COMPARATIVE EFFICACY OF QUADRICEPS STRENGTHENING AND INFRARED RADIATION, ORAL DICLOFENAC SODIUM, AND THE COMBINATION OF THE THREE THERAPIES, IN THE MANAGEMENT OF OSTEOARTHRITIS OF THE KNEE

M.Sc. Project

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Declaraton
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DEDICATION

This work is dedicated to all the patients who participated in the study.
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**ABSTRACT**

There is presently a dearth of literature on the use of physiotherapy alone in the management of osteoarthritis of the knee. Oral diclofenac sodium is the most widely prescribed NSAID in the management of osteoarthritis of the knee, but the inhibition of prostaglandin biosynthesis is directly related to many common and occasional severe side effects of this therapy. The study was carried out to determine if quadriceps strengthening and infrared radiation alone will be effective in the management of osteoarthritis of the knee compared with oral diclofenac sodium and the combination of the three therapies respectively.

Ethical approval was sought and obtained from Nnamdi Azikiwe University Teaching Hospital, Nnewi. One hundred and thirty outpatients (87 females and 43 males), mean age 53.08 ±5.77 years; mean BMI 28.24 ± 2.19 kg/m², who gave their informed consent and met inclusion criteria, participated in the study. They were randomized into four groups thus: quadriceps strengthening and infrared group, diclofenac sodium group, combined group, and placebo group. The Non-steroidal Anti-inflammatory drug (NSAID) used in this study was oral diclofenac sodium (Norvatis) while the placebo drug used was oral vitamin B complex (Emzor) containing 1mg each of Vitamin B1 and B2 and 15mg of Nicotinamide. The patients in diclofenac sodium and combined groups had 50mg of oral diclofenac sodium and oral vitamin B complex twice daily (morning and evening) while patients in the placebo and quadriceps strengthening and infrared group had only vitamin B complex twice daily (morning and evening). Only patients in the combined and quadriceps
strengthening and infrared groups were treated with quadriceps strengthening and infrared radiation. Sham infrared was also used for the diclofenac sodium and placebo groups.

Their pain intensity score, knee joint flexion range of motion, quadriceps strength and 30.4m walk time were evaluated at initial visit and at seven weeks and used as parameters for comparison. The result revealed that after seven weeks of treatment, the quadriceps strengthening and infrared radiation group and combined group showed significant improvement in all the outcome measures (p<0.05). The diclofenac sodium group showed significant improvement in all outcome measures (p<0.05) except in muscle strength (p>0.05).

It was concluded that quadriceps strengthening and infrared radiation alone could be used in the management of osteoarthritis of the knee. It was also recommended that other physiotherapeutic modalities should be investigated for their effects on osteoarthritis of the knee.

keywords: osteoarthritis of the knee, quadriceps strengthening, infrared radiation, oral diclofenac sodium, pain intensity, joint flexion range of motion, muscle strength, walk-time.
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CHAPTER 1

Introduction

1.1 Background to the study.

Osteoarthritis (OA) is a term that refers to degenerative changes occurring in a synovial joint (Porter, 2004). It is the most common synovial joint disease and usually involves all the tissues that form the synovial joint – articular cartilage, subchondral and metaphyseal bone, synovium, ligaments, joint capsules and muscles that act across the joint (Solomon, 2001). It may be thought of as “failure of the joint as an organ” (Lozada and Altman, 2001). Osteoarthritis is associated with a breakdown of articular cartilage in the joint and can occur in almost any joint in the body. The fingers, hips, spine and knees are particularly vulnerable (Kelley, 2005). Despite the frequency and impact of osteoarthritis, it has long been considered an inevitable consequence of ageing and an unpleasant fact of life (Jones, 2004).

Osteoarthritis of the knee is the commonest degenerative joint disease and is one of the five leading causes of long-term disability among elderly men and women in most populations (Parmet, 2003). The risk for disability from osteoarthritis of the knee is as great as that from cardiovascular disease (Grainger and Cicuttini, 2004). In some populations, 80% of persons over 65 years of age have evidence of osteoarthritis of the knees and of these, 10% to 20% have symptomatic complaints and limitations of daily activity (Brandt, 2000).

Osteoarthritis of the knee only infrequently has an associated inflammatory component hence if examination or laboratory studies detect joint inflammation, the physician should consider diagnoses other than osteoarthritis. Inflammation, if present, is usually very mild and located in the affected joint (Bulkwalter and Mow, 1995). Osteoarthritis of the knee is characterized by pain, joint stiffness and loss of mobility due to
degeneration of the joint. Joint pain may originate not only from synovitis, but also stretching of the joint capsule, of ligaments, periosteal irritation due to osteophytes formation, interosseous hypertension or muscle spasm (Brandt, 2005). In more advanced stages of the disease, the pain becomes constant. Most patients also notice joint stiffness, particularly in the morning or after prolonged inactivity (Porter, 2004). As joint degeneration progresses, patients may notice weakness of the quadriceps, reduced ambulation speed, locking, catching and grinding sensations in the joint [Jones, 2004]. Major joint trauma, repetitive stress, joint overload, obesity, congenital defects, genetic factors, prior inflammatory joint disease, quadriceps weakness, female gender and race are risk factors for osteoarthritis of the knee (Kelley, 2005), and are all important in its pathogenesis (Solomon et al., 2001).

Most people with osteoarthritis generally seek medical attention, because of pain. They often describe the pain as an increasing deep aching sensation, which is poorly localized and has been present for years (Parmet, 2003). The pain may be aggravated by weather changes and increased activity (Porter, 2004). Activity-associated pain typically begins immediately or shortly after the patient begins to use the joint, and may persist for hours after the activity is stopