THE EFFECTIVENESS AND RELATIVE EFFECTIVENESS OF COMBINING A TOPICAL CAPSAICIN CREAM AND KNEE JOINT MOBILIZATION IN THE TREATMENT OF OSTEOARTHRITIS OF THE KNEE

By

Denham Fish

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I, Denham Fish do hereby declare that this dissertation is representative of my own work

Denham Fish

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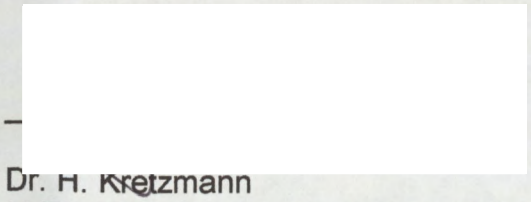
Date

Approved for final submission



Dr. H. Kretzmann
M.Dip. Chiropractic (Technikon Natal)
C.C.F.C (Tech Natal)

8-03-02

Date

DEDICATION

I would like to dedicate this work to my parents. It is thanks to your immeasurable sacrifice and generosity that I have had the opportunity to pursue my goals and dreams. Your love, support and belief in me is never taken for granted and will not be forgotten.

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ABSTRACT

The purpose of this study was to determine the effectiveness and relative effectiveness of a topical Capsaicin cream and knee joint mobilization in the treatment of Osteoarthritis (OA) of the knee.

The study was a prospective, randomized, study involving three groups of 20 subjects diagnosed with OA of the knee, which were selected from the general population. Group 1 applied Capsaicin cream (OsteoEze® rub) daily for 3 weeks. Group 2 received Maitland knee mobilization six times over three weeks. Group 3 received a combination of knee mobilization and Capsaicin cream. All three groups had a 1-week follow-up, which was for data capture only.

Subjective assessments consisted of the short form McGill pain questionnaire, Numerical Pain rating Scale-101 and the Western Ontario and McMaster Universities Osteoarthritis index. Objective measurements were taken using a universal goniometer to measure knee range of motion in flexion and extension. Assessments for the objective data were gathered before the commencement of the first treatment, the day after the sixth treatment for groups two and three

(the day after consultation two for group 1) and at a 1week follow-up consultation. The subjective data was collected prior to commencement of the first treatment, the day after the sixth treatment for groups two and three (the day after consultation two for group 1) and at a 1week follow-up consultation for all three groups.

Statistical analysis was conducted at a 95% confidence interval. The non-parametric Kruskal-Wallis test was used to analyze data between each group. The Friedman's T-test was used to analyze data within each group.

Inter-group analysis revealed that there was no significant difference between the three groups for all measurement parameters. Intra-group analysis demonstrated that all three groups were equally effective in treating osteoarthritis of the knee. All three groups showed an improvement with no group being statistically better than the other.

Further studies using greater specificity regarding homogeneity and larger sample sizes are recommended. Long-term efficacy of the treatments using a longer follow-up consultation is also recommended.

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List of Abbreviations

OA	-Osteoarthritis
WOMAC	-Western Ontario and McMaster Universities Index
NPRS-101	-Numerical Pain Rating Scale-101
H_0	-Null Hypothesis
H_1	-Alternate Hypothesis
Kg	-Kilograms
®	-Registered
α	-Alpha

CHAPTER ONE

CHAPTER 1

1.0 INTRODUCTION

1.1 The problem and its setting

Knee osteoarthritis (OA) is one of the major causes of pain and physical disability in older adults. The World Health Organization has reported that knee OA is likely to become the fourth most important cause of disability in woman and the eighth most important cause of disability in men (Cooper et al. 2000).

Although OA can affect any joint containing hyaline cartilage, troublesome symptoms often occurs in the weight-bearing joints of the lower extremities (Puett and Griffin 1994).

Clinically, the patients with OA of the knee may have pain in and around the knee that is typically worse with weight bearing and improves with rest, morning stiffness is also common. On physical examination there may be the presence of tenderness on palpation, bony enlargement, crepitus on motion and/or limitation of joint motion. The causes of OA are not always known but biomechanical stresses may affect the articular cartilage and subchondral bone that may result in biochemical changes in the articular cartilage and synovial membrane (Hochberg et al.1995).

McAlindan et al. (1996) conducted an epidemiological study that revealed that the incidence of OA is up to 1% in the population in Southern Africa and that it incurs significant socio economic and psychological costs.

The natural history of knee OA is uncertain. A few longitudinal studies have shown that 30 to 50% of patients seen in a hospital clinic will continue to deteriorate, but many remain stable over many years (Spector and Hart 1992). OA is detectable radiographically in many persons in the United States by the age of 40 years with the disease causing pain or dysfunction in 20% of elderly persons (Puett and Griffin: 1994). Although traditionally associated with morbidity, OA has also been shown to increase mortality. It is likely that comorbid factors are partly responsible, but it has also been suggested that there is a marked excess of deaths from gastrointestinal disease related to the use of non-steroidal anti-inflammatory drugs (NSAID's) and analgesic drugs, though attributable risks are unclear (Spector and Hart 1992).

OA is an incurable condition for which there are a number of effective treatments for pain and disability. In the early stages of OA much can be done to alleviate the symptoms but the degenerative changes of OA are irreversible (Edwards et al.1991: 800).

Conventional nonsurgical management of OA in some patients is inadequate or inappropriate due to the lack of efficacy or adverse medical reactions. NSAID's have known toxic effects to the stomach, gastrointestinal tract, liver and kidney.

Most of these adverse effects occur more commonly in the elderly (Zizic et al. 1995:1757).

Physical disability due to musculoskeletal symptoms is a major problem, particularly in the elderly. Knee OA is responsible for much suffering, disability and handicap in the community. "Inability by practitioners to recognize and treat aspects of the disease has implications for clinical decision-making, particularly in a chronic, disabling disease where treatment decisions are not about saving but enhancing life" (Williams 1996: 586).

1.2 Aims and Objectives of the Study

The aim of this study was to evaluate the effectiveness and relative effectiveness of knee mobilization alone, compared to the use of topical Capsaicin cream alone, compared to a combination of knee mobilization and topical Capsaicin cream in the management of Osteoarthritis of the knee.

The first objective was to determine the effectiveness and relative effectiveness of knee mobilization alone compared to the use of topical Capsaicin cream alone in terms of subjective measures in the management of OA of the knee.

The second objective was to determine the effectiveness and relative effectiveness of knee mobilization alone compared to the use of topical

Capsaicin cream alone in terms of objective measures in the management of OA of the knee.

The third objective was to determine the effectiveness and relative effectiveness of topical Capsaicin cream alone compared to the use of a combination of knee mobilization and topical Capsaicin cream in terms of subjective measures in the management of OA of the knee.

The fourth objective was to determine the effectiveness and relative effectiveness of topical Capsaicin cream alone compared to the use of a combination of knee mobilization and topical Capsaicin cream in terms of objective measures in the management of OA of the knee.

The fifth objective was to determine the effectiveness and relative effectiveness of knee mobilization alone compared to the use of a combination of knee mobilization and topical Capsaicin cream in terms of subjective measures in the management of OA of the knee.

The sixth objective was to determine the effectiveness and relative effectiveness of knee mobilization alone compared to the use of a combination of knee mobilization and topical Capsaicin cream in terms of objective measures in the management of OA of the knee.

1.3 Benefits of the Study

The goals of the contemporary management of the patient with OA continue to include control of pain and improvement in function and the quality of life, with avoidance, if possible, of toxic effects of therapy. Although there is no known cure for OA, treatment designed for the individual patient can reduce pain, maintain and/or improve joint mobility and limit functional impairment (American College of Rheumatology Subcommittee 2000-no authors listed).

Traditionally NSAID's have been the treatment of choice, since it is believed that the pain of OA is due to inflammation. "However, these drugs are expensive and cause gastrointestinal toxicity in the elderly, thus alternative treatment options should be initiated" (Lane and Thompson 1997).

Puett and Griffin (1994) reviewed nonmedicinal and noninvasive therapies used in treating hip and knee OA and determined that more data is needed to determine the role that conservative therapies (including topical capsaicin cream) may play in the treatment of this disease. Hochberg (2000) believes that topical capsaicin cream, either as a monotherapy or as an adjunctive therapy, is recommended for patients who do not respond to analgesics or who do not wish to take systemic therapy.

Deyle et al. (2000) evaluated the effectiveness of manual physical therapy (which included passive physiologic and accessory joint movements, muscle stretching and soft tissue mobilization) and exercise in treating OA of the knee. The study concluded that these treatments together were beneficial in

improving walking distance, decreasing pain, dysfunction and stiffness in patients with OA of the knee. The conclusion drawn by the researchers was that this treatment approach may decrease the need for surgical intervention.

Capsaicin which is derived from red peppers has been used for many centuries to remedy pain and recently been shown to provide relief for patients suffering from OA of the knee (Fusco and Giacovazzo: 1997). Puett and Griffon (1994) believe that other trials are required to confirm this result.

It is evident that there is a need to find a safe and effective way of managing the altered mobility and pain associated with OA of the knee. Therefore it is the author's opinion that an investigation using two conservative therapies with relatively few side effects aimed at reducing pain and improving knee function be evaluated. This study will attempt to compare the effectiveness and relative effectiveness of a topical Capsaicin cream and knee joint mobilization in the treatment of OA of the knee. Each treatment deals essentially with an aspect of OA (Capsaicin- pain; mobilization-knee function) thus the effectiveness of combining the two treatment approaches needs to be evaluated against each treatment on it's own in treating of OA of the knee.

CHAPTER TWO

CHAPTER 2

2.0 REVIEW OF 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 capsaicin cream (OsteoEze Rub) and knee mobilization are also discussed.

2.2 Anatomy of the knee joint

The tibiofemoral or knee joint is a hinge type of synovial (diarthrodial) joint surrounded by a joint capsule, with the rest of the joint being composed of cartilage, numerous ligaments and muscle tendons (Thibodeau and Patton 1999: 262-264).

According to Palastanga et al. (2000:432) three separate articulations can be identified: the two tibiofemoral (medial and lateral) joints and the patellofemoral articulation.

- Knee ligaments

The knee ligaments as a whole maintain the integrity of the knee and act as primary stabilizers and guide the movement of the bones in proper relation to one another (Magee 1997: 534).

The collateral ligaments for example provide medial and lateral stability as well as support for the knee while also preventing excessive rotation of the tibia (Bergmann et al. 1993:659).

The cruciate ligaments are found within the joint capsule but outside the synovial cavity; the anterior cruciate ligament (ACL) prevents posterior displacement of the femur on the tibia and hyperextension of the knee joint; the posterior cruciate ligament (PCL) prevents anterior displacement of the femur on the tibia or posterior displacement of the tibia as well as hyperflexion of the knee joint (Moore 1992: 483).

The patella ligament is a continuation of the quadriceps tendon (Palastanga et al. 2000:440) and blends with the medial and lateral retinacula, which are aponeurotic expansions of the vastus medialis and lateralis muscles and the overlying deep fascia (Moore and Dalley 1999:619).

- Articular cartilage

  The hyaline articular cartilage covering the subchondral bone is involved in distributing and transmitting loads and shear forces to the underlying bone, protecting it and permitting synovial joints containing the articular cartilage to have a wide range of almost frictionless movement. This cartilage is aneural, largely avascular and sparsely cellular, with the main ingredient being up to 80% water. Chondrocytes synthesize the proteoglycans and collagen fibres that comprise this cartilage matrix (Walker and Helewa 1996:21). Proteoglycans are complex glycoprotein macromolecules that are

hydrophillic and are composed of glycosaminoglycans, keratin sulphate, chondroitin-6-sulphate and chondroitin-4-sulphate. These polysaccharides and proteoglycan aggregates along with the collagen framework create an osmotic effect that is expansive and contributes to the weight bearing ability of cartilage. The collagen of the extracellular matrix is type 2, composed of three polypeptide chains in a triple helix configuration. Most of the collagen's outstanding tensile strength is a result of cross-linking. The large water content within the cartilage combines with the proteoglycans to create significant supportive pressure against the retraining collagen, this water-laden structure allows the cartilage to have a viscoelastic nature to withstand forces up to seven times the body weight and more (Martin 1994:1431).

- Articular capsule/ Joint capsule

The knee joint is surrounded by a thick ligamentous sheath composed of mainly muscle tendons and their expansions. Normally there is no complete, independent fibrous capsule uniting the two bones, only occasionally are there true capsular fibres running between them (Palastanga et al. 2000:438). The capsule essentially acts to contain the nutrient synovial fluid. It gives little support to the joint's stability (Calliet 1991:13).

- Synovial membrane

The synovial membrane is a vascular connective tissue that lines the knee joint (Moore 1992: 17-18). It is composed of a cellular inner layer with a fibrous and adipose supportive, backing layer. Synovial fluid has three basic functions:

1.) the regulation of the content of synovial fluid,

2.) the removal of waste by phagocytosis,

3.) secretion of synovial fluid and other macromolecules important in the lubrication and nutrition of articular cartilage (Martin 1994: 1430).

- Bursae

These are closed sacs, which are lined with a synovial-like membrane containing synovial fluid and are usually located in areas subjected to friction (Moore 1992:411). There are numerous bursae around the knee (Moore 1992:482) which facilitate gliding and provide a low friction movement of one tissue over another (Walker and Helewa 1996:26).

- Menisci

The medial and lateral menisci are crescentic plates of fibrocartilage on the articular surface of the tibia with the basic function of shock absorption. The menisci deepen articular surfaces of the tibia where they articulate with the femoral condyles (Moore 1992: 485). The medial meniscus has a thickened outer and thinner inner edge and it attaches centrally to the intercondyler tubercles, medial to the capsule. The lateral meniscus attaches to the popliteus

muscle and is more mobile than the medial meniscus and therefore less easily torn (Doherty and Doherty 1992: 108).

- Vascular supply

The articular arteries are branches of the vessels that form the genicular anastomoses around the knee. The middle genicular artery, a branch of the popliteal artery, penetrates the fibrous capsule and supplies the cruciate ligaments, synovial capsule and the peripheral margins of the menisci (Moore 1992: 486).

- Innervation

The articular nerves are branches of the obturator, femoral, tibial and common peroneal nerves (Moore 1992:486).

2.3 Biomechanics of the knee

Due to the structure of the knee, hinge-like movements of flexion and extension are created; with knee flexion some internal and external rotation can occur (Thibodeau and Patton: 1999).

"Flexion and extension of the knee is a combination of roll, slide and spin movements, which effectively shift the axis of movement posterior as the knee moves from extension into flexion" (Bergmann et al. 1993:666-667). Range of motion in the knee varies from 140-150 degrees in flexion and 5-10 degrees of hyperextension (Hertling and Kessler 1996:320). Flexion is limited by soft

tissues and extension is limited by locking of the joint from bony and soft tissue elements in the joints closed packed position. The "screw-home " mechanism (a combination of external rotation of the tibia with knee extension) further approximates the osseous structures and tightens ligaments to stabilize the joint. The marked incongruent positions of the tibiofemoral joint are reduced by the menisci which also help in distributing compressive loading over a greater area and reducing compressive stresses to the joint surfaces (Bergmann et al. 1993:667).

