value is $< \alpha$.

2. Accept Ho if the p – value is $\geq \alpha$.

where, p = [reported p- value / 2] if {H1 is of form > and z is positive}
{H1 is of form < and z is negative}

p = 1 - [reported p – value / 2] if {H1 is of form > and z is negative}
{H1 is of form < and z is positive}

The null hypothesis is rejected at the α level of significance if $p/2 < \alpha$ where p is the observed significance level or p-value. Otherwise, the null hypothesis is accepted at the same level.

Three methods were used to measure central tendency : mean, median and mode. Other summary statistics obtained were standard error and the coefficient of variation.

The purpose of this investigation is to evaluate the relative effectiveness of Action Potential Therapy, Transcutaneous Electrical Nerve Stimulation, and placebo in terms of objective and subjective patient findings in the treatment of osteoarthritis of the knee.

CHAPTER FOUR

Chapter Four

4.0 The Results

4.1 Introduction

This chapter discusses the data collected using the methodology outlined in Chapter Three. Also presented is the interpretation of the results with the relevant tables and bar charts.

Group 1 – Action Potential Therapy Treatment Group

Group 2 – Transcutaneous Electrical Nerve Stimulation Treatment group

Group 3 – Placebo Action Potential Therapy Treatment Group

Group 4 – Placebo Transcutaneous Electrical Nerve Stimulation Treatment group

4.2 Recruitment

The study consisted of sixty patients: twenty in group 1, twenty in group 2, ten in group 3 and ten in group 4.

Seventy-eight volunteers were screened, of which sixty-five were accepted into the study. From the thirteen who were rejected (Table 4.1), six volunteers lacked reliable transport; two could not be released from business commitments; one suffered an open laceration to the knee, two had instability of the knee (ligamentous) and two contracted the flu virus and were unable to follow up on the treatments. Five patients dropped out of the study during the course of the treatment (Table 4.2) : 2 volunteers lacked reliable transport; one had to attend to family issues out of town and two could not get time off work to attend the treatment sessions.

Table 4.1 – Reasons for patients not meeting selection criteria

Reason	No. Of patients and percentage
Lack reliable transport	6 (46,15%)
Business Commitments	2 (15,38%)
Injury to the knee	1 (7,69%)
Knee Instability	2 (15,38%)
Contracted flu Virus	2 (15,38%)
Total	**13 out of 78 = 16,67%**

Table 4.2 – Reasons for patients not completing the study

Reason	No. Of patients and percentage
Lack reliable transport	2 (40%)
Family Issues	1 (20%)
Work Commitments	2 (40%)
Total	**5 out of 65 = 7,69%**

4.3 Demographic Data

Table 4.3 – Age distribution within the sample of 60

Age	Group 1	Group 2	Group 3	Group 4	Total %
40 – 49	4	5	1	3	21,66%
50 – 59	8	11	5	3	45,00%
60 - 65	8	4	4	4	33,34%

The average age (mean) for group 1 : 56,65 years old

The average age (mean) for group 2 : 54,25 years old

The average age (mean) for group 3 : 28,65 years old

The average age (mean) for group 4 : 26,95 years old

Table 4.4 – Gender distribution within the sample of 60

Gender	Group 1	Group 2	Group 3	Group 4	Total %
Male	10	11	3	7	51,67%
Female	10	9	7	3	48,33%

Table 4.5 – Racial group within sample of 60

Patients Racial Group	Group 1	Group 2	Group 3	Group 4	Total %
White	17	16	7	6	76,67%
Indian	3	4	3	4	23,33%

Table 4.6 – Occupation of patients with sample of 60

Occupation	Group 1	Group 2	Group 3	Group 4
Unemployed	1	1	0	0
Loss Adjuster	1	0	0	0
Engineer	1	0	0	0
Housewife	6	5	6	2
Secretary	1	1	0	0
Retired	5	6	2	2
Administrator	1	0	1	0
Coach	1	0	0	1
Security	1	3	0	1
Manager	1	0	0	1
Clerk	1	1	1	0
Self Employed	0	1	0	1
Sales	0	2	0	1
Lecturer	0	0	0	1

Table 4.7 – Average Height and Weight in sample group

Average	Group 1	Group 2	Group 3	Group 4
Height	1,67	1,66	1,65	1,67
Weight	87,8	84,2	77,5	85

Overall Mean Height: 1,66m

Overall Mean Weight: 84,42kg

Table 4.8 – Average pain duration within sample of 60

Av. No of years	Group 1	Group 2	Group 3	Group 4
	4,75	6,88	3,8	7,4

Table 4.9 – Knee affected by and diagnosed with OA within sample group

Knee Affected	Group 1	Group 2	Group 3	Group 4
Left knee	6	4	2	3
Right knee	9	13	4	2
Both knees	5	3	4	5

Table 4.10 – Most painful knees (side treated) within sample group

Most painful & treated knee	Group 1	Group 2	Group 3	Group 4
Left	7	5	3	3
Right	13	15	7	7

4.4 The Analyzed Data

4.4.1 Hypothesis testing

The following hypothesis relates to intra and inter group comparisons:

4.4.1.1 Inter group comparison

The null hypothesis (Ho) states that there is no difference between the groups being compared in terms of subjective and objective clinical findings. The alternate hypothesis (Hi) states that there is a difference between the groups being compared in terms of subjective and objective clinical findings. The data was analysed at the $\alpha = 0,05$ level of significance.

Decision Rule : Reject the null hypothesis if the p-value is less than or equal to $\alpha/2$ ($p \leq 0,025$) and accept the alternate hypothesis. Accept the null hypothesis if the p value is greater than $\alpha/2$ ($p > 0,025$) and reject the alternate hypothesis.

4.4.1.2 Intra group comparison

The null hypothesis (Ho) states that there is no improvement within the groups being compared in terms of subjective and objective clinical findings. The alternate hypothesis states that there is an improvement between the groups being compared in terms of subjective and objective clinical findings. The data was analysed of the α = 0,05 level of significance.

Decision Rule : Reject the null hypothesis if the p-value is less than or equal to α ($p \leq 0,05$), and accept the alternate hypothesis.

Accept the null hypothesis if the p-value is greater than α ($p > 0,05$) and reject the alternate hypothesis.

4.4.2 P-value

The P-value is the observed level of significance. The smaller the p-value, the larger the difference between the groups being compared.

4.4.3 Two sample paired t-test

Table 4.11 – Statistical results of the objective data comparing the 1st and 2nd consultation in Group 1

	Consultation 1			Consultation 2	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	8,8704	115,5000	1,000	115,5000	8,8704
Algometer	1,4486	9,8800	0,427	9,8900	1,4444

When comparing the objective data between consultation 1 and 2 for Group 1, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.12 - Statistical results of the objective data comparing the 1st and 2nd consultation in Group 2

	Consultation 1			Consultation 2	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	11,8405	114,2500	0,317	114,7500	11,5251
Algometer	1,5134	10,0000	0,865	9,9500	1,4081

When comparing the objective data between consultation 1 and 2 for Group 2, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.13 - Statistical results of the objective data comparing the 1st and 2nd consultation in Group 3

	Consultation 1			Consultation 2	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	13,7032	116,0000	0,157	117,0000	13,3749
Algometer	1,9505	9,80000	0,138	10,0400	2,0173

When comparing the objective data between consultation 1 and 2 for Group 3, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.14 - Statistical results of the objective data comparing the 1st and 2nd consultation in Group 4

	Consultation 1			Consultation 2	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	11,0050	111,0000	1,000	111,0000	11,0050
Algometer	0,9615	10,2000	0,317	10,1800	0,9864

When comparing the objective data between consultation 1 and 2 for Group 4, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.15- Statistical results of the objective data comparing the 2nd and 4th consultation in Group 1

	Consultation 2			Consultation 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	8,8704	115,5000	0,317	115,000	8,8852
Algometer	1,4444	9,8900	0,590	9,9600	1,4933

When comparing the objective data between consultation 2 and 4 for Group 1, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.16 - Statistical results of the objective data comparing the 2nd and 4th consultation in Group 2

	Consultation 2			Consultation 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	11,5251	114,7500	0,334	115,7500	11,6161
Algometer	1,4081	9,9500	0,850	9,9350	1,5500

When comparing the objective data between consultation 2 and 4 for Group 2, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.17 - Statistical results of the objective data comparing the 2nd and 4th consultation in Group 3

	Consultation 2			Consultation 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	13,3749	117,0000	0,317	115,000	14,3372
Algometer	2,0173	10,0400	0,786	10,0000	2,1644

When comparing the objective data between consultation 2 and 4 for Group 3, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.18 - Statistical results of the objective data comparing the 2nd and 4th consultation in Group 4

	Consultation 2			Consultation 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	11,0050	111,0000	1,000	111,0000	11,0050
Algometer	0,9864	10,1800	1,000	10,1800	0,9818

When comparing the objective data between consultation 2 and 4 for Group 4, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.19 - Statistical results of the objective data comparing the 1st and 4th consultation in Group 1

	Consultation 1			Consultation	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	8,8704	115,5000	0,317	115,5000	8,8852
Algometer	1,4486	9,8800	0,301	9,9600	1,4933

When comparing the objective data between consultation 1 and 4 for Group 1, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.20 - Statistical results of the objective data comparing the 1st and 4th consultation in Group 2

	Consultation 1			Consultation 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	11,8405	114,2500	0,216	115,7500	11,6161
Algometer	1,5134	10,0000	0,633	9,9350	1,5500

When comparing the objective data between consultation 1 and 4 for Group 2, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.21- Statistical results of the objective data comparing the 1st and 4th consultation in Group 3

	Consultation 1			Consultation 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	13,7032	116,0000	1,000	115,000	14,3372
Algometer	1,9505	9,8000	0,324	10,0000	2,1644

When comparing the objective data between consultation 1 and 4 for Group 3, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.22 - Statistical results of the objective data comparing the 1st and 4th consultation in Group 4

	Consultation 1			Consultation 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	11,0050	111,000	1,000	111,000	11,0050
Algometer	0,9615	10,2000	0,655	0,9818	10,1800

When comparing the objective data between consultation 1 and 4 for Group 4, it can be seen that there is statistically no improvement for the algometer and goniometer readings. The null hypothesis was therefore accepted.

Table 4.23 - Statistical results of the subjective data comparing the 1st and 4th consultation in Group 1

	Consultation 1			Consultation 4	
	Std Dev.	**Mean**	**P-value**	**Mean**	**Std Dev.**
NRS	13,7763	47,6250	0,040	40,2500	17,3755
McGill	7,4018	13,4500	0,913	13,6500	8,2160
WOMAC	51,9500	23,5919	0,338	49,4500	22,3759

When comparing the subjective data between consultation 1 and 4 for Group 1, it can be seen that there is statistically an improvement in NRS-101 readings, but no improvement for the McGill and WOMAC readings. The null hypothesis was

therefore rejected for the NRS-101, but was accepted for the McGill and WOMAC.

Table 4.24 - Statistical results of the subjective data comparing the 1st and 4th consultation in Group 2

	Consultation 1			Consultation 4	
	Std Dev.	**Mean**	**P-value**	**Mean**	**Std Dev.**
NRS	17,8336	46,0250	0,021	38,3500	20,4322
McGill	17,1089	15,3000	0,070	11,400	9,2986
WOMAC	33,9901	60,2000	0,077	43,8000	34,2062

When comparing the subjective data between consultation 1 and 4 for Group 2, it can be seen that there is statistically an improvement in NRS-101 readings, but no improvement for the McGill and WOMAC readings. The null hypothesis was therefore rejected for the NRS-101, but was accepted for the McGill and WOMAC.

Table 4.25 - Statistical results of the subjective data comparing the 1st and 4th consultation in Group 3

	Consultation 1			Consultation 4	
	Std Dev.	**Mean**	**P-value**	**Mean**	**Std Dev.**
NRS	11,1679	39,5000	0,053	45,5000	12,5720
McGill	7,1833	14,6000	0,878	14,6000	8,5531
WOMAC	28,6659	59,2000	0,760	59,8000	31,4989

When comparing the subjective data between consultation 1 and 4 for Group 3, it can be seen that there is statistically no improvement in NRS, McGill and Womac readings. The null hypothesis was therefore accepted.

Table 4.26 - Statistical results of the subjective data comparing the 1st and 4th consultation in Group 4

	Consultation 1			Consultation 4	
	Std Dev.	**Mean**	**P-value**	**Mean**	**Std Dev.**
NRS	10,3448	34,2500	0,144	31,0000	13,0277
McGill	9,2760	14,6000	0,202	10,9000	7,1095
WOMAC	21,2992	48,1000	0,009	39,2000	19,9321

When comparing the subjective data between consultation 1 and 4 for Group 4, it can be seen that there is statistically an improvement in WOMAC readings, but no improvement for the McGill and NRS readings. The null hypothesis was therefore rejected for the WOMAC, but was accepted for the McGill and NRS reading.

4.4.4 Independent sample t-test

Table 4.27 – Statistical results comparing groups 1 and 2 in terms of subjective and objective data from the 1st Consultation

	Group 1			Group 2	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	8,8704	115,5000	0,732	114,2500	11,8405
Algometer	1,4486	9,8800	0,533	10,000	1,5134
NRS	13,7763	47,6250	0,978	46,0250	17,8336
McGill	7,4018	13,4500	0,342	15,3000	7,1089
WOMAC	23,5919	51,9500	0,372	60,2000	33,9901

When comparing the subjective and objective data from the 1st consultation in group 1 and 2, it can be seen that there was no statistical difference between the two groups. Therefore, the null hypothesis was accepted.

Table 4.28 – Statistical results comparing groups 1 and 3 in terms of subjective and objective data from the 1st Consultation

	Group 1			Group 3	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	8,8704	115,5000	0,521	116,0000	13,7032
Algometer	1,4486	9,8800	0,982	9,80000	1,9505
NRS	13,7763	47,6250	0,090	39,5000	11,1679
McGill	7,4018	13,4500	0,675	14,6000	7,1833
WOMAC	23,5919	51,9500	0,523	59,2000	28,6659

When comparing the subjective and objective data from the 1st consultation in group 1 and 3, it can be seen that there was no statistical difference between the two groups. Therefore, the null hypothesis was accepted.

Table 4.29 – Statistical results comparing groups 2 and 4 in terms of subjective and objective data from the 1st Consultation

	Group 2			Group 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	11,8405	114,2500	0,349	111,0000	11,0050
Algometer	10,0000	1,5134	0,740	10,2000	0,9615
NRS	17,8336	46,0250	0,038	34,2500	10,3448
McGill	7,1089	15,3000	0,758	14,6000	9,2760
WOMAC	33,9901	60,2000	0,333	48,1000	21,2992

When comparing the subjective and objective data from the 1st consultation of group 2 and 4, it can be seen that there was no statistical difference except for the NRS-101 reading between the two groups. Therefore, the null hypothesis was accepted except for the NRS-101, where it was rejected.

Table 4.30 – Statistical results comparing groups 1 and 2 in terms of subjective and objective data from the 4th Consultation

	Group 1			Group 2	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	8,8852	115,0000	0,713	115,7500	11,6161
Algometer	1,4933	9,9600	0,892	9,9350	1,5500
NRS	17,3755	40,2500	0,839	38,3500	20,4322
McGill	8,2160	13,6500	0,343	11,4000	9,2986
WOMAC	22,3759	49,4500	0,365	43,8000	34,2064

When comparing the subjective and objective data from the 4th consultation in group 1 and 2, it can be seen that there was no statistical difference between the two groups. Therefore, the null hypothesis was accepted.

Table 4.31 – Statistical results comparing groups 1 and 3 in terms of subjective and objective data from the 4th Consultation

	Group 1			Group 3	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	8,8852	115,0000	0,784	115,0000	14,3372
Algometer	1,4933	9,9600	0,982	10,0000	2,1644
NRS	17,3755	40,2500	0,377	45,5000	12,5720
McGill	8,2160	13,6500	0,691	14,6000	8,5531
WOMAC	22,3759	49,4500	0,367	59,8000	31,4989

When comparing the subjective and objective data from the 4th consultation in group 1 and 3, it can be seen that there was no statistical difference between the two groups. Therefore, the null hypothesis was accepted.

Table 4.32 – Statistical results comparing groups 2 and 4 in terms of subjective and objective data from the 4th Consultation

	Group 2			Group 4	
Goniometer	**Std Dev.**	**Mean**	**P-value**	**Mean**	**Std Dev.**
Flexion	11,6161	115,7500	0,223	111,0000	11,0050
Algometer	1,5500	9,9350	0,930	10,1800	0,9818
NRS	20,4322	38,3500	0,260	31,000	13,0277
McGill	9,2986	11,4000	0,965	10,9000	7,1095
WOMAC	34,2062	43,8000	0,930	39,2000	19,9321

When comparing the subjective and objective data from the 4th consultation in group 2 and 4, it can be seen that there was no statistical difference between the two groups. Therefore, the null hypothesis was accepted.

CHAPTER FIVE

Chapter Five

5.0 Discussion

5.1 Introduction

This chapter deals with the objective and subjective data presented in chapter four.

The objective data : algometer and goniometer.

The subjective data : Numerical pain rating scale-101; McGill pain questionnaire and WOMAC.

The results are discussed in two sections :

Intra-group Comparison : The evaluation of data comparing the 1st and 2nd consultation giving an indication of the initial efficacy of each treatment regime. Comparing the within-group data of the 2nd and 4th consultation gives an indication of the end stage efficacy. Finally, analysis of the subjective and objective intra-group results between the initial and final consultation represents the efficacy of each treatment regime.

Inter-group Comparison : A comparison of the data from the initial consultation of each group gives an indication of any baseline differences in subjective and objective findings between the groups, in terms of their original signs and symptoms. The intergroup analysis of the final treatment indicates the difference in mean value changes and therefore possible differences in efficacy.

5.2 Intra-group Comparison :

5.2.1 Objective data : Algometer and Goniometer readings

Tables 4.11 – 4.22 show range of motion and pain threshold data for the intra-group comparisons.

When comparing the algometer and goniometer data for the APT treatment group; TENS treatment group; placebo APT treatment group and placebo TENS treatment group, it was noted that there was no significant improvement in the goniometer readings as well as the algometer readings for treatment interval one to two; treatment two to four and treatment one to four.

This indicates that the APT, TENS and placebo had no significant improvement in the patients range of motion or pain threshold at the 95% level of significance. ($\alpha = 0.05$)

5.2.2 Subjective data :

5.2.2.1 Numerical Pain Rating Scale-101 :

The APT treatment group and the TENS treatment group demonstrate a statistically significant improvement in the NRS-101 values between the 1st and 4th consultations. This indicates that both the active treatment protocols were effective in reducing pain over a period of time. The placebo treatment group showed no improvement over the treatment period.

5.2.2.2 The McGill Pain Questionaire :

The APT treatment group, TENS treatment group and placebo group showed no improvement in the McGill pain questionnaire data, between the 1st and 4th consultation. This indicates that these treatment protocols were ineffective in reducing pain over the treatment period.

5.2.2.3 The Western Ontario and MacMaster Universities Index (WOMAC) :

The placebo TENS treatment group showed significant improvement in the WOMAC data. This indicated that the placebo TENS treatment protocol was effective in improving the patients perspective of his or her disability, with regard to OA of the knee. However the APT treatment group, TENS treatment group and placebo APT treatment group showed no significant improvement in the WOMAC data. This indicates that these treatment protocols were ineffective in reducing the patients disability.

5.3 Inter-group Comparison :

5.3.1 Objective Data : Algometer and goniometer

When comparing the algometer (pain threshold) and goniometer (range of motion) readings between each group (i.e. APT versus TENS; APT versus placebo APT; TENS versus placebo TENS), it was noted that no significant difference existed between the groups at the 1st consultation and the 4th consultation. These results indicated that at the

95% level of confidence, each treatment protocol was equally effective in improving range of motion and improving pain threshold or being equally ineffective in improving range of motion and pain threshold.

5.3.2 Subjective Data :

5.3.2.1 Numerical Pain Rating Scale-101 :

In comparing the APT group and TENS group , and the APT and placebo APT group, no significant difference was noted in the NRS-101 readings, at the 1st consultation and the 4th consultation. This indicates that all three groups were equally effective or ineffective in improving pain threshold in patients with OA of the knee.

However in comparison of the TENS and placebo TENS treatment group, at the 1st consultation, a statistical difference was noted, but no difference was evident at the 4th consultation. This difference would be indicative of baseline variation in terms of pain, however, this was nullified by the 4th consultation.

5.3.2.2 McGill Pain Questionnaire :

In comparing APT to TENS; APT to placebo APT and TENS to placebo TENS, no statistical difference was evident at the 1st and 4th consultations. This indicates that all four treatment protocols were equally effective or ineffective in producing any signifficant change in the pain threshold in OA of the knee.

5.3.2.3 Western Ontario and MacMaster Universities Index (WOMAC) :

Statistical analysis revealed that there was no statistical difference between the groups in respect to function of the knee over the treatment period. This indicates that the treatment protocols were equally effective or equally ineffective in improving the function of OA knees.

5.4 Outcome :

The intra-group analysis reveal that all four treatment protocols were ineffective in producing any statistically signifficant results in the objective readings (algometer and goniometer). However the APT and TENS treatment group showed signifficant improvement in the subjective data between the 1st and 4th consultations. This indicated that the APT and TENS treatment was effective in reducing pain over the period time, at a 95% level of confidence (α=0.05).

The inter-group analysis revealed no difference between the treatment groups. There was statistically no difference between the treatment groups, with regard to objective and subjective data. This indicated that each treatment protocol was equally effective or ineffective in the treatment of OA.

The null hypothesis for the inter-group data analysis was that ther would be no statistical difference between the groups at α=0.05 level of confidence, in terms of subjective and objective clinical findings.

Except for the WOMAC readings between the TENS treatment group and placebo TENS treatment group, the null hypothesis for all three data collecting consultations was accepted as there was no statistical difference between the groups. Although this study could not demonstrate any signifficant difference between the groups, it has demonstrated that each treatment protocol (APT and TENS) is equally effective or ineffective in the treatment of OA of the knee.

5.5 Discussion of the Demographic data :

The age distribution of patients in each group were fairly similar (Table 4.3), with the majority of patients falling between the age 50 – 59 years old. The average age distribution was very similar for the APT and TENS treatment group (APT group = 56.65 ; TENS group = 54.25)

The gender distribution within the sample of 60 was also fairly equal (Males = 51.67% ; females = 48.33%). (Table 4.4)

The racial distribution (Table 4.5) is not a true reflection of the population in Durban, that suffer of OA of the knee, but was largely influenced by the response of the public to the advertisements and by the population that uses the facilities offered by the Technikon Natal Chiropractic Day clinic.

The majority of patients who were part of the population of 60 were retired (Table 4.6). This correlates with the average age distribution and with the nature of the OA disease process.

The average height and weight was fairly similar (Table 4.7), however the placebo APT group being slightly lighter in weight, but of equal height.

There was a big difference between the groups in respect to average pain duration (Table 4.8). The TENS and placebo TENS treatment groups showed longer pain duration than the APT and placebo APT treatment group. (i.e. APT group = 4.75; TENS = 6.88; placebo APT = 3.8; placebo TENS = 7.4)

Records were captured on which knee was commonly affected and diagnosed with having OA (Table 4.9). It was revealed that the right knee was more commonly affected than left knee.

Data gathered also revealed that the right knee was commonly the most painful knee. The knee that was treated in each treatment group (Table 4.10) differed, however it was evident that the right knee was most commonly treated.

5.6 Limitations :

In a randomized clinical trial, the goal is that the study groups should be similar in the relevant patient characteristics. It is not always possible to have a study population with comparable baseline characteristics and still have randomallocation of subjects. Baseline characteristics that are fairly similar for patients in each group were age; height; weight and which knee was affected. The baseline characteristics that were different for each group were gender distribution; racial distribution; occupation and duration of knee pain.

There is also a wide variation in occupation which poses a bias effect in the outcome result. Patients, after receiving treatment returned to routine working activity, unlike the retired patients who returned to a more dormant routine. The patients that worked often had symptoms that were a result of their activity and inevitably aggravated the condition of the knee.

A close connection between the sample size and the power of statistical analysis exists. The smaller the sample size the greater the risk of type-2 error occurring. Due to the shortage of time and financial constraints, 60 patients were recommended by the Technikon Natal Research Committee.

To reduce bias and to evaluate the relative effectiveness of the treatment modalities (APT and TENS), placebo therapy was introduced into the study to the naïve patients. The study was conducted solely by the author, thus the possibility of practitioner bias does exist. It would be advantageous if an independent observer be allocated to take objective and subjective measurements, thus preventing investigator bias. In this study it was not practically possible to include an independent observer or to conduct a double blinded study.

As technology is advancing it is important to update the manner in which the objective and subjective data is collated, in order to obtain more accurate and specific outcomes. The subjective measurements in this study were not specifically designed for patients suffering of OA of the knee. The patients may not fully understand the questionnaires and there is always the possibility that the results are exaggerated in order to please the

researcher.

The possibility of human error when taking objective measurements may also affect the outcome results. Objective measurements in this study were obtained using an algometer and goniometer. The goniometer reading may be influenced by the researchers interpretation of the exact positioning of the instrument and the possibility of human error when taking this readings does exist. The Technikon Natal Chiropractic Day Clinic utilizes three algometers that are caliberated prior to the commencement of the study. Due to the availability, the same algometer was not used at each of the data collating consultations. Inter-algometric discrepancies can exist.

Enviromental changes also influence the measurements obtained by the algometer and goniometer. Patient showed increased sensitivity to pain and a decrease in knee function during cold periods. According to Yochum and Rowe (1996:803) environmental changes such as cold and lowered barometric pressure may also aggravate joint symptoms. This correlates with the findings in this study.

Another limitation was the number of treatment consultations. If the number of consultations were increased from three to six or eight, the results might have been significantly different, in respect to long term effects of APT and TENS in the treatment of OA of the knee.

5.7 Comparative results from other studies:

A wide range of treatment protocols have been administered by various researchers in the hope to identify a protocol that will produce long term effectiveness in the treatment of OA of the knee.

However, due to the limited understanding in the pathology of OA of the knee, the result in respect to each study protocol, differed.

A study by Nell (2001), comparing Action Potential Therapy to Transcutaneous patches containing Flurbiprofen showed that both protocols were found to be equally effective in the short-term management of OA of the knee.

Tucker (2001) compared the administration of Meloxicam (NSAIDS) to manipulation of the knee, in patients with OA of the knee. The results revealed that both manipulation and Meloxicam were equally effective in the short-term management of OA of the knee. Neither proved to have any advantage over the other.

The results in this study proved to be no different from the results obtained by previous researchers, although the interventions were different. The outcome results of this study, showed to have equal advantages in the short-term management of OA of the knee and proved to be a useful conservative approach.

Therefore, it would seem that more attention should be placed on underlying mechanisms of pain production in OA and addressing these specifically in future research.

CHAPTER SIX

Chapter Six

6.0 Recommendations and Conclusions

6.1 Recommendations

It is recommended by the author that a study with a larger sample size be investigated, in order to obtain more accurate results in respect of treatment efficacy. It is recommended that each treatment group have a larger test sample taking into account age, gender, race, location and occupation of each patient. These factors aid in making the sample more linear in distribution and this produces more valid conclusions.

Researcher bias could be eliminated by introducing a double-blinded study design or introducing an independent observer to collect and collate data. It is important that the independent observer not know into which group each patient fits.

Data should be collected and collated using more technologically advanced strategies in order to obtain more accurate and significant results that are sensitive and specific. Instrumentation used in the study should not be changed at each consultation. By using a particular instrument throughout the study, will prevent instrument bias. The newest and most sensitive instrumentation need to be used in order to allow for more accurate readings and greater detection of small but significant difference in effect of the treatment.

Environmental changes need to be evaluated and controlled so as to prevent any influence on the result outcome. It has been evident in the study that changes in

temperature and barometric pressure influenced the patients perception of intensity of OA of the knee.

The number of treatment consultations should be increased in order to evaluate the long term effect and benefits of the treatment protocol. In this study three treatment consultations were not enough to produce significant outcome results. The author recommends that a minimum of six treatment consultations be administered in order to note any significant change.

The intensity of the modality (APT or TENS) should not be limited (i.e. In this study the intensity was a constant 2mA for each treatment consultation). The current should be administered according to the patients perceived level of comfort. A study by Berger (1999) states that the higher the intensity, the greater the improvement of the condition being treated.

6.2 Conclusion

The controlled clinical trial consisted of a sample of 60 patients. All patients were diagnosed with OA of the knee according to diagnostic criteria outlined in chapter three. The patients were randomly divided into four groups and each group received three treatments over a period of a seven days.

Intra-group and inter-group analysis revealed no significant difference at the $\alpha=0.05$ level of signifficace. The APT and TENS produced similar outcome results and neither showed any advantage over the other.

According to the statistical evaluation of the data collected, it is concluded that neither the APT or TENS has any effectiveness in the short-term treatment of OA of the knee.

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APPENDICES

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

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

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

Case History:

Examination:
Previous: Current:

X-Ray Studies:
Previous: Current:

Clinical Path. lab:
Previous: Current:

Case Status:

PTT: Conditional: Signed Off: Final Sign out:

Recommendations:

Intern's Case History

1. Source of History:

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

3. Present Illness:

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

4. Other Complaints:

5. Past Medical History:

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

6. Current health status and life-style:

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

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

TECHNIKON NATAL

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

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

1. VITALS

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

2. GENERAL EXAMINATION

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

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

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

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

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

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

Percussion: - borders of heart

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

4. RESPIRATORY EXAMINATION

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

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

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

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

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

5. ABDOMINAL EXAMINATION

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

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

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

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

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

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

b. Motor - Masseter:
- Jaw lateral movement:

c. Reflexes - Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

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

b. Taste - Anterior two-thirds of tongue:

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

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

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

XII Inspection of tongue (deviation):

Motor System:

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

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

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

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

Sensory System:

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

b. Joint position sense
- Finger:
- Toe:

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

Cerebellar function:

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

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

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

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

9. **BREAST EXAMINATION:**

Summon female chaperon.