The patellofemoral joint allows the quadriceps femoris tendon to move freely over the lower end of the femur, even in full flexion of the joint therefore reducing approximation of the patella thus reducing friction . It also increases the distance between the tendon and the axis of rotation of the femur about the tibia, increasing the efficiency of the quadriceps muscle and thus improving function. In full extension of the knee, the distal parts of the patellar facet are in contact with the most proximal parts of the femoral articular surface. As flexion increases, the patella is drawn down the femoral articulation until, in full flexion, it lies largely in the intercondylar notch. (Rogers 1992:285).

2. 4 OSTEOARTHRITIS

2.4.1 Introduction

Osteoarthritis (OA), also known as degenerative joint disease, osteoarthrosis, and degenerative arthritis (Calliet 1992: 190), is the most prevalent form of arthritis and is a major cause of disability in the elderly (Creamer and Hochberg 1997). The site most commonly affected by OA is the knee joint (Berman et al. 1998). According to Brandt (1998) OA is the most common disease affecting the joints in human beings, with knee OA resulting in more disability than any other joint affected by OA. The prevalence of OA of the knee varies from 4% among those aged 18 – 24 years to 85% among those aged 75 – 79 years (Helewa and Walker 1996:13).

The exact etiology of knee osteoarthritis remains unknown (Hochberg et al. 1995). Between 40-60% of people effected with the disease is as a result of genetic determinants while the remainder is mainly due to environmental factors such as previous injury or overuse (Specter et al. 1996). Risk factors in the development of osteoarthritis includes gender (increased female predisposition), obesity and increasing age, while there is also some evidence of an inverse relationship between bone density and osteoarthritis (decreased density increases risk of OA) (Hart et al. 1999).

2.4.2 Classification of OA

A classification system has been developed for primary (idiopathic) and secondary OA by the American College of Rheumatology (ACR):

- Idiopathic: Localized to one particular joint eg. Hands, feet, knees, hips and other single sites; Generalized (three or more joints listed previously).
- Secondary: Post-traumatic, congenital or developmental diseases, localized (eg hip dysplasia, generalized (eg chondrodysplasias, inherited metabolic diseases), calcium-deposition disease, other bone and joint disorders (eg avascular necrosis, Rheumatoid arthritis, Paget's disease).
- Other diseases: Endocrine diseases (eg acromegaly, hyperthyroidism), neuropathical (Charcot's) arthropathy, miscellaneous (Creamer and Hochberg: 1997).

2.4.3 Risk factors

Age: This is the strongest determinant of OA with prevalence rates for all joints rising with increasing age (Creamer and Hochberg: 1997). By the age of 65, 80% of people have some radiographic evidence of OA (Edwards et al. 1995: 877).

Sex Predisposition: Woman are at a higher risk of developing OA than men, particularly after menopause (Creamer and Hochberg: 1997). Hart et al. (1999: 21) discovered that 3% of middle-aged women will develop new knee

osteophytes and joint space narrowing each year, the susceptibility to these changes in older women is twice as great compared with those twenty years younger. On review of epidemiological studies Creamer and Hochberg (1997) suggest that hormone replacement therapy offers a protective effect on the development of hip and knee OA. Prior to the age of 50, knee OA is more frequent in men, but after that age it is more common and the incidence increases more rapidly in women. This suggests that postmenopausal hormone deficiency may be a risk factor for OA and therefore possible knee pain development in woman (Nevitt et al. 2001:811).

Obesity: This is strongly linked to the development of OA involving the knee. A widespread assumption is that the link between obesity and OA of the knee is the repetitive application of a greater axial load. Knee malalignment is a factor how load is distributed at the knee, for example, varus malalignment intensifies the effect of excess body weight on the medial tibiofemoral compartment and valgus malalignment increasing the lateral compartment load. The relationship between obesity and OA knee incidence and progression may be stronger in varus knees than has been detected for knee OA as a whole (Sharma et al. 2000: 568). In a study done by Slemenda et al. 1998: 1958) it was shown that women with incident OA who had greater body weight showed poorer quadriceps function, which raises the possibility that the well-recognized association of obesity with knee OA in women is mediated through quadriceps weakness.

Structural Malalignment: Stability is an important component of the mechanical environment of the knee. Knee instability or laxity may be broadly defined as abnormal displacement or rotation of the tibia with respect to the femur (Sharma et al. 1999:861). Eckhoff et al. (1994: 608) showed that there is a correlation between malalignments such as decreased tibial torsion and femoral anteversion with the development of OA of the knee.

Metabolic factors: Hypertension, hypercholestrolemia and high blood glucose are associated with both unilateral and bilateral knee OA according to Hart et al. (1995:1118).

Mechanical Derangement: Joint trauma is a major risk factor in developing OA of the knee according to Creamer and Hochberg (1997: 503). Menisectomy following knee injury also represents a significant risk factor for developing OA seen on radiographs (Roos et al. 1998: 687). Loss of cartilage and bone height is associated with greater varus-valgus laxity and this may increase the risk of knee OA and cyclically contribute to progression (Sharma et al. 1999: 861).

2.4.4 Pathophysiology

Articular Cartilage: Here there is disruption of the surface collagen where, instead of having the normal smooth appearance of articular cartilage, it

becomes rough and/or eroded. Alteration of the cartilage at a macroscopic level involves fibrillation, erosion (ulceration) and cracking. This results in softening of the cartilage where there is an increase in the ratio of water to the proteoglycans in the cartilage matrix (Bullough 1998: 8.4). Thus the cartilage becomes less able to withstand stresses in the region, with the resultant death of local chondrocytes, which is believed to allow the release of proteolytic enzymes that have a further degradative effect on chondroitin sulphate. The adjacent areas of cartilage must now absorb stresses and thus the process tends to spread (Hertling and Kessler 1996: 45). The progressive thinning eventually results in full-thickness loss of articular cartilage (Walker and Helewa 1996: 67).

Bone: Arthritis effects not only the overlying articular cartilage but also the underlying bone and structures around the joint. Proliferation of osteoblasts and formation of new bone occurs in subarticular bone that has been denuded to buttress and strengthen the existing bone trabeculae giving rise to the sclerosis seen on radiographs. Subarticular cysts are usually only seen where the overlying cartilage is absent. They are believed to result from the transmission of interarticular pressure through defects in the articulating bony surface into the marrow spaces of the subchondral bone. Separated fragments of bone and cartilage from a damaged joint surface may remain as loose bodies in the joint cavity (Bullough 1998: 8.4).

Synovial membrane: The synovial membrane undergoes villous hypertrophy and synovial effusion (Golding 1989: 146). The synovial irritation caused by the release of proteolytic enzymes and cartilagenous debris as a result of fibrillation during the degenerative cycle results in an effusion which can cause pain and stiffness (Hertling and Kessler 1996:45).

Capsule: The low grade inflammation associated with OA can result in capsular fibrosis, or thickening. Scarring causes reduced extensibility from loss of elasticity, gradual contracture, and adherence to adjacent tissues. The lack of mobility of the joint capsule contributes to the cycle of degeneration because of the alteration of normal joint mechanics (Hertling and Kessler 1996: 45).

2.4.5 Clinical features and diagnostic criteria

1. *Pain:* This is usually of insidious onset, mild to moderate in intensity and worsened by the use of the involved joint. There are numerous sources of pain, for example the synovial membrane, joint capsule and periarticular ligaments (Creamer and Hochberg: 1997). The pain is aggravated by activity or weight bearing, but may also be aggravated by rest, particularly if the knee is held in one position for a prolonged period of time (Hertling and Kessler 1996:364). Activities that involve climbing or prolonged standing tend to worsen the pain especially if the patellafemoral compartment is involved as it undergoes major compressive forces when rising from

kneeling or squatting positions and on climbing stairs and hills (Walker and Helewa 1996:69).

2. *Stiffness:* The sensation of stiffness is reported by most OA patients, involving difficulty initiating movement, problems moving a joint through a range of movement or an ache or pain on movement. The stiffness rarely lasts longer than 30 minutes and abates after initiation of activity involving the knee joint. Accumulation of hyaluronate in and around the thickened capsule and synovium may explain this phenomenon (Dieppe and Lin:1998 8 3.3).

3. *Joint effusion/Swelling:* This is due to synovial irritation and abnormal stress to the joint capsule from altered joint mechanics (Hertling and Kessler 1996:45)

4. *Limitation of range of motion:* Physical disability is frequently reported in patients with OA with a number of factors being responsible for the level of disability in these patients of which reduced range of motion is one of them (Steultjens et al. 2000). Steultjens et al. (2000) evaluated all ranges of movement and concluded that knee flexion was most strongly associated with disability. Range of movement in any direction may be decreased by capsular fibrosis, osteophytes, irregular articular surfaces or impaction of

loose bodies. Fine or course crepitus may occur on motion (Golding 1989: 149)

5. *Muscle wasting and instability:* In persons with symptomatic knee OA, quadriceps muscle weakness is commonly found and is widely believed to result from disuse atrophy secondary to joint pain. In research conducted by Slemenda et al. (1997) it was concluded that quadriceps weakness is a primary risk factor for knee pain, disability and progression of joint damage in persons with OA of the knee. Hertling and Kessler (1996:36) believe that episodes of the knee "giving way" occur secondarily to muscle wasting, transient severe pain or impingement of degenerated menisci, the pressure of loose bodies or a missed step.

6. *Malalignment, Deformity, Laxity:* In research conducted on 164 patients with knee OA by Sharma et al. (1999:869), varus-valgus laxity was greater in those patient's knees that were uninvolved or had mild OA than in the older controlled knees. This suggests that laxity in knee OA is not exclusively a consequence of pathologic changes that develop at later stages of the disease. Valgus-varus laxity might increase variably with the normal aging process, predisposing some people to developing knee OA. With progressive OA, loss of cartilage/bone height appeared to override a potentially stabilizing of osteophytes increasing the potential for joint laxity. If the medial compartment is affected this often results in a varus deformity, a

very common finding in knee OA. Predominant lateral compartment OA is the least common type, but can result in valgus deformities (Dieppe and Lin 1998: 8.3.5).

7. *Bony swelling and Crepitus:* Firm swellings due to bony changes of the joint margin are often palpable and may be tender. Coarse crepitations are usually felt on movement of an osteoarthritic joint. This audible "cracking" is due to the roughening of the joint surface and bony outgrowths at the rim of the joint interfering with normally smooth movement between the joint surfaces. "Cavitation" or the formation of gas bubbles within the synovial fluid may also contribute to the presence of crepitus. In patellofemoral OA, anterior crepitus with abnormal movement and tracking of the patella with tenderness on patella compression. (Dieppe and Lim 1998:8.3.5).

Diagnosis:

The American Rheumatism Association have criteria used for the diagnosis of idiopathic arthritis based on several clinical, radiological and laboratory parameters.

The various combinations include: osteophyte formation, knee pain, characteristic synovial fluid, age of over 50 years, rheumatoid factor level less than 1:40, stiffness, ESR under 40, crepitus, bony tenderness, absence of palpable warmth and bony enlargement. This has resulted in sensitivity of

diagnosis ranging from 91% to 95% and a specificity ranging from 69% to 86% (Martin 1994: 1430).

2.4.6 Radiographic Evidence

According to Yochum and Rowe (1996:804) there are eight essential radiographic signs of degenerative joint disease: asymmetric distribution, nonuniform loss of joint space, osteophytes, subchondral sclerosis, subchondral cysts, intraarticular loose bodies, intraarticular deformity and joint subluxation. These 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.

For subjects over the age of 45 years most population surveys show that the prevalence of radiographically determined knee OA ranges from 14 to 30% in men and in women. These rates being consistently higher in women and also increasing steadily with an increase in age. If knee pain is used as a definition of OA similar prevalence rates are found, showing a range of between 12 and 38% of subjects over 45 years being affected. It has been shown that the proportion of radiological disease which is symptomatic is between 40 and 80%, increasing with disease severity (Spector and Hart: 1992).

According to McAlindon (1999) there is discordance between radiographic OA and knee pain. There are recent findings that suggest problems with both the validity and the reproducibility of several of these radiographic features related to the signs and symptoms OA of the knee. The distribution of the various radiographic characteristics in the general population, and the relationship between them and their clinical significance remain for the most part unknown (Doherty 1994:27). According to Hart and Spector (1995:421), there is limited data available on the classification based on the clinical assessment for OA, and little is known on how reproducible these clinical findings are, and whether they correlate with radiographic change at the same joint.

The radiographic features conventionally used to define the severity of OA of the knee include joint space narrowing, osteophytosis, subchondral sclerosis, cyst formation and abnormal bony contour. The distribution of these features in the general population and the relationship regarding associative clinical signs and symptoms between them remains unclear (Cooper 1994).

2.4.7 Medical management of OA

Treatment of OA involves therapeutic goals which focus on reducing pain and improving function (Puett and Griffin 1994).

Hochberg et al. (1995) reviewed commonly used non-pharmacologic therapies which were as follows: patient education, health professional social support via

telephone contact, weight loss (if overweight), physical therapy (which included range of motion exercises, quadriceps strengthening exercises and assistive devices for ambulation), occupational therapy and exercise programs.

Pharmacologic therapy involves intraarticular steroid injections, non-opioid analgesics (eg acetaminophen), topical analgesics (eg capsaicin and methylsalicylate creams), non-steroidal anti-inflammatory drugs and opioid analgesics. Acetaminophen, cortisone injections, joint replacement surgery and exercise programs are also used in the management of patients suffering from osteoarthritis (Deyle 2000).

The mainstay of pharmacological management includes the use of non-steroidal anti-inflammatory drugs (NSAIDS) but their use is associated with risks and the efficacy whether being safer or more effective than pure analgesics is questionable (Puett 1994). NSAIDS can lead to gastric complications, increased risk for hospitalization and even death.

Efficacy appears to be individualized with some patients responding better than others to a certain treatment approach regarding physical therapy and medication. Surgery occasionally needs to be considered to prolong the life of the malaligned joints as well as relieving pain by reducing interosseous pressure (Edwards et al. 1995:880).

2.5 CAPSAICIN

2.5.1 Introduction

Capsaicin is the most pungent ingredient among those present in red pepper (Fusco and Giacovazzo: 1997) and has been used for centuries to remedy pain. In recent years a great interest has developed towards Capsaicin as an effective instrument in biochemical research. The scientific interest in this pharmaceutical compound is motivated by the fact that Capsaicin exerts a peculiar action on a population of sensory neurons with a possible nociceptive function.

2.5.2 Indications and therapeutic uses

Topically applied Capsaicin cream for muscles and joints may provide a natural alternative for pain management in muscles and joints. In a double-blind randomized placebo controlled trial conducted by Deal et al. (1991) 70 patients assigned to one of two groups with OA of the knee received Capsaicin cream or a placebo for 4 weeks. The patients were instructed to apply 0.025% Capsaicin cream or a placebo cream to the painful knees four times daily. 80% of the Capsaicin treated patients experienced a reduction in pain after 2 weeks of treatment. The reduction in pain was statistically significant compared to that of the placebo cream (P=0.003 and P=0.033, respectively); no mention was made

of the long-term effects of the capsaicin cream. The study concluded that capsaicin cream is a safe and effective method for treating OA.

McCleane (2000) also conducted a randomized, double blind, placebo controlled trial on 200 osteoarthritic patients. Patients received one of four different creams which were being evaluated, one being 0.025% Capsaicin cream which was used over the affected osteoarthritic joint for six weeks. The trial showed that Capsaicin has a statistically significant analgesic effect in painful OA.

Other clinical trials showing the benefit of Capsaicin have included postherpetic neuralgia, post-mastectomy pain, pain conditions resulting from diabetic neuropathy, trigeminal neuralgia, reflex sympathetic reflex dystrophy and Guillain-Barre syndrome (Fusco and Giacovazzo 1997).

2.5.3 Mechanism of action

Capsaicin applied topically to human skin produces itching, pricking and burning sensations due to excitation of nociceptors; with repeated application these positive sensory responses are followed by a period of hypalgesia (Nolano et al. 1999). The Capsaicin acts selectively on a sub-population of primary sensory neurons with a nociceptive function. The first exposure to capsaicin activates neurons involving two senses; orthodromic (pain sensation) and antidromic sensations; initially there is a release of excitatory neurotransmitters such as Substance P promoting the activation of these neurons at the central level.

Following this, the antidromic action takes place with the release of neuropeptides from the peripheral terminals (Fusco and Giacovazza: 1997). Initially, the Capsaicin irritates due to the stimulated release of Substance P but then the "numbing" effect takes over with repeated application as the neuron produces less Substance P (Cordell and Oscar: 1993).

Thus after the first exposure the neurons become insensitive to all further stimulation (including the Capsaicin itself) producing selective analgesia, with repeated application to the painful area there is desensitization of the sensory neurons due to the depletion of Substance P and thus disruption of the pain producing pathways. This "counter-irritation" contributes to the inhibition of the pain signal entering at the central level (Fusco and Giacovazza: 1997).

2.5.4 OsteoEze® Rub

A new capsaicin cream called OsteoEze® Rub for muscles and joints has been developed. Each 10 grams of cream contains 5 milligrams of capsaicin, which is the active ingredient.

Contra-Indications include those who have a hypersensitivity to Capsaicin or cayenne peppers. Side effects are reported to be minimal in humans. (Package Insert: Appendix A).

2.6 MOBILIZATION

2.6.1 Introduction

Mobilizations are passive movements performed in such a way that at all times they are within the control of the patient so that he/she can prevent the movement if he/she chooses (Maitland 1999: 9).

Two main types of movement are:

a.) Passive oscillatory movements, 2 or 3 per second, of small or large amplitude, and applied anywhere in a range of movement.

b.) Sustained stretch with or without tiny amplitude oscillations at the limit of range.

These oscillatory movements may consist of the joints accessory movements or it's physiological movements. Physiological movements are those that the patient can carry out actively. Accessory movements are movements that a person cannot perform himself but which can be performed on him by someone else (Maitland 1999: 9).

2.6.2 Role/ Indications

If OA may be caused by the loss of normal joint mechanics, the primary treatments should be aimed at restoration of normal mechanics (Hertling and Kessler 1996: 48).

Mobilization has it's best effect when directed at mechanical type problems for which they perform the following main roles:

1.) Restoring structures within a joint to their normal positions or pain-free positions so as to recover a full-range painless movement.

2.) Stretching a stiff joint to restore range of motion.

3.) Stretching: mobilizing to stretch has three other roles:

a.) Slow passive movement to retain range of movement.

b.) Stretching to increase an otherwise normal range to make it more mobile.

c.) Stretching to lengthen contracted or fibrosed muscle tissue

4.) Relieving pain by using special techniques.

5.) Treating sports injuries and trauma (Maitland 1999: 10-12).

Stretching the joint capsule by applying rhythmical sweeping movements as produced by the mobilization, facilitates synovial fluid movement across the cartilage and may help to diminish degeneration by improving nutrition (Thomson et al. 1991:112). Mobilizations are performed with the overall goal being improved range of motion and mechanics within the affected joint (Oloff 1994:455).

2.6.3 Efficacy of Mobilization

Moncur (1996:277) is of the opinion that a person with OA suffering from hypomobility, pain, disability and a decreased range of motion may benefit from the use of mobilizations to the affected joints.

In a randomized, control trial done on 83 patients by Deyle (2000) evaluating the effectiveness of manual therapy and exercise therapy in the management of OA of the knee, it was concluded that those patients treated with manual

physical therapy and exercise, experienced clinically and statistically significant improvements in self-perception of pain, stiffness, functional ability and walking distance. The manual therapy treatment techniques consisted of passive physiologic and accessory joint movements, muscle stretching and soft tissue mobilization. The researchers decided that the observed improvements were most likely due to the physical therapy.

2.7 Summary

The review of literature reveals that there are numerous factors involved in the pathogenesis of OA, resulting in a method of management that needs to consider various etiological factors in alleviating the signs and symptoms associated with OA of the knee. Due to the fact that there is no established healing agent, most treatment strategies goals are aimed at slowing down the degenerative process and improving the patient's quality of life.

The use of capsaicin cream (OsteoEze® Rub) is a noninvasive therapy used in dealing essentially with the painful aspect of OA of the knee. Knee mobilization is another conservative technique that has been shown to have beneficial effects in the management of biomechanical aspects and pain associated with OA of the knee.

This study will determine the role of each therapy in the management of OA as well as the efficacy of combining the two treatments.

CHAPTER THREE

CHAPTER 3

3.0 MATERIALS AND METHODS

3.1 Introduction

This chapter gives a detailed description of the design, primary and secondary data, the subjects and interventions used. An overview of each questionnaire and the validity of each measurement parameter are discussed. Statistical analysis and data evaluation methods are also discussed.

The objective of this study was to compare the effectiveness and relative effectiveness of combining a topical Capsaicin cream (OsteoEze® Rub) and knee mobilization, in terms of subjective and objective findings in order to determine which is more effective in treating osteoarthritis of the knee.

3.2 The Data

The data consisted of primary and secondary data.

3.2.1 The primary data

The primary data consisted of

- The case history, physical examination (including recording of vital signs), a knee regional examination and radiographic findings of the patients used in this study.
- Knee ranges of motion were measured with a goniometer

- Patient's perception of their worst and least levels of pain intensity was measured using the Numerical Pain Rating Scale-101 (NPRS- 101) questionnaire.
- A short-form McGill Pain questionnaire to measure the quality of pain.
- Patients perception of their disability using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

3.2.2 The Secondary Data

Relevant literature was obtained from various sources, including journal articles, books and medical search engines on the internet (Medline, Mantis, Pubmed and Medscape).

3.3 The Subjects

The subjects consisted of volunteers from the population of Durban.

3.3.1 Selection of subjects

Patients were notified of this study through advertisements placed on notice boards at the Technikon Natal Chiropractic Day Clinic, in local newspapers and radiostations inviting free participation in a clinical trial for people with OA of the knee. The advertisement called on people having had painful knees for at least six months running. Any patient presenting to the clinic with knee pain, for longer than six months duration, was also considered as a candidate for the study.

Upon reply, the patients were telephonically interviewed to assess their legibility for the study, with questions pertaining to the history and progression of their complaint and to explain the nature of the study to the prospective participants.

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 B), a relevant physical examination (Appendix C), and a full knee regional examination (Appendix D) were conducted. A diagnosis of OA was then confirmed via radiographs of both knees.

3.3.2 Inclusion and Exclusion Criteria

The criteria were as follows:

1.) Only patients between the ages of 40 and 75 years were to be accepted. No restrictions were placed on the patient's sex, racial group, occupation, income bracket or area of residence.

2.) Patients were immediately excluded if they were known to be allergic to chilli as Capsaicin is derived from chilli's.

3.) Pregnant or lactating women were also excluded.

4.) Patients receiving any other form of treatment for OA were excluded.

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

6.) Only patients diagnosed by the researcher as having OA of the knee were included in the study. The diagnosis was confirmed by the consulting clinician in accordance with the treatment protocol. A diagnosis of OA was made if patients presented with the following clinical signs and symptoms (not all signs and symptoms had to be present to make the diagnosis of OA) of OA, namely:

- joint pain
- morning stiffness
- loss of function
- bony enlargement
- limited range of motion
- crepitus on motion
- tenderness on pressure
- pain on motion
- joint effusion
- malalignment, joint deformity, or both (Creamer and Hochberg 1997:505).

7.) Radiographs were taken to confirm the presence of OA of the knees and to rule out other pathology. Weight bearing anterior/posterior, lateral and skyline radiographs were taken. Evidence of radiographic OA includes:

- narrowing of the joint space in either the medial or lateral compartments
- subchondral bony sclerosis
- subchondral bone cysts
- osteophyte formation

- deformity (genu valgus or varus)

Not all of the criteria were needed to make a diagnosis of OA (Yochum and Rowe 1996:803-824)

8.) Patients were excluded if they presented with any of the following:

- a known hypersensitivity to chilli peppers
- broken or fragile skin or dermatomes or infection at the site of application of the cream
- severe ligamentous instability of the knee
- osteomyelitis
- infectious arthritis
- malignancy
- haemangioma
- systemic arthritis: rheumatoid arthritis, psoriatic arthritis

3.3.3 Allocation of Subjects

If after examination the patients were shown to be suitable, they were asked to complete an informed consent form (Appendix E). Random assignment was used to allocate each patient into either the OsteoEze® Rub, mobilization or the combination of OsteoEze® Rub and mobilization groups. As the total size of the population was sixty patients, participants numbered 1-20 received a tube of OsteoEze® Rub (Capsaicin cream) which was be applied 4 times daily by the

patient to the back, front and sides of the affected knee for a period or 3 weeks. Before issuing the cream, the patients had the side effects, precautions and directions for use read to them. Participants numbered 21-40 received knee mobilizations to the affected knee for 6 treatments over 3 weeks. The same mobilization technique was used throughout the study. It was applied to the tibiofemoral, patellofemoral and superior tibiofibular joints if deemed necessary. Participants 41-60 received a combination of knee mobilization (6 mobilization treatments) and OsteoEze® Rub (Capsaicin cream applied by the patient) for a period of 3 weeks. The participants were asked to draw a number out of a box with their eyes closed, the number was recorded and the piece of paper was discarded, the process was repeated until all 60 patients were allocated into the three treatment groups.

3.4 Ethics

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

3.5 Assessments

The objective data was gathered before commencement of the first treatment, the day after the sixth treatment for Groups 2 and 3 (at the second consultation for group 1) and at a 1week follow-up consultation for all three groups. The

subjective data was collected prior to commencement of the first treatment, the day after the sixth treatment for Groups 2 and 3 (at the second consultation for group 1) and at a 1week follow-up consultation. Any patients who became clinically asymptomatic before completion of consultations continued to receive treatment until completion to maintain standardization within the treatment protocol.

3.6 Measurements

3.6.1 Subjective Measurements

Subjective information was obtained using the NPRS-101 (Jensen et al. 1988) (Appendix F), Short Form McGill questionnaires (Melzack 1987) (Appendix G) and WOMAC index (Bellamy et al. 1988) (Appendix H).

3.6.1.1 The Numerical Pain Rating Scale-101 (NPRS-101)

The NPRS-101 is a questionnaire used to evaluate the intensity of pain a patient is experiencing. The patient was presented with two lines marked with 0 at the beginning and ending with 100. The patient was informed that 0 represented "no pain at all", and the 100 represented the "pain as bad as it could be". On the first line, the patient was asked to identify the number which best represented the level of pain they were experiencing when the pain was at its worst. On the second line, they were asked to identify the number which best represented the level of pain when it was at its least. The average between

these two figures was then taken as the percentage intensity of pain they were experiencing prior to the treatment session.

Jenson et al. (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 (Jenson et al. 1986).

3.6.1.2 The Short Form McGill Pain Questionnaire

The short form Mcgill pain questionnaire provides valuable information on the patient's sensory, affective and evaluative dimensions of pain experiences in a limited time frame. It was derived from the standard McGill Questionnaire for more rapid acquisition of data. The questionnaire consists of representative words (descriptors) which are rated on an intensity scale as 0=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.

3.6.1.3 Western Ontario and Mcmaster Universities Scale (WOMAC)

The WOMAC osteoarthritis index consisting of 24 questions, each corresponding to a five point (none, slight, moderate, severe and extreme) likert scale. The index utilizes pain (5 items), stiffness (2 items) and physical function (17 items) subscales. WOMAC offers two main advantages over other previously utilized scales, the first is that it has been shown to offer superior

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 a reliable, valid and responsive multi-dimensional outcome measure for evaluation of patients with OA of hips or knee (Bellamy et al. 1988).

On completion of the index, the values for each subsection were added to attain a score for the consultation.

3.6.2 Objective Measurements

Objective measurements were obtained using a goniometer (Appendix I).

3.6.2.1 The Goniometer

A universal goniometer was used to measure the knee range of motion (ROM). Readings were taken at full extension and at full flexion.

The procedure for assessing knee ROM was as follows:

- The patient was asked to sit with both legs hanging off the examination table.
- The center binding ring of the goniometer was placed over the central aspect of the lateral femoral condyle.
- One arm of the goniometer was extended to line up with the trochanteric notch of the femur, while the second arm hung perpendicularly to the examination table.

◊ The patient was then asked to fully extend the knee, the second arm of the goniometer was extended to line with the lateral malleolus of the ankle, and the angle was measured and recorded. This was repeated with flexion.

3.7 Interventions

Each patient in a group receiving knee mobilization (groups two and three) underwent a total of six consultations over a three-week period. Group one, using the Capsaicin cream (OsteoEze® Rub) alone was only consulted three times; at the first visit, then after three weeks and again at the follow-up consultation. If a patient in any of the groups became asymptomatic during that period, the patient continued to receive treatment and was assessed for the remainder of the treatment period.

3.7.1 Knee Mobilization

The involved tibiofemoral, patellofemoral and superior tibia/fibula joints of the most painful knee were treated according to the method described by Maitland (1999: 239-257). Six mobilization treatments were given. At each consultation the treated joint was reassessed and the most appropriate mobilization was then applied.

3.7.2 Medication

A newly developed Capsaicin cream with the trade name Osteoeze® Rub was chosen for the following reasons:

- Previously discussed studies have determined that capsaicin cream was a safe and effective method for the treatment of OA.
- OsteoEze® Rub is an over-the-counter medication, which is freely available.
- The side effects appear to be minimal in humans.

Patients using the OsteoEze® Rub were instructed to apply the cream sparingly 3-4 times daily to the affected area only when the knee was painful for three weeks. If the patients showed any signs of side effects or intolerance they were excluded from the study.

3.8 Specific treatment of the subproblem

3.8.1 The First Subproblem

The first subproblem was to determine the effectiveness and relative effectiveness of knee mobilization alone compared to the use of topical Capsaicin cream alone in terms of subjective measures in the management of OA of the knee.

3.8.2 The second subproblem

The second subproblem was to determine the effectiveness and relative effectiveness of knee mobilization alone compared to the use of topical

Capsaicin cream alone in terms of objective measures in the management of OA of the knee.