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

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

KNEE REGIONAL EXAMINATION

ati(^): _____ File No.: _____ Date: _____
Intern / Resident: _____ Signature: _____
:linician: _____ Signature: _____

)BSERVATION:

- General: - posture and gait _____
  - skin (scars, bruises) _____
  - swelling / bony enlargements _____

Anterior: - genu varum / valgum _____
- patella position _____
- tibial torsion _____
- symmetrical extension _____

Lateral - genu recurvatum _____
- patella alta / baja _____
- symmetrical extension _____

Posterior: - swelling _____

Seated: - patella position _____
- tibial tubercle _____
- tibial torsion (toe-in / toe-out) _____

PALPATION:

nterior :
- patella - base, apex, pre-patella bursa _____
  retinaculum, cartilagenous surface _____
- patella tendon, infrapatella bursa, fat pad, tibial tuberosity _____
- quadriceps tendon, suprapatella pouch _____
  quadriceps and sartorious _____

Medial:
MCL, medial joint line, pes anserinus _____

ateral:
LCL, lateral joint line, TFL, ITB, head of fibula _____

nee flexed 45° + 90°:
joint line, tibial plateaux, menisci, femoral condyles _____
- adductor tubercle and adductor muscles _____

osterior:
- Popliteal artery _____

Lateral - lateral meniscus, arcuate popliteus complex _____
- lateral head gastrocnemius, biceps femoris _____

- Medial - medial meniscus, posterior oblique ligament _____
- medial head gastroc, semimembranosis, semitendonosis _____

CTIVE MOVEMENTS:

- lexion (0-35°) _____
- xtension (0-15°) _____
- edial rotation (20-30°) _____
- ateral rotation (30-40°) _____

PASSIVE MOVEMENTS:

- Flexion (tissue approximation) _____
- Extension (bone to bone) _____
- Medial rotation (tissue stretch) _____
- Lateral rotation (tissue stretch) _____

ESISTED ISOMETRIC MOVEMENTS:

- exion (neutral, int rot, ext rotation) _____
- Extension (0°, 30°, 60°, 90°) _____
- edial rotation _____
- teral rotation _____
- nkle plantarflexion _____
- ikle dorsiflexion _____

NCTIONAL TESTS: _____

INT PLAY MOVEMENTS

- A / A-P movement of tibia on femur _____
- Medial / lateral translation of tibia on femur _____
- ng-axis distraction of tibio-femoral joint _____
- atella movement (sup-inf, med-lat) _____
- -A / A-P movement of superior tib-fib joint _____

GAMENTOUS ASSESSMENT:

ne-plane medial instability (valgus stress)
- extended _____ - resting position _____

ne-plane lateral instability (varus stress)
- extended _____ - resting position _____

ne-plane anterior instability
- Lachman (0-30°) _____ - anterior draw (90°) _____

ne-plane posterior instability
- posterior sag sign (90°) _____ - posterior draw (90°) _____

ntero-lateral rotary instability
- Slocum _____ - Macintosh (lat. pivot shift) _____

ntero-medial rotary instability
- Slocum _____

ostero-lateral rotary instability
- Houghston's drawer _____

ostero-medial rotary instability
- Houghston's Drawer _____

TESTS FOR MENISCAL PATHOLOGY:

- McMurray _____
- Bou..ce-Home _____
- Anderson's Grind _____
- Apley's _____

PLICA TESTS

- Mediopatellar plica _____
- Plica stutter _____
- Houghston's Plica _____

WELLING

- Brush / stroke test _____
- Patella tap test _____

TESTS FOR PATELLO-FEMORAL PAIN SYNDROME

- Clarke's sign _____
- Waldron test _____
- Passive patella tilt _____

OTHER TESTS:

- Wilson's test (osteochondritis dessicans) _____
- Fairbank's test (dislocated patella) _____
- Noble compression test (ITB friction) _____
- Quadriceps contusion test _____
- Leg length _____

NEUROLOGICAL:

Reflexes - Patella (L3/4) R _____ L _____
- Medial hamstring (L5/S1) R _____ L _____

Dermatomes L1 _____ L2 _____ L3 _____ L4 _____ L5 _____
S1 _____ S2 _____

RADIOLOGICAL EXAMINATION:

_____
_____
_____

DIAGNOSIS:

_____
_____
_____

MANAGEMENT PLAN:

_____
_____
_____
_____

INFORMED CONSENT FORM

(To be completed by patient / subject)

Date :

Title of research project : **The relative effectiveness of action Potential Therapy versus Transcutaneous Electrical Nerve Stimulation and Placebo in the treatment of osteoarthritis of the knee**

Name of supervisor : **Dr Myburgh**

Name of research student : **Seelan Naidoo**

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

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

Please Print in block letters:

Patient /Subject Name:_____ Signature:_____

Parent/ Guardian:_____ Signature:_____

Witness Name:_____ Signature:_____

Research Student Name:_____ Signature:_____

Dear Participant,

The aim of this study is to compare the relative effectiveness of two treatment modalities in the management of osteoarthritis of the knee.