3.8.3 The Third Subproblem

The third subproblem was to determine the effectiveness and relative effectiveness of topical Capsaicin cream alone compared to the use of a combination of knee mobilization and topical Capsaicin cream in terms of subjective measures in the management of OA of the knee.

3.8.4 The Fourth Subproblem

The fourth subproblem was to determine the effectiveness and relative effectiveness of topical Capsaicin cream alone compared to the use of a combination of knee mobilization and topical Capsaicin cream in terms of objective measures in the management of OA of the knee.

3.8.5 The Fifth subproblem

The fifth subproblem was to determine the effectiveness and relative effectiveness of knee mobilization alone compared to the use of a combination of knee mobilization and topical Capsaicin cream in terms of subjective measures in the management of OA of the knee.

3.8.6 The Sixth Subproblem

The sixth subproblem was to determine the effectiveness and relative effectiveness of knee mobilization alone compared to the use of a combination of knee mobilization and topical Capsaicin cream in terms of objective measures in the management of OA of the knee.

3.9 Statistical Analysis

3.9.1 Treatment of the data

3.9.1.1 Subjective Data

The subjective data was examined in the following way:

- The information was tabulated once the scores of the questionnaires were tallied using methods previously mentioned.
- The raw data from the three questionnaires was statistically analyzed using a 95% level of confidence.

3.9.1.2 Objective Data

The objective data was examined in the following way:

- The goniometer readings for knee ranges of motion (flexion and extension), recorded in degrees, were recorded separately for each of the three groups.
- The data was analyzed statistically using a 95% level of confidence.

3.9.2 Statistical analysis of the data

The SPSS (version 9.0) 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 whether any significant changes occurred between the initial and sixth consultation, the initial and seventh consultation as well as between the sixth and seventh consultations, within each study group as well as any significant differences at the time of the initial, sixth and seventh consultations between different study groups. As the OsteoEze® Rub group (group 1) only had three consultations (the initial consultation, a consultation 3 weeks later and then a 1 week follow-up consultation), visits two and three were assessed statistically as consultations six and seven.

3.9.2.1 Comparison between two independent samples

The inter-group comparison of all three groups {group 1(OsteoEze® Rub), group 2 (Knee mobilization) and Group3 (OsteoEze® and Mobilization)} for all the treatment parameters (the goniometer readings in flexion and extension, NPRS, McGill and WOMAC questionnaires)

The Kruskal-Wallis non-parametric test was used to compare differences in improvement between the three treatment groups at consultations one, six and seven.

1) Hypothesis testing

In each test, the null hypothesis stated that there was no difference in improvement among the groups for each treatment parameter being compared.

$H_0: \mu_1 = \mu_2 = \mu_3$

2) Decision Rule

At α =0.05 level of significance, the null hypothesis is rejected if $P < \alpha$ where P is the observed significance level or probability value. Otherwise the null hypothesis is accepted at the same level of significance.

Reject H_0 if $P<\alpha$

Accept H_0 if $P \geq \alpha$

P is the observed significance level or probability value.

3.9.2.2 Intra-group comparison for each measurement parameter.

The Friedman's T-test was used to determine whether any significant change occurred between:

The initial, sixth and seventh consultations, within each group.

The variables listed were the NPRS-101, McGill and WOMAC Questionnaires as well as the goniometer readings for flexion and extension.

Hypothesis testing and the decision rule:

The null hypothesis (H_0) stated that there was no improvement within each group. The alternative hypothesis (H_1) stated that there was an improvement within each group.

Decision Rule

$\alpha = 0.05$ = level of significance

For a two-tailed test,

If $p<\alpha$, reject the null hypothesis H_0

If $p\geq\alpha$, do not reject the null hypothesis H_0

(p is the reported p- value)

For a one tailed test,

Reject H_0 if $p < \alpha = 0.05$

Accept H_0 if $p \geq \alpha = 0.05$ where:

P = (reported p-value) / 2 if H_1 is of form < and z is negative

H_1 is of form > and z is positive

P = 1 – (reported p-value / 2) if H_1 is of form < and z is positive

H_1 is of form > and z is negative

If the null hypothesis H_0 was rejected for Friedman's T-test, then the multiple comparison procedure (Dunn procedure) was applied to determine which of the treatment intervals made a statistically significantly difference.

Summary statistics including the mean, standard deviation and standard error were obtained to support the data from the various tests.

The results of these tests were used to discuss and draw conclusions as to the efficacy and relative efficacy of Capsaicin cream (OsteoEze® Rub) and knee mobilization in the treatment of OA of the knee.

CHAPTER FOUR

CHAPTER 4

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 relevant tables and bar charts.

Group 1- Capsaicin cream (OsteoEze® Rub) group.

Group 2- Knee Mobilization group.

Group 3- Combination (Capsaicin cream and mobilization) group.

4.2 Recruitment

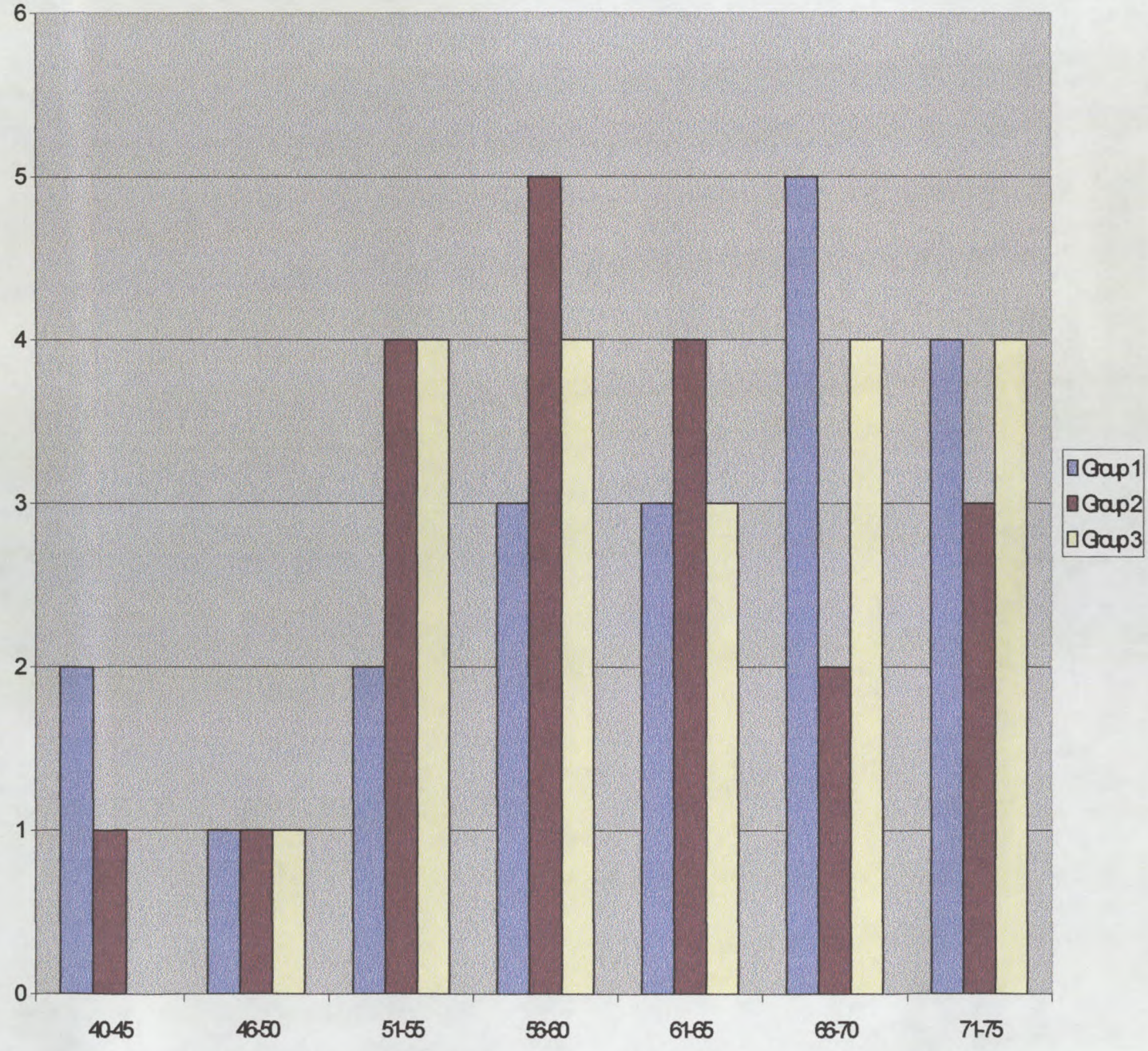
The study consisted of sixty patients: twenty in group 1, twenty in group 2 and twenty in group 3. Seventy-four volunteers were screened. Of the eleven which were rejected, six suffered from other arthritides which excluded them from this study. One subject could not be released from work commitments and four were not within the age limits of the study. Three patients dropped out of the study: two were rejected due to non-compliance to the study protocol and one moved out of the immediate Durban region.

4.3 Demographic Data

Table 4.1 Age distribution within the sample of 60.

Age	Group 1	Group2	Group 3	Total %
40-45	2	1	0	5%
46-50	1	1	1	5%
51-55	2	4	4	16.66%
56-60	3	5	4	20%
61-65	3	4	3	16.66%
66-70	5	2	4	18.33%
71-75	4	3	4	18.33%

Figure 1: Age distribution in years within the sample of 60



The average age (mean) for group 1: 61.90 years

The average age (mean) for group 2: 59.55 years

The average age (mean) for group 3: 62.1 years

Table 4.2 Gender distribution

Gender	Group 1	Group 2	Group 3	Total
Male	6	9	8	23
Female	14	11	12	37

Figure 2: Gender distribution within groups

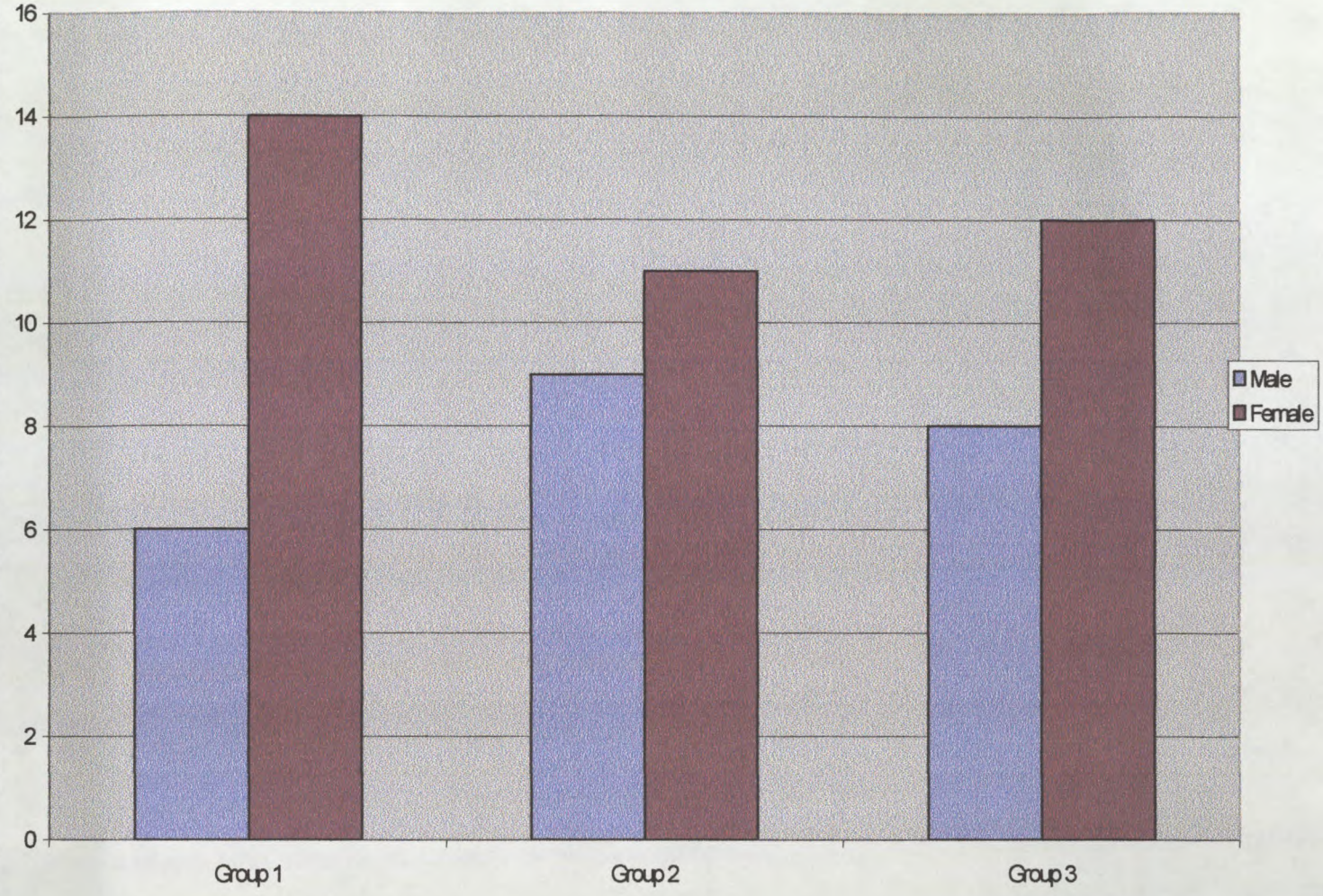


Table 4.3 Racial distribution

Racial group	Group 1	Group 2	Group 3
Black	0	1	0
White	14	13	18
Indian	5	5	2
Mixed Race	1	1	0

Figure 3: Racial distribution within groups

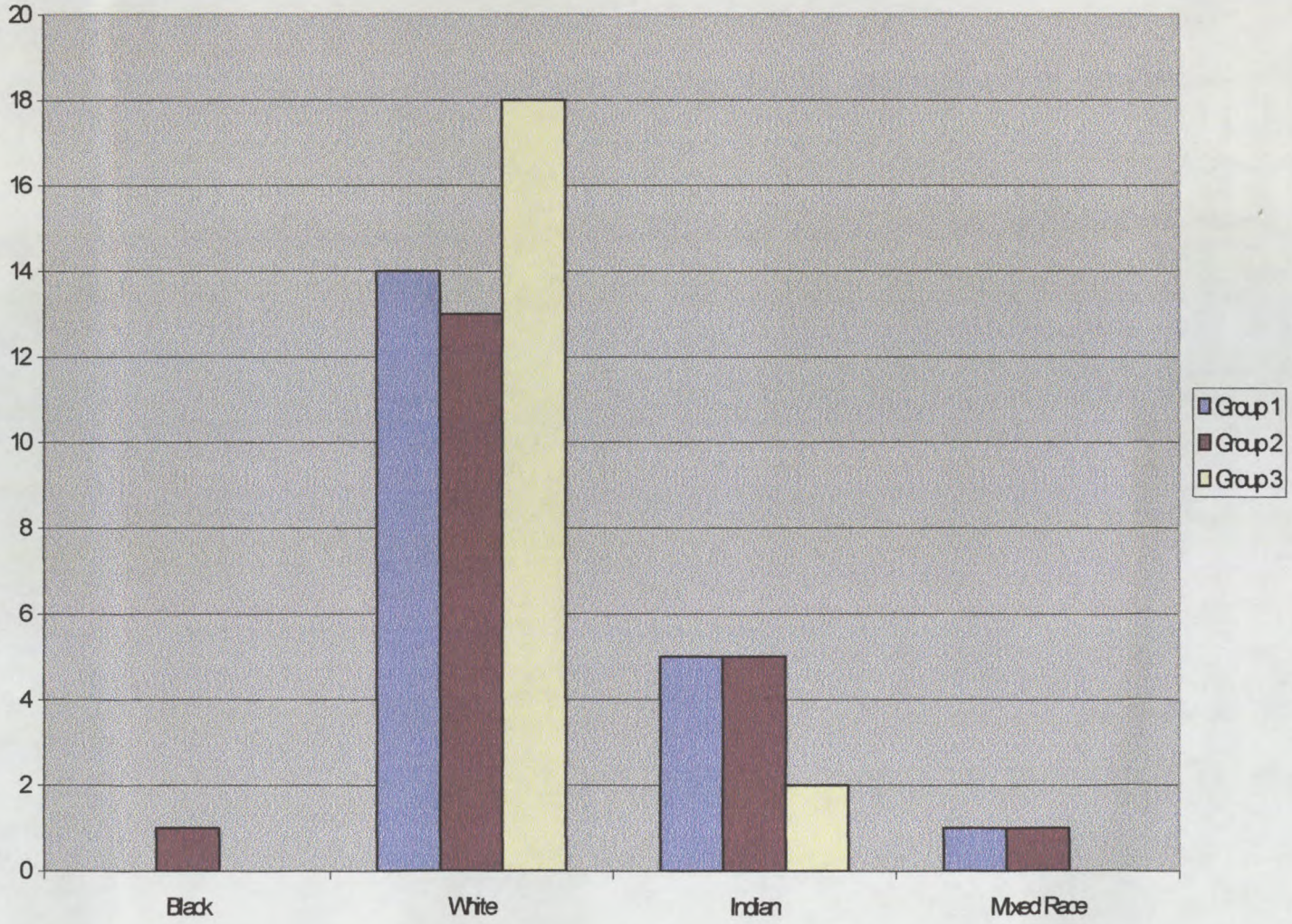


Table 4.4 Occupation

Occupation	Group 1	Group 2	Group 3
Retired	9	9	11
Accountant	1	2	1
Artist	1	0	0
Unemployed	1	0	1
Housewife	3	5	1
Self employed	1	0	0
Manager	1	2	2
Salesman	1	1	0
Company Director	1	0	1
Toolmaker	1	0	0
Driver	0	1	0
Teacher	0	0	1
Builder	0	0	1
Secretary	0	0	1

Table 4.5 Average height and weight

Ave Ht and Wt	Group 1	Group 2	Group 3
Height	1.69m	1.66m	1.71m
Weight	77.6kg	71.0kg	85.3kg

Table 4.6 Average pain duration within the sample of 60

Ave. No of years	Group 1	Group 2	Group 3
	3.1	3.8	3.4

4.4 The Analyzed Data

4.4.1 Hypothesis testing

The following hypotheses relate to intra and inter group comparisons:

4.4.1.1 Inter group comparison

The null hypothesis (H_0) stated that there was no difference between the two groups being compared in terms of subjective and objective clinical findings.

The alternative hypothesis (H_1) stated that there was a difference between the two groups being compared in terms of subjective and objective clinical findings. The data was analyzed at the α=0.05 level of significance.

Decision Rule:

If $p<\alpha$, reject the null hypothesis H_0.

If $p\geq\alpha$, do not reject the null hypothesis H_0.

(*p* is the reported *p*-value)

4.4.1.2 Intra group comparison

The null hypothesis (H_0) stated that there was no improvement within the groups being compared in terms of subjective and objective clinical findings. The alternate hypothesis (H_1) stated that there was an improvement between the groups being compared in terms of subjective and objective clinical findings. The data was analyzed at the α=0.05 level of significance.

Decision Rule:

If $p<\alpha$, reject the null hypothesis H_0.

If $p\geq\alpha$, do not reject the null hypothesis H_0.

(*p* is the reported *p*-value)

4.4.1.3 P-Value

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

4.4.1.4 Abbreviations

S.D.	= Standard deviation
P-value	= The observed significance level of the test
α	= The level of significance of the test
GON F	= Goniometer flexion reading
GON E	= Goniometer extension reading
NPRS-101	= The Numerical Pain Rating Scale-101 Questionnaire
WOMAC	= Western Ontario and McMaster Universities Index
Con 1	= Consultation One
Con 6	= Consultation Six
Con 7	= Consultation Seven

4.5 Intergroup Analysis

4.5.1 Kruskall-Wallis H-Test (Two-Tailed)

Table 4.7 The inter-group comparison of the NPRS questionnaire between group 1(OsteoEze® Rub), group 2 (Knee mobilization) and Group 3 (OsteoEze®Rub and Mobilization)

NPRS-101	P-Value
NPRS 1	0.710
NPRS 6	0.186
NPRS 7	0.143

Conclusions at Visit 1

At consultation one, p= 0.710. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 6

At consultation six, p=0.186. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 7

At consultation seven, p= 0.143. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Table 4.8 The inter-group comparison of the McGill questionnaire between group 1(OsteoEze® Rub), group 2 (Knee mobilization) and Group 3 (OsteoEze®Rub and Mobilization)

McGill	P-Value
McGill 1	0.447
McGill 6	0.566
McGill 7	0.350

Conclusions at Visit 1

At consultation one, p=0.447. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 6

At consultation six, p= 0.566. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 7

At consultation seven, p= 0.350. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Table 4.9 The inter-group comparison of the WOMAC questionnaire between group 1(OsteoEze® Rub), group 2 (Knee mobilization) and Group 3 (OsteoEze®Rub and Mobilization)

WOMAC	P-Value
WOMAC 1	0.763
WOMAC 2	0.099
WOMAC 3	0.148

Conclusions at Visit 1

At consultation one, p= 0.763. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 6

At consultation six, p= 0.099. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 7

At consultation seven, p= 0.148. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Table 4.10 The inter-group comparison of the goniometer readings in flexion between group 1(OsteoEze® Rub), group 2 (Knee mobilization) and Group 3 (OsteoEze®Rub and Mobilization)

GON F	P-Value
GON F 1	0.522
GON F 2	0.246
GON F 3	0.428

Conclusions at Visit 1

At consultation one, p= 0.522. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 6

At consultation six, p= 0.246. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 7

At consultation seven, p= 0.428. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Table 4.11 The inter-group comparison of the goniometer readings in extension between group 1(OsteoEze® Rub), group 2 (Knee mobilization) and Group 3 (OsteoEze®Rub and Mobilization)

GON E	P-Value
GON E 1	0.671
GON E 2	0.897
GON E 3	0.943

Conclusions at Visit 1

At consultation one, p= 0.671. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 6

At consultation six, p= 0.897. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

Conclusions at Visit 7

At consultation seven, p= 0.943. Therefore the null hypothesis was accepted. This indicates that there was statistically no difference in the treatment outcome between groups (no difference in the condition of the patients).

4.6 Intragroup Analysis

4.6.1 Friedman's Test

4.6.1.1 Analysis of objective findings of GROUP 1 (OsteoEze® Rub)

Table 4.12: Intra-group results of Friedman's test comparing the goniometer readings of group 1 taken for flexion and extension on the first, sixth and seventh consultations.

GROUP ONE OsteoEze® Rub							
	Con One		Con Six		Con Seven		
Goniometer							
	Mean	S.D.	Mean	S.D.	Mean	S.D.	P-value
Flexion	113.7000	9.6959	116.0000	7.5950	116.6500	7.6933	**0.033**
Extension	168.0000	4.9418	168.3500	5.0915	168.7000	4.0275	0.810

For the goniometer readings of flexion, the null hypothesis was rejected ($p=0.033$) and it was concluded that at the 5% level of significance there was an improvement between consultations one, six and seven.

For the goniometer readings of extension the null hypothesis was accepted and concluded that at the 5% level of significance there was no improvement between consultations one, six and seven.

The standard deviation showed the spread of data around the mean value. In all instances above the S.D. values were similar enough to render the data reliable and consistent.

4.6.1.2 Analysis of subjective findings of GROUP 1 (OsteoEze® Rub)

Table 4.13: Intra-group results of Friedman's test comparing the Numerical Pain Rating Scale-101, Mcgill and WOMAC questionnaire readings of group 1 taken on the first, sixth and seventh consultations.

GROUP ONE OsteoEze® Rub							
Con One			Con Six		Con Seven		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	P-value
NPRS	44.6000	14.9223	37.5500	20.4617	35.7000	18.7114	**0.012**
Mcgill	13.8500	9.0628	10.0500	10.1176	9.8000	10.1494	0.066
Womac	66.3500	27.7873	58.8000	28.9366	54.3500	28.1018	0.154

For the NPRS-101 readings, the null hypothesis was rejected which meant that at the 5% level of significance there was an improvement between consultations one, six and seven.

For the McGill and Womac readings the null hypothesis was accepted and concluded that at the 5% level of significance there was no improvement between consultations one, six and seven.

The S.D. values showed the spread of data around the mean. In the instance above the values are similar enough to render the data reliable and consistent.

4.6.1.3 Analysis of the objective findings of GROUP 2 (Knee Mobilization)

Table 4.14: Intra-group results of Friedman's test comparing the goniometer readings of group 2 taken for flexion and extension on the first, sixth and seventh consultations.

GROUP TWO Knee Mobilization							
Con One			Con Six		Con Seven		
Goniometer							
	Mean	S.D.	Mean	S.D.	Mean	S.D.	P-value
Flexion	116.0000	8.5162	117.7000	8.6578	118.6500	8.6223	**0.007**
Extension	166.4000	5.4522	168.2000	3.7219	168.6500	4.2708	0.066

For the goniometer readings of flexion the null hypothesis was rejected, and it was concluded that at the 5% level of significance there was an improvement between consultations one, six and seven.

For the goniometer readings of extension the null hypothesis was accepted and it was concluded that at the 5% level of significance there was no improvement between consultations one, six and seven.

The S.D. values showing the spread of data around the mean were similar enough to render the data reliable and consistent.

4.6.1.4 Analysis of the subjective findings of GROUP 2 (Knee Mobilization)

Table 4.15: Intra-group results of Friedman's test comparing the Numerical Pain Rating Scale-101, McGill and WOMAC questionnaire readings of group 2 taken on the first, sixth and seventh consultations.

GROUP TWO Knee Mobilization							
	Con One		Con Six		Con Seven		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	P-value
NPRS	42.4500	19.4597	33.4500	22.0704	33.3500	21.0920	**0.000**
Mcgill	12.4000	9.5774	11.4000	11.2830	10.5000	9.9868	**0.002**
Womac	61.7500	31.9768	53.6000	36.8288	50.8000	35.3711	**0.000**

For the NPRS-101, McGill and Womac readings, the null hypothesis was rejected, which meant that at the 5% level of significance there was an improvement between consultations one, six and seven.

The S.D. values showing the spread of data around the mean were similar enough to render the data reliable and consistent.

4.6.1.5 Analysis of the objective findings of GROUP 3 (OsteoEze® Rub and Mobilization)

Table 4.16: Intra-group results of Friedman's test comparing the goniometer readings taken for flexion and extension of Group 3 between the first, sixth and seventh consultations.

GROUP Three OsteoEze® Rub and Mobilization							
Con One			Con Six		Con Seven		
Goniometer							
	Mean	S.D.	Mean	S.D.	Mean	S.D.	P-value
Flexion	114.5500	8.9588	119.3000	7.0270	118.7500	7.5594	**0.000**
Extension	167.4000	4.3577	168.9500	3.9799	168.9500	4.0714	0.239

For the goniometer readings of flexion the null hypothesis was rejected, and it was concluded that at the 5% level of significance there was an improvement between consultations one, six and seven.

For the goniometer readings of extension the null hypothesis was accepted and it was concluded that at the 5% level of significance there was no improvement between consultations one, six and seven.

The S.D. values showing the spread of data around the mean were similar enough to render the data reliable and consistent.

4.6.1.6 Analysis of the subjective findings of GROUP 3 (OsteoEze®Rub and Knee Mobilization)

Table 4.17: Intra-group results of Friedman's test comparing the Numerical Pain Rating Scale-101, McGill and WOMAC questionnaire readings of group 3 taken on the first, sixth and seventh consultations.

GROUP Three OsteoEze® Rub and Mobilization							
	Con One		Con Six		Con Seven		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	P-value
NPRS	41.2500	14.2603	26.2500	18.1104	24.0500	18.4718	**0.000**
Mcgill	10.8000	7.2736	6.7000	5.8947	6.1000	6.1806	**0.004**
Womac	63.1500	30.7285	38.9000	27.1291	37.0500	26.9961	**0.000**

For the NPRS-101, McGill and Womac readings, the null hypothesis was rejected, which meant that at the 5% level of significance there was an improvement between consultations one, six and seven.

The S.D. values showing the spread of data around the mean were similar enough to render the data reliable and consistent.

Table 4.18: Ranking for NPRS-101 readings for Group1.

BLOCKS	ONE	THREE	SIX
1	(3)60	(2)55	(1)40
2	(3)25	(1.5)20	(1.5)20
3	(3)50	(1.5)45	(1.5)45
4	(2)45	(3)51	(1)39
5	(1.5)45	(3)50	(1.5)45
6	(3)35	(1.5)10	(1.5)10
7	(1)45	(2.5)50	(2.5)50
8	(2)85	(2)85	(2)85
9	(2)30	(2)30	(2)30
10	(3)58	(1)48	(2)50
11	(2)25	(3)40	(1)20
12	(3)55	(2)45	(1)40
13	(2)50	(2)50	(2)50
14	(2)50	(2)50	(2)50
15	(3)40	(1.5)11	(1.5)11
16	(3)45	(1)2	(2)20
17	(2)38	(2)38	(2)38
18	(2)16	(2)16	(2)16
19	(2)45	(2)45	(2)45
20	(3)50	(1.5)10	(1.5)10
RANK	47.5 (R1)	39 (R2)	33.5 (R3)

Table 4.19: Ranking for Goniometer flexion readings for Group 1

BLOCKS	ONE	THREE	SIX
1	(1)95	(2.5)105	(2.5)105
2	(1)100	(3)110	(2)108
3	(2)105	(1)104	(3)106
4	(1)100	(2.5)108	(2.5)108
5	(1)118	(2)119	(3)120
6	(2.5)118	(1)110	(2.5)118
7	(1)115	(2)116	(3)120
8	(1)125	(2.5)126	(2.5)120
9	(1)102	(3)110	(2)108
10	(1)115	(3)116	(1)112
11	(2)130	(2)130	(2)130
12	(3)118	(1)112	(2)115
13	(3)130	(1.5)122	(1.5)122
14	(2)115	(2)115	(2)115
15	(1)120	(2.5)122	(2.5)122
16	(1)108	(2)120	(3)123
17	(2)115	(2)115	(2)115
18	(2)120	(2)120	(2)120
19	(2)110	(2)110	(2)110
20	(1)115	(2.5)130	(2.5)130
RANK	32.5 (R1)	42 (R2)	45.5 (R3)

Table 4.20: Ranking for NPRS-101 readings for Group 2.