Sixty people will be required to complete this study. These participants will be randomly divided into three treatment groups of 20 patients each. Patients in each group will receive treatment.

Group one will receive Action Potential Therapy, group two will receive Transcutaneous Electrical Nerve Stimulation and group three will receive placebo Action Potential Therapy. All three groups will receive three treatments over a period of seven days.

All patients in the study will be x-rayed, in order to confirm the diagnosis of Osteoarthritis of the knee and to grade the severity thereof. Patients with broken or damaged skin, systemic arthritis, malignancy and implanted mechanical devices will be excluded from this study. Patients are free to withdraw from this study at any time.

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

Thank you.

Yours faithfully

Seelan Naidoo
(Chiropractic Intern)

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
THROBBING				
SHOOTING				
STABBING				
SHARP				
CRAMPING				
GNAWING				
HOT-BURNING				
ACHING				
HEAVY				
TENDER				
SPLITTING				
TIRING-EXHAUSTING				
SICKENING				
FEARFUL				
PUNISHING-CRUEL				

Numerical Rating Scale - 101 Questionnaire

Date:_____ **File no:**_____ **Visit no:**_____

Patient name:_____

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

Please write only **one** number.

_____

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

Please write only **one** number.

_____

WOMAC (The Western Ontario and McMaster Universities Osteoarthritis Index)

Please indicate your response to the question by crossing (with a X) the relevant number on the scale next to each item. The Scale is graded from 0 to 4.

0=none, 1=slight, 2=moderate, 3=severe, 4=extreme

SECTION A

The following questions concern the amount of pain you are currently experiencing due to arthritis in your knee/s. For each situation please enter the amount of pain recently experienced. How much pain do you have while:

1. Walking on a flat surface (0 1 2 3 4)
2. Stair climbing (0 1 2 3 4)
3. Nocturnal (at night) (0 1 2 3 4)
4. At rest (0 1 2 3 4)
5. Weight bearing (0 1 2 3 4)

SECTION B

The following questions concern the amount of joint stiffness (not pain) you are currently experiencing in your knee/s. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

1. Morning stiffness (0 1 2 3 4)
2. Stiffness occurring later in the day. (0 1 2 3 4)

SECTION C

The following questions concern your physical function. By this we mean your ability to move around and look after yourself . For each of the following activities, please indicate the degree of difficulty you are currently experiencing due to arthritis of your knee/s.)

1. Descending stairs (0 1 2 3 4)
2. Ascending stairs (0 1 2 3 4)
3. Rising from sitting (0 1 2 3 4)
4. Standing (0 1 2 3 4)
5. Bending to the floor (0 1 2 3 4)
6. Walking on a flat surface (0 1 2 3 4)
7. Getting in/out of a car (0 1 2 3 4)
8. Going shopping (0 1 2 3 4)
9. Putting on socks (0 1 2 3 4)
10. Rising from bed (0 1 2 3 4)
11. Taking off socks (0 1 2 3 4)
12. Lying in bed (0 1 2 3 4)
13. Getting in/out of a bath (0 1 2 3 4)
14. Sitting (0 1 2 3 4)
15. Getting on/off the toilet (0 1 2 3 4)
16. Heavy domestic duties (0 1 2 3 4)
17. Light domestic duties (0 1 2 3 4)

SECTION D

The following questions concern your social function. By this we mean your ability to interact socially in the following activities or with the following people. For each of the following interactions, please indicate the degree of difficulty you are currently experiencing due to arthritis of your knee/s.

1. Leisure activities	(0	1	2	3	4)
2. Community events	(0	1	2	3	4)
3. Church attendance	(0	1	2	3	4)
4. With spouse	(0	1	2	3	4)
5. With family	(0	1	2	3	4)
6. With friends	(0	1	2	3	4)
7. With others	(0	1	2	3	4)

SECTION E

The following questions concern your emotional function. By this we mean your patterns of thoughts and feelings and how they relate to your life. For each of the following, please indicate the degree of difficulty you are currently experiencing due to arthritis in your knee/s.

1. Anxiety	(0	1	2	3	4)
2. Irritability	(0	1	2	3	4)
3. Frustration	(0	1	2	3	4)
4. Depression	(0	1	2	3	4)
5. Relaxation	(0	1	2	3	4)
6. Insomnia	(0	1	2	3	4)
7. Boredom	(0	1	2	3	4)
8. Loneliness	(0	1	2	3	4)
9. Stress	(0	1	2	3	4)
10. Wellbeing	(0	1	2	3	4)

Patient Name: .....

File No: .....

ALGOMETER READINGS					
Visit	Date	Reading 1	Reading 2	Reading 3	Average
1					
2					
3					
4					

APPENDIX J

GONIOMETER READINGS					
Visit	Date	Reading 1	Reading 2	Reading 3	Average
1					
2					
3					
4					