BLOCKS	ONE	THREE	SIX
1	(3)25	(1)5	(2)13
2	(3)63	(1.5)60	(1.5)60
3	(3)40	(1.5)5	(1.5)5
4	(3)13	(1.5)8	(1.5)8
5	(2)40	(2)40	(2)40
6	(3)13	(1.5)10	(1.5)10
7	(2)66	(2)66	(2)66
8	(3)40	(2)10	(1)8
9	(2)15	(1)13	(3)20
10	(3)80	(1.5)60	(1.5)60
11	(3)60	(2)45	(1)30
12	(3)43	(1.5)41	(1.5)41
13	(1.5)35	(1.5)35	(3)38
14	(2.5)75	(2.5)75	(1)70
15	(3)30	(1.5)25	(1.5)25
16	(3)53	(1.5)50	(1.5)50
17	(3)45	(1.5)40	(1.5)40
18	(3)30	(1.5)20	(1.5)20
19	(3)33	(1.5)13	(1.5)13
20	(2)50	(2)50	(2)50
RANK	54 (R1)	32.5 (R2)	33.5 (R3)

Table 4.21: Ranking for Mcgill questionnaire readings for Group 2.

BLOCKS	ONE	THREE	SIX
1	(3)6	(1)1	(2)2
2	(1)16	(2.5)22	(2.5)22
3	(3)21	(2)4	(1)3
4	(2)2	(2)2	(2)2
5	(2)2	(2)2	(2)2
6	(3)5	(1.5)4	(1.5)4
7	(3)20	(2)18	(1)13
8	(3)8	(2)3	(1)2
9	(3)5	(1.5)2	(1.5)2
10	(3)21	(1.5)20	(1.5)20
11	(1)17	(3)40	(2)34
12	(3)23	(1.5)21	(1.5)21
13	(1)4	(2.5)5	(2.5)5
14	(3)37	(2)30	(1)25
15	(2.5)3	(2.5)3	(1)2
16	(3)18	(2)16	(1)15
17	(3)6	(1.5)5	(1.5)5
18	(2)10	(2)10	(2)10
19	(3)3	(1)0	(2)1
20	(3)21	(1.5)20	(1.5)20
RANK	50.5 (R1)	37.5 (R2)	32 (R3)

Table 4.22: Ranking for WOMAC index readings for Group 2.

BLOCKS	ONE	THREE	SIX
1	(3)41	(1.5)7	(1.5)7
2	(1.5)75	(3)88	(1.5)75
3	(3)40	(1.5)3	(1.5)3
4	(3)15	(2)9	(1)5
5	(1)62	(3)64	(2)63
6	(3)40	(2)29	(1)27
7	(1)73	(2)79	(3)85
8	(3)42	(2)23	(1)20
9	(3)54	(2)29	(1)25
10	(2.5)115	(1)110	(1.5)115
11	(3)128	(2)112	(1)99
12	(1.5)68	(3)71	(1.5)68
13	(3)42	(2)33	(1)32
14	(3)123	(2)116	(1)100
15	(3)52	(2)44	(1)40
16	(3)79	(2)78	(1)77
17	(2)40	(2)40	(2)40
18	(3)52	(1.5)50	(1.5)50
19	(3)13	(2)7	(1)5
20	(3)81	(1.5)80	(1.5)80
RANK	47 (R1)	40 (R2)	33 (R3)

Table 4.23: Ranking for goniometer flexion readings for Group 2.

BLOCKS	ONE	THREE	SIX
1	(1)112	(2)117	(3)118
2	(1.5)110	(3)111	(1.5)110
3	(2)123	(3)125	(1)122
4	(1)118	(2)120	(3)123
5	(2)118	(1)112	(3)120
6	(1)110	(2.5)120	(2.5)120
7	(1)90	(2.5)92	(2.5)92
8	(1.5)120	(1.5)120	(3)122
9	(2)120	(2)120	(2)120
10	(1.5)120	(1.5)120	(3)123
11	(2)105	(2)105	(2)105
12	(1.5)118	(1.5)118	(3)120
13	(1)115	(2)116	(3)120
14	(1)128	(3)132	(2)131
15	(1)110	(2.5)120	(2.5)120
16	(2)120	(2)120	(2)120
17	(2)125	(2)125	(2)125
18	(2.5)113	(2.5)113	(1)112
19	(1)125	(2.5)130	(2.5)130
20	(2.5)120	(1)118	(2.5)120
RANK	31 (R1)	42 (R2)	47 (R3)

Table 4.24: Ranking for NPRS-101 questionnaire readings for Group 3.

BLOCKS	ONE	THREE	SIX
1	45(3)	35(2)	33(1)
2	70(3)	0(1.5)	0(1.5)
3	30(3)	15(2)	10(1)
4	25(2)	30(3)	15(1)
5	43(3)	3(1)	15(2)
6	63(3)	18(2)	15(1)
7	40(2.5)	40(2.5)	25(1)
8	50(3)	13(1.5)	13(1.5)
9	55(3)	52(1)	54(2)
10	40(3)	30(1.5)	30(1.5)
11	38(3)	13(1.5)	13(1.5)
12	25(3)	15(1.5)	15(1.5)
13	55(3)	40(1.5)	40(1.5)
14	25(1.5)	25(1.5)	40(3)
15	18(3)	10(1)	14(2)
16	60(1)	80(2.5)	80(2.5)
17	35(3)	30(2)	23(1)
18	28(2)	28(2)	28(2)
19	45(3)	25(1.5)	25(1.5)
20	35(3)	23(1.5)	23(1.5)
RANK	54 (R1)	34.5 (R2)	31.5 (R3)

Table 4.25: Ranking for McGill questionnaire readings for Group 3.

BLOCKS	ONE	THREE	SIX
1	22(3)	8(2)	6(1)
2	26(3)	0(1.5)	0(1.5)
3	5(3)	1(1)	2(2)
4	7(2.5)	5(1)	7(2.5)
5	20(3)	5(2)	3(1)
6	2(1)	3(2.5)	3(2.5)
7	8(3)	5(2)	2(1)
8	15(3)	14(1.5)	14(1.5)
9	19(2)	19(2)	19(2)
10	13(2)	13(2)	13(2)
11	12(3)	2(2)	1(1)
12	9(3)	0(1.5)	0(1.5)
13	2(2)	2(2)	2(2)
14	4(1)	10(2.5)	10(2.5)
15	4(2.5)	4(2.5)	1(1)
16	13(1)	19(2.5)	19(2.5)
17	7(3)	6(2)	3(1)
18	5(3)	3(1.5)	3(1.5)
19	19(3)	12(1.5)	(121.5)
20	4(3)	3(2)	2(1)
RANK	50 (R1)	37.5 (R2)	32.5 (R3)

Table 4.26: Ranking for WOMAC index readings for Group 3.

BLOCKS	ONE	THREE	SIX
1	113(3)	65(2)	42(1)
2	131(3)	0(1.5)	0(1.5)
3	31(3)	6(1)	20(2)
4	31(1)	40(2.5)	40(2.5)
5	60(3)	22(2)	19(1)
6	104(3)	34(1.5)	34(1.5)
7	34(3)	10(2)	6(1)
8	98(3)	95(1.5)	95(1.5)
9	93(3)	90(1.5)	90(1.5)
10	40(3)	34(1.5)	34(1.5)
11	77(3)	18(1.5)	18(1.5)
12	44(3)	26(1.5)	26(1.5)
13	19(2)	20(3)	18(1)
14	51(3)	40(2)	37(1)
15	46(2)	42(1)	56(3)
16	67(1)	72(2.5)	72(2.5)
17	53(3)	41(2)	18(1)
18	74(2)	74(2)	74(2)
19	48(3)	19(1.5)	19(1.5)
20	49(3)	30(2)	23(1)
RANK	53 (R1)	36 (R2)	41 (R3)

Table 4.27: Ranking for goniometer flexion readings for Group 3.

BLOCKS	ONE	THREE	SIX
1	120(3)	119(2)	118(1)
2	92(1)	123(2.5)	123(2.5)
3	120(2)	119(1)	124(3)
4	109(1)	122(3)	115(2)
5	110(1)	115(3)	111(2)
6	120(1)	122(2.5)	122(2.5)
7	118(1.5)	118(1.5)	120(3)
8	110(1)	112(2.5)	112(2.5)
9	98(1.5)	99(3)	98(1.5)
10	135(1)	136(2.5)	136(2.5)
11	119(1)	128(2)	130(3)
12	115(1)	116(2.5)	116(2.5)
13	115(1)	117(2)	118(3)
14	110(1)	115(2.5)	115(2.5)
15	115(1)	125(3)	122(2)
16	115(1)	120(2.5)	120(2.5)
17	110(1)	120(3)	115(2)
18	120(2)	120(2)	120(2)
19	120(2)	120(2)	120(2)
20	120(2)	120(2)	120(2)
RANK	27 (R1)	47 (R2)	46 (R3)

4.6.2 THE DUNN'S PROCEDURE (MULTIPLE COMPARISON TEST)

The null hypothesis was rejected for the goniometer readings of flexion and NPRS questionnaire for Group 1, goniometer readings of flexion, NPRS, McGill and WOMAC questionnaires for Group 2 and Group 3.

The multiple comparison procedure was performed to determine the significance of each treatment.

Let *Rj* and *Rj'* be the *jth* and *j'th* consultation rank totals.

Let α be the experiment-wise error rate. $\alpha = 0.10$

(Experiment wise error rate is usually higher than α and it depends on the sample size.)

Decision Rule:

$$| Rj - Rj' | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

In the above formula:

b = the number of blocks

k = the number of consultations

z = value in the inverse normal distribution corresponding to $\{1 - [\alpha/k(k-1)]\}$

In order to compute the consultation rank totals, the values in each block were ranked and then the sum of the ranks for each consultation was computed.

In this case $k = 3$, $\alpha = 0.10$, $z = 2.12$, $b = 20$

Dunn's procedure for the NPRS readings for Group 1

$$| Rj - Rj' | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$|47.5-39| \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$8.5 \geq 13.41$$

for $j = 1$ and $j' = 2$, the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 47.5-33.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$14 \geq 13.41$$

for $j = 1$ and $j' = 3$, the above inequality was true, hence the result was declared significant, indicating an improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 39–33.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$5.5 \geq 13.41$$

for $j = 2$ and $j' = 3$, the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations six and seven.

Dunn's procedure for the goniometer readings for flexion Group 1.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 32.5–42 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$9.5 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was not true, hence the result was declared insignificant, indicating that there was no improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 32.5–45.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$13 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, indicating that there was no improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 42–45.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$3.5 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, indicating that there was no improvement between consultations six and seven.

Dunn's procedure for the readings of NPRS for Group 2.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 54–32.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$21.5 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was true, hence the result was declared significant, indicating that there was an improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 54–33.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$20.5 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was true, hence the result was declared significant, which indicated an improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 32.5–33.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$1 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, indicating that there was no improvement between consultations six and seven.

Dunn's procedure for the McGill readings for Group 2.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 50.5–37.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$13 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 50.5–32 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$18.5 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was true, hence the result was declared significant, indicating that there was an improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 37.5–32 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$5.5 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations six and seven.

Dunn's procedure for the WOMAC readings for Group 2.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 47–40 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$7 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 47–33 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$14 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was true, hence the result was declared significant, indicating an improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 40–33 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$7 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations six and seven.

Dunn's procedure for the goniometer readings for flexion Group 2.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 31–42 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$11 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 31–47 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$16 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was true, hence the result was declared significant, indicating an improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 42–47 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$5 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, indicating no improvement between consultations six and seven.

Dunn's procedure for the NPRS readings for Group 3.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 54–34.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$19.5 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was true, hence the result was declared significant, indicating that there was an improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 54–31.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$22.5 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was true, hence the result was declared significant, indicating an improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 34.5–31.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$3 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations six and seven.

Dunn's procedure for the Mcgill readings for Group 3.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 50\text{–}37.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$12.5 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 50\text{–}32.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$17.5 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was true, hence the result was declared significant, indicating an improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 37.5–32.5 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$5 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations six and seven.

Dunn's procedure for the WOMAC readings for Group 3.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 53–36 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$17 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was true, hence the result was declared significant, indicating an improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 53\text{–}41 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$12 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 36\text{–}41 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$5 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations six and seven.

Dunn's procedure for the goniometer readings for flexion Group 3.

$$| R1 - R2 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 27\text{–}47 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$20 \geq 13.41$$

for $j = 1$ and $j' = 2$ the above inequality was true, hence the result was declared significant, indicating an improvement between consultations one and six.

$$| R1 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 27\text{–}46 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$19 \geq 13.41$$

for $j = 1$ and $j' = 3$ the above inequality was true, hence the result was declared significant, which indicated an improvement between consultations one and seven.

$$| R2 - R3 | \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$| 47-46 | \geq 2.12 \sqrt{\frac{20x3(3+1)}{6}}$$

$$1 \geq 13.41$$

for $j = 2$ and $j' = 3$ the above inequality was not true, hence the result was declared insignificant, which indicated no improvement between consultations six and seven.

CHAPTER FIVE

CHAPTER 5

5.0 Discussion

5.1 Introduction

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

- The objective data: Goniometer readings
- The subjective data: Numerical pain rating scale-101, McGill pain questionnaire and WOMAC index.

The results are discussed in two sections:

Intra-group comparison: The evaluation of the data comparing the initial and sixth and initial and final consultations gives and indication the efficacy of each treatment regime. Comparing the data between the sixth and seventh consultations gives an indication of any short term lasting effect.

Inter-group comparison: A comparison of the data from the initial consultation of all three groups gives an indication of any base line differences in subjective and objective findings between the three groups, in terms of the original signs and symptoms. Comparison of the data at the sixth consultation of all three

groups gave an indication of which treatment was more effective at this point where treatment was completed. The inter-group comparison of the final consultation indicated which treatment protocol was more effective in maintaining any short term lasting effects.

5.2 Inter-group Comparison

5.2.1 Objective Data

5.2.1.1 Goniometer Readings

Inter-group comparison of the flexion and extension readings revealed that there was no statistically significant difference between the three groups. These results indicated that, at a 95% level of confidence, the three treatment protocols were equally effective in treating the impaired range of motion of OA of the knees.

5.2.2 Subjective Data

5.2.2.1 Numerical Pain Rating Scale-101

Statistical analysis revealed that there was no statistically significant difference between the three groups with respect to pain intensity over the treatment period. This indicated that all three treatments were equally effective in treating the pain associated with OA of the knees.

5.2.2.2 McGill Questionnaire

Statistical analysis revealed that there was no statistically significant difference between the three groups with respect to pain quality over the treatment period. This indicated that all three treatments were equally effective in treating the pain quality in OA of the knees.

5.2.2.3 Western Ontario and McMaster Universities Index (WOMAC)

Statistical analysis revealed that there was no statistically significant difference between the three groups with respect to knee function over the treatment period. This indicated that all three treatments were equally effective in treating knee function in OA of the knees.

5.3 Intra-group Comparison

5.3.1 Discussion of the intra-group Analysis

In **Group 1** (Capsaicin cream), Friedman's test was performed and showed a significant difference between the first, sixth and seventh consultations for the NPRS-101 questionnaire and the goniometer flexion readings.

For the NPRS-101 there was a mean difference of 7.05 between the first and sixth consultations (*consultation* 1:44.6000; *consultation* 6:37.5500). Dunn's procedure was then performed and proved this difference to be statistically

insignificant. Between consultations one and seven there was a mean difference of 8.9 (consultation 1:44.6000; consultation 7:35.7000), and between six and seven 1.85 (consultation 6:37.5500; consultation 7:35.7000). Dunn's procedure showed a statistically significant difference between consultations 1 and 7 but no significance between consultations 6 and 7.

For the goniometer readings in flexion there was a mean difference of 2.3 between the first and sixth consultations (consultation 1:113.7000; consultation 6:116.0000). Dunn's procedure was then performed and proved this difference to be statistically insignificant. Between consultations one and seven there was a mean difference of 2.95 (consultation 1:113.700; consultation 7:116.6500), and between six and seven 0.65 (consultation 6:116.0000; consultation 7:116.6500). Dunn's procedure showed no difference between consultations 1 and 7 as well as 6 and 7.

In **Group 2** (knee mobilization), Friedman's test was performed and showed a significant difference between the first, sixth and seventh consultations for the NPRS-101, McGill and WOMAC questionnaires as well as for goniometer flexion readings.

For the NPRS-101 questionnaire there was a mean difference of 9.0000 between the first and sixth consultations (consultation 1:42.4500; consultation 6:33.4500). Dunn's procedure was then performed and proved this difference to be statistically significant. Between consultations one and seven there was a

mean difference of 9.15 (consultation 1:42.4500; consultation 7:33.3500), and between six and seven 0.1000 (consultation 6:33.4500; consultation 7:33.3500). Dunn's procedure showed a statistically significant difference between consultations 1 and 7 but no significance between consultations 6 and 7.

For the McGill questionnaire there was a mean difference of 1.0000 between the first and sixth consultations (consultation 1:12.4000; consultation 6:11.4000). Dunn's procedure was then performed and proved this difference to be insignificant. Between consultations one and seven there was a mean difference of 1.9 (consultation 1:12.4000; consultation 7:10.5000), and 0.9 between six and seven (consultation 6:11.4000; consultation 7:10.5000). Dunn's procedure showed a statistically significant difference between consultations 1 and 7 but no significance between consultations 6 and 7.

For the WOMAC index there was a mean difference of 8.15 between the first and sixth consultations (consultation 1:61.7500; consultation 6:53.6000). Dunn's procedure was then performed and proved this difference to be insignificant. Between consultations one and seven there was a mean difference of 10.95 (consultation 1:61.7500; consultation 7:50.8000), and 2.8 between six and seven (consultation 6:53.6000; consultation 7:50.8000). Dunn's procedure showed a statistically significant difference between consultations 1 and 7 but no significance between consultations 6 and 7.

For the goniometer readings in flexion there was a mean difference of 1.7 between the first and sixth consultations (consultation 1:116.0000; consultation 6:117.7000). Dunn's procedure was then performed and proved this difference to be statistically insignificant. Between consultations one and seven there was a mean difference of 2.65 (consultation 1:116.0000; consultation 7:118.6500), and 0.95 between six and seven (consultation 6:117.7000; consultation 7:118.6500). Dunn's procedure showed a statistically significance difference between consultations 1 and 7 but no difference between consultations 6 and 7.

In **Group 3** (Capsaicin cream and knee mobilization), Friedman's test was performed and showed a significant difference between the first, sixth and seventh consultations for the NPRS-101, McGill and WOMAC questionnaires as well as for goniometer flexion readings.

For the NPRS-101 questionnaire there was a mean difference of 15 between the first and sixth consultations (consultation 1:41.2500; consultation 6:26.2500). Dunn's procedure was then performed and proved this difference to be statistically significant. Between consultations one and seven there was a mean difference of 17.2 (consultation 1:41.2500; consultation 7:24.0500), and 2.2 between six and seven (consultation 6:26.2500; consultation 7:24.0500). Dunn's procedure showed a statistically significant difference between consultations 1 and 7 but no significance between consultations 6 and 7.

For the McGill questionnaire there was a mean difference of 4.1 between the first and sixth consultations (consultation 1:10.8000; consultation 6:6.7000). Dunn's procedure was then performed and proved this difference to be insignificant. Between consultations one and seven there was a mean difference of 4.7 (consultation 1:10.8000; consultation 7:6.1000), and 0.6 between six and seven (consultation 6:6.7000; consultation 7:6.61000). Dunn's procedure showed a statistically significant difference between consultations 1 and 7 but no significance between consultations 6 and 7.

For the WOMAC index there was a mean difference of 24.25 between the first and sixth consultations (consultation 1:63.1500; consultation 6:38.9000). Dunn's procedure was then performed and proved this difference to be statistically significant. Between consultations one and seven there was a mean difference of 26.1 (consultation 1:63.1500; consultation 7:37.0500), and 1.85 between six and seven (consultation 6:38.9000; consultation 7:37.0500:). Dunn's procedure showed no significant difference between consultations 1 and 7 or between consultations 6 and 7.

For the goniometer readings in flexion there was a mean difference of 4.75 between the first and sixth consultations (consultation 1:114.5500; consultation 6:119.3000). Dunn's procedure was then performed and proved this difference to be statistically significant. Between consultations one and seven there was a

mean difference of 4.2 (consultation 1:114.5500; consultation 7:118.7500), and 0.55 between six and seven (consultation 6:119.3000; consultation 7:118.7500). Dunn's procedure showed a statistically significant difference between consultations 1 and 7 but no statistically significant between consultations 6 and 7.

5.4 Outcome

It was concluded from the intra-group data analysis that Group 1 (Capsaicin cream) showed an improvement in pain intensity between consultations 1 and 7. Group 2 (knee mobilization) showed improvements in pain intensity between consultations 1 and 6 and 1 and 7, improvement in quality of pain, knee function and flexion range of motion between consultations 1 and 6. Group 3 (Capsaicin cream and knee mobilization) showed improvements in pain intensity between consultations 1 and 6 as well as between 1 and 7, an improvement in quality of pain between consultations 1 and 7, improvement in knee function between consultations 1 and 6 and flexion range of motion between consultations 1 and 6 and 1 and 7.

The inter-group analysis demonstrated no difference between the groups receiving Capsaicin cream, knee mobilization and a combination of the two treatments in terms of subjective and objective findings. The null hypothesis for all three data collecting consultations was accepted as there was no statistical difference between the three groups for subjective and objective clinical

findings. It can thus be concluded that the use of Capsaicin cream, knee mobilization or a combination of the treatments are equally effective in the treatment of OA of the knee.

5.5 Discussion of the demographic data

The age distribution of the patients in all three groups were very similar. The average age distribution was fairly similar between groups (group 1: 61.90 years, group 2: 59.55 years, group 3: 62.1 years). The gender distribution showed an increased ratio of females to males within each group and also in the sample group as a whole. The average height and weight were also similar within the group with the exception of group 3 who were slightly heavier on average. The average duration of pain was also similar within the three groups. In terms of race most of the patients were white or indian.

5.6 Study Limitations

In any randomized clinical trial the goal is that the study groups should be similar in relevant patient characteristics. A higher degree of comparability between groups allows for more valid trial conclusions. Baseline characteristics for patients between the three groups were similar for age, gender distribution, height, weight and duration of pain. Occupation may have had an impact on the study as a result of the wide variation, many of the patients were retired and information regarding hobbies or extra-mural activities were not obtained. Patients may thus have returned from the consultation to their occupation or

hobby which aggravated the extent of the condition of the knee. It was not possible to ensure absolute homogeneity in this study due to financial and time constraints.

A close connection between the sample size and the power of statistical analyses exists. The smaller the sample size the greater the risk of a type two error occurring. Due to the shortage of time and financial constraints, 60 patients were recommended by the Technikon Natal research committee.

The subjective measurements used were not specifically designed for OA of the knee. Patients may also not have fully understood the subjective questionnaires or may have exaggerated their improvement so as to please the researcher. The study was conducted solely by the author, thus the possibility of practitioner bias did exist. The use of an independent observer taking the subjective and objective measurements would have prevented this bias.

The possibility of human error, when taking the objective measurements, may also have affected the outcome results. Objective measurements were taken using a goniometer, the readings of which may have been influenced by the researchers interpretation of the exact positioning of the instrument and the possibility of human error, when taking these readings, did exist.

A further limitation involved the one week follow-up consultation, the author feels that one week is not a sufficient time period to evaluate the long-term efficacy of the three treatments. This needed to be extended to at least one month to fully evaluate the effects of the three treatments used.

An improvement in outcome in the groups receiving knee mobilization may have been increased had the mobilization been performed by a practitioner with several years experience and not by a student.

Whilst every effort was made to ensure that patients were compliant in using the Osteo® Eze rub, there was the possibility that this may not have been the case.

CHAPTER SIX

CHAPTER 6

6.0 RECOMMENDATIONS AND CONCLUSIONS

6.1 Recommendations

The author is of the opinion that a study with a larger sample size be undertaken. This would have resulted in more accurate results in determining treatment efficacy. Homogeneity could also have been improved by taking into account the age, gender, the extent of the pain and disability, the duration of the patient's symptoms, severity of the disease and the specific site of involvement.

The data should have been collected using more technologically advanced strategies which would have shown more accurate and significant results that were sensitive and specific. Instrumentation used in the study should not have been changed at each consultation. There were three goniometers of the same type in the Technikon Natal Chiropractic Day Clinic which were all being used in different studies, none of which were assigned to a particular study for the duration of each investigation. Study instrument bias would have been prevented by using the same instrument throughout the study. The newest and most sensitive instrumentation should have been used to allow for more accurate readings and greater detection of small but significant differences in the effect of the treatment.

An adequate follow-up period is also recommended. The author is of the opinion that a 1-month follow-up consultation would have provided more vital information regarding pain relief and differences in knee function than the 1 week follow-up used in the study.

6.2 Conclusion

This controlled clinical trial was comprised of a sample size of sixty. All patients had to be diagnosed with OA of the knee according to the diagnostic criteria outlined in Chapter 3. The patients were randomly divided into three groups of 20. Group one received Capsaicin cream (OsteoEze® rub) for three weeks which was applied 3-4 times daily when the knee was painful, Group two received Maitland knee mobilization and Group three received a combination of the two treatments. Groups two and three received six treatments over three weeks.

Intra-group and inter-group analysis revealed no statistically significant differences at the α=0.05 level of significance. The three treatment groups produced similar outcome results and neither showed any advantage over the other.

According to the statistical evaluation of the data collected, it was shown that all three treatments: Capsaicin cream, knee mobilization and a combination of capsaicin cream and knee mobilization were all equally effective in managing OA of the knee. All three groups showed improvements in presenting clinical signs and symptoms but statistically no one treatment approach was more

effective than the other in treating this condition. From a chiropractic viewpoint it is the author's opinion that further studies be conducted evaluating cost effective, effective and safe methods of treatment involving OA of the knee.

REFERENCES

American College of Rheumatolgy Subcommittee (no authors listed). 2000. Guidelines for the medical management of osteoarthritis of the hip and knee. Arthritis and Rheumatism. 43(9):1905-1915.

Bellamy, B., Buchanon, W.W., Goldsmith, C.H., Campbell, J. and Stitt, L. 1988. Validation of WOMAC: A health status instrument for measuring clinical important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. Journal of Rheumatology. 15:1833-1840.

Bergmann, T.F., Peterson, D.H. and Lawrence, D.L. 1993. Chiropractic Principles and Procedures. 3rd Edition. New York: Churchill Livingstone. Pp 124-667. ISBN 0-443-08752-0.

Berman, B.M., Singh, B.B., Lao, L., Langenberg, P., Li, H., Hadhazy, V., Bareta, J. and Hochberg, M. 1998. A randomised trial of acupuncture as an adjunctive therapy in osteoarthritis of the knee. Rheumatology. 38(4):346-354.

Brandt, K.D. 1998. The importance of nonpharmacologic approaches in management of osteoarthritis. American Journal of Medicine. 105(1B):39s-44s.

Bullough, G. 1998. Osteoarthritis and related disorders. In: Rheumatolgy. 2nd Edition. Klippel, J.H. and Dieppe, P.A. Mosby. pp 8.1-8.5. ISBN 0723424055

Calliet, R. 1992. Knee Pain and Disability: pain series. 3rd Edition. Pp 190-202. Philadelphia F.A. Davis company. 287p. ISBN 0803616228.

Cooper, C. 1994. Osteoarthritis: Epidemiology. In: Klippel, J.H. and Dieppe, P.A. Rheumatolgy. Pp7.3.1 London:Mosby

Cordell, G.A. and Oscar, E.A. (1993). Capsaicin: Identification, nomenclature and pharmacotherapy. The annals of Pharmacotherapy. 27(330-335).

Creamer, P. and Hochberg, M.C. 1997. Osteoarthritis. Lancet . 350(503-509).

Deal, C.L., Schnitzer, T.J., Lipstein, E., Seibold, J.R., Stevens, R.M., Levy, M.D., Albert, D., Renold, F. 1991. Treatment of arthritis with topical Capsaicin: A double blind trial. Clinical Therapeutics. 13(3):383-95.

Deyle, G.D., Henderson, N.E., Matekel, R.L., Ryder, M.G., Garber, M.B and Allison S.C. 2000. Efffectiveness of Manual Physical Therapy and Exercise in Osteoarthritis of the Knee. Annals of Internal Medicine. 132(3) 173-181.

Dieppe, P. and Lin, K.1998. Osteoarthritis and related disorders. Clinical features and diagnostic problems. In: Rheumatology. 2nd Edition. Klippel, J.H. and Dieppe, P.A. Mosby. pp 8.1-8.5. ISBN 0723424055

Doherty, M.1994. Colour Atlas and Text of Osteoarthritis. Pp27-73. Times Mirror International Publishers. ISBN 616-72-002(084).

Doherty, M and Doherty, J. 1992. Clinical Examination in Rheumatology. Pp107-108. BPCC Hazells Ltd, Aylesbury, England. ISBN 0723416850.

Eckoff, D.G., Kramer, R.C., Alongi, C.A. and van Gervan, D.P. 1994. Femoral Anteversion and Arthritis of the Knee. Journal of Pediatric Orthopaedics. 14:608-610.

Edwards, C.R.W., Bouchier, I.A.D., Haslett, C. and Chilvers, E.R. 1995. Davidson's Principles and Practice of Medicine. 17th Edition.pp877-880. Churchill Livingstone. ISBN 0443056072.

Fisher, A.A. 1987. Pressure threshold measurements for the diagnosis of myofascial pain and evaluation of results. The Clinical Journal of Pain. 2:207-214.

Fusco, B.M. and Giacovazzo, M.1997. Peppers and Pain. The Promise of Capsaicin. Drugs. 53(6) 909-914.

Golding, D.N.1989. Rheumatic Diseases: (A Synopsis of). 5th Edition. London: Wright. Pp 3-148. ISBN 0-7236-0850-4.

Hart,D.J. and Spector,T.D.1995. The classification and assessement of ostearthritis. In: Baillere, T. Bailliere's Clinical Rheumatology: Classification and Assessment of Rheumatic Diseases: Part1. Pp424 London. ISBN 07020-1939-9

Hart, D.J., Doyle, D.V. and Specter,T.D. 1999. Incidence and Risk Factors For Radiographic Knee Osteoarthritis In Middle Aged Women: The Chingford study. Arthritis and Rheumatism. 42(1):17-24.

Hertling, D. and Kessler, R.M. 1996. Management of Common Musculoskeletal Disorders. Physical Therapy Principles and Methods. 3rd Edition. Philadelphia: T.B.Lippincott. pp 36-364. ISBN 0-397-55150-9.

Hochberg, M.C., Altman, R.D., Brandt, K.D., Clark, B.M., Dieppe, P.A., Griffin, M.R., Moskowitz, R. W. and Schnitzer, T.J. 1995.Guidelines for the medical management of osteoarthritis. Part Two.Osteoarthritis of the knee. Arthritis and Rheumatism. 38(11):1541-1546.

Helewa, A and Walker,J,M. 1996. Epidemiology and Economics of Arthritis. In: Walker, J, M and Helewa, A. Physical Therapy in Arthritis. W.B. Saunders Company. Pp 13. ISBN 0-7216-4999-8.

Jensen, M.P., Karoly, P. and Braver, S. 1986. The measurement of Clinical Pain Intensity: A comparison of Six Methods. Pain. 27:117-126.

Magee, D.J. 1997. Orthopedic Physical Assessment. 3rd Edition.pp506-589. W. B. Saunders Company. ISBN 0-7216-6290-0.

Maitland, G.D. 1999. Peripheral Manipulation. 3rd edition.p 9. Reed Educational and Professional Publishing Ltd. ISBN 075061031 x.

Martin, D.F. 1994. Pathomechanics of knee osteoarthritis. Medicine and Science in Sports and Exercise. 26 (12):1429-34.

McAlindon, T.E., Zhang, Y., Hannan, M., Naimark, A., Weissman, B., Castelli, W. and Felson, D. 1996. Are Risk Factors for Patellofemoral and Tibiofemoral Knee Osteoarthritis different? Journal of Rheumatology. 23: 332-337.

McAlindon, T.E. 1999. The Knee. In Croft, P., and Brooks, P.M. eds. Baillier's Clinical Rheumatology: Regional musculoskeletal pain. Pp 329-344. London. Tindall. 378p. ISBN 15216942.

McCleane, G. 2000. The analgesic efficacy of topical capsaicin is enhanced by glyceryl trinitrate in painful osteoarthritis: a randomised, double blind, placebo controlled study. European Journal of Pain. 4(4): 355-60.

Melzack, R. 1987. The short Form McGill Pain Questionnaire. Pain. 30:191-197.

Moncur, C.1996. Physical Therapy Management of the Patient with Osteoarthritis. In: Walker, J. and Helewa, A. Physical Therapy in Arthritis. W.B. Saunders Company. Pp 277. ISBN 0-7216-4999-8.

Moore, K.L.1992. Clinically Oriented Anatomy. 3rd Edition. Canada: Williams and Wilkins. ISBN 0-683-06133-X.

Moore, K.L. and Dalley, A.F.1999. Clinically Oriented Anatomy. 4th Edition. Canada: Williams and Wilkins. ISBN 0-683-06141-0.

Nolano, M., Simone, D.A., Wendelschafer-Crabb, G., Johnson, T., Hazen, E. and Kennedy, W.R. 1999. Topical Capsaicin in humans: parallel loss of epidermal nerve fibres and pain sensation. Pain. 81(1-2):135-45.

Nevitt, M.C., Felson, D.T., Williams, E.N. and Grady, D. 2001. The Effect of Estrogen Plus Progestin on Knee Symptoms and Related Disability in Postmenopausal Woman. Arthritis and Rheumatism. 44(4):811-818.

Oloff, M.L. 1994. Musculoskeletal Disorders of the Lower Extremities. Pp 455. W.B. Saunders Company. USA. ISBN 0-7216-3716-7.

Palastanga, N., Field, D and Soames, R.2000. Anatomy and Human Movement. Structure and Function. Pp 432. 3rd Edition. Butterworth-Heinemann. ISBN 0750632682.

Puett, D.W. and Griffon, M.R. 1994. Published Trials of Nonmedicinal and Noninvasive Therapies for Hip and Knee Osteoarthritis. Annuls of Internal Medicine.121 (3):133-140.

Rogers, A.W. 1992. Textbook of Anatomy. Pp271-286. Churchill Livingstone. ISBN 0-443-02672-6.

Roos, H., Lauren, M., Aidalberth, T., Roos, D.M., Jonsson, K. and Lohmander, S.1998. Knee Osteoarthritis After Meniscectomy. Arthritis and Rheumatism. 41(4):687-693.

Sharma, L., Lou, C., Cahue, S. and Dunlop, D.D.2000. The Mechanism of the Effect of Obesity in Knee Osteoarthritis. Arthritis and Rheumatism. 43(3);568-575.

Sharma, L., Lou, C., Felson, D.T., Dunlop, D.D., Kirwan-Mellis, G., Hayes, K.W., Weinrach, D. and Buchanan, T.S. 1999. Laxity in Osteoarthritic Knees. Arthritis and Rheumatism. 42(5):861-870.

Slemenda, C., Heilman. D.K., Brandt, K.D., Katz, B.P., Mazzuca, S.A., Braunstein, E.M. and Byrd, D.1998. Reduced Quadriceps Strength relative to Body Weight. A risk factor for knee ostearthritis in woman? Arthritis and Rheumatism. 42(11):1951-1959.

Slemenda, C, Brandt, K.D., Heilman, D.K., Mazzuca, S., Braunstein, E.M., Katz, B.P. and Wolinsky, F.D. 1997. Quadriceps weakness and osteoarthritis of the knee. Annals of Internal medicine. 127(2):97-104.

Spector, T.D., Cicuttini, F., Baker, J., Loughlin, J. and Hart, D.1996. Genetic influences of osteoarthritis in women: a twin study. British Medical Journal. 312:914-944.

Spector, T.D. and Hart, D.J.1992. How serious is knee osteoarthritis? Annals of the Rheumatic Diseases. 51(10):1105-1106.

Steultjens, M.P.M., Dekker, J., van Baar, M.E., Oostendorp, R.A.B. and Bijlsma, J.W.J. 2000. Rheumatology. 39(9):955-961.

Rogers, A.1992. Textbook of Anatomy. p285. Churchill Livingstone. ISBN 0-443-02672-6.

Thibodeau, G.A. and Patton, K.T. 1999. Anatomy and Physiology. 262-264. 4th Edition. Mosby Inc. ISBN 0-323-00192-0.

Thomson, A., Skinner, A., Piercy, J.1991. Tidy's Physiotherapy. p12. 12th Edition. Butterworth-Heinemann Ltd. ISBN 750613467.

Williams, M.H. 1996. Challenges for Clinical Decision Making in the management of Osteoarthritis of the knee. Journal of Rheumatology. 23(4):586-589.

Yochum, T.R. and Rowe, L.J. 1996. Essentials of Skeletal Radiology. 2nd Edition. Williams and Wilkins. USA. Pp803-824. ISBN 0-683-09330-4.

Zizic, T.M., Hoffman, K.C., Holt, P.A., Hungerford, D.S., O'Dell, J.R., Jacobs, M.A., Lewis, C.G., Deal, C.L., Caldwell, J.R., Cholewcyzynski, J.G and Free,

S.M. 1995. The Treatment of Osteoarthritis of the Knee with pulsed Electrical Stimulation. Journal of Rheumatology. 22(9): 1757-1761.

TARY NAME (AND DOSAGE FORM):

O e® Rub

COM TION:

Eac g of cream contains:

Capsaicin (from *Capsicum annuum*): 5 mg

USAGE:

Capsaicin cream for muscles and joints. Capsaicin provides temporary, warming pain relief from minor aches and pains of muscles and joints associated with arthritis.

When topically applied to the skin or mucous membranes, capsaicin is known to stimulate and then block small-diameter pain fibers by depleting them of the neurotransmitter, substance P. Substance P is thought to be the principal chemomediator of pain impulses from the periphery.

In addition, substance P has been shown to activate inflammatory mediators in joint tissues. Recent studies have shown that Capsaicin decreases the amount of prostaglandins at the site of injury.

ONTRA-INDICATIONS:

Hypersensitivity to capsaicin or cayenne peppers. If in doubt, ask your pharmacist or doctor.

WARNING:

Safety in pregnancy and lactation has not been established.

Individuals with thin skin (i.e. the elderly or chronic users of topical corticosteroids) should be cautious when applying OsteoEze® Rub to their skin

Avoid contact with the eyes and mucous membranes.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects appear to be minimal in humans.

On application, some patients will experience a slight stinging or burning sensation as OsteoEze® Rub goes to work.

DOSAGE AND DIRECTIONS FOR USE:

Apply sparingly 3-4 times daily to the affected area. Occlusive dressings should not be used.

Do not apply OsteoEze® Rub to irritated skin.

Wash hands thoroughly after application. Avoid contact with eyes or mucous membranes.

IDENTIFICATION:

Caramel-coloured cream with a characteristic odour.

PRESENTATION:

100 g, non-collapsible tubes.

STORAGE INSTRUCTIONS:

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient:..... Date: .....

File # :..... Age : .....

Sex :..... Occupation:.....

Intern :.....Signature:.....

FOR CLINICIANS USE ONLY:

Initial visit

Clinician:..... Signature :.....

Case History:

Examination:

Previous: Current:

X-Ray Studies:

Previous: Current:

Clinical Path. lab:

Previous: Current:

Case Status:

PTT:.....

Signature:..... **Date:**.....

Conditional:

Reason for Conditional:.....

Signature: ..... **Date:** .....

All Conditions met in Visit No.:.....

To be signed into PTT:.....

Signature:..... **Date:** .....

Signed off:.....

Intern's Case History:

1. **Source of History:**

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

3. **Present Illness:**

	Complaint 1	Complaint 2
▸ Location		
▸ Onset : Initial:		
Recent:		
▸ Cause:		
▸ Duration		
▸ Frequency		
▸ Pain (Character)		
▸ Progression		
▸ Aggravating Factors		
▸ Relieving Factors		
▸ Associated S & S		
▸ Previous Occurrences		
▸ Past Treatment		
▸ **Outcome:**		

4. **Other Complaints:**

5. **Past Medical History:**

- General Health Status
- Childhood Illnesses
- Adult Illnesses

- Psychiatric Illnesses
- Accidents/Injuries
- Surgery
- Hospitalizations

6. Current health status and life-style:

- Allergies
- Immunizations
- Screening Tests incl. xrays

- Environmental Hazards (Home, School, Work)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
  Analgesics/week:

- Tobacco
- Alcohol
- Social Drugs

7. Immediate Family Medical History:

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

8. **Psychosocial history:**

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

9. **Review of Systems:**

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

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:

TECHNIKON NATAL

Knee regional examination

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

Observation (Standing, Seated and during gait cycle).

A. Anterior view.
Genu Varum:_____
Genu Valgum:_____
Patellar position:_____
Tibial Torsion:_____
Skin:_____
Swelling:_____

B. Lateral view
Genu Recurvatum:_____
Patella Alta:_____
Patella Baja:_____
Skin:_____

C. Posterior view.
Swelling:_____
Skin:_____

Active movements:
Flexion (0 - 135°)_____
Extension (0 - 15°)_____
Medial Rotation (20 - 30°)_____
Lateral rotation (30 - 40°)_____

Passive movements:
Tissue approx_____
Bone-bone_____
Tissue stretch_____
Tissue stretch_____
Patellar movement_____

Resisted isometric movements:
Knee: Flexion:_____
Extension:_____
Internal rotation:_____
External rotation:_____

Ankle: Plantarflexion_____
Dorsiflexion_____

Ligamentous assessment:

One-Plane Medial Instability:
Valgus stress (abduction)
- Extended_____
- Resting Position_____

One-Plane Lateral Instability:
Varus stress (adduction)
- Extended_____
- Resting Position_____

One-Plane Anterior Instability
Lachman Test (0-30°)_____
Anterior Drawer Sign _____

One-Plane Posterior Instability
Posterior "sag" Sign_____
Posterior Drawer Test_____

Anterolateral Rotatory Instability
Slocum Test_____
Macintosh Test_____

Anteromedial Rotatory Instability
Slocum Test_____

Posterolateral Rotatory Instability
Jacob _____
Hughston's Drawer Sign_____
Reverse pivot shift test_____

Posteromedial Rotatory Instability
Hughston's Drawer Sign_____

Tests for meniscus injury:
McMurray_____
"Bounce Home"_____
Anderson med-lat grind_____
Apley's_____

Plica tests:
Mediopatellar Plica _____
Plica "Stutter"_____
Hughston's Plica_____

Tests for swelling:
Brush/Stroke Test _____
Patellar Tap Test_____

Tests for patella femoral pain syndrome:
Clarke's Sign _____
Waldron test_____
Passive patella tilt test_____

Other tests
Wilson's_____
Fairbank's_____
Noble Compression_____
Quadriceps Contusion Test_____
Leg Length Discrepancy_____

Joint play:
P-A movement of the tibia on the femur_____
A-p movement of the tibia on the femur_____
Medial translation of the tibia on the femur_____
Lateral translation of the tibia on the femur_____
Inf, sup, lat, + med glide of the patella_____
A-P movement of the inf. tibiofibular joint_____
A-P movement of the sup. tibiofibular joint_____
Inf-sup movement of the sup tibiofibular joint_____
Long axis distraction of the tibiofemoral joint_____

Palpation:
Tenderness_____
Joint line pain _____
Swelling_____
Nodules/exostoses_____

Reflexes and cutaneous distribution:
Patellar Reflex (L3,L4) R____L____
Medial Hamstring Reflex (L5,S1) R____L____

Dermatomes

L2	R____L____	S1	R____L____
L3	R____L____	S2	R____L____
L4	R____L____	S3	R____L____
L5	R____L____		

INFORMED CONSENT FORM

(To be completed by patient / subject)

Date :

Title of research project :**The effectiveness and relative effectiveness of combining a topical Capsaicin cream with knee joint mobilisation in the treatment of osteoarthritis of the knee.**

Name of supervisor : **Dr Kretzmann**

Name of research student : **Denham Fish**

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:_____

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.

_____

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				

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)

Table for Goniometer Readings

Goniometer Readings Flexion	Goniometer Readings Extension
Visit 1	Visit 1
Visit 6	Visit 2
Follow-up	Follow-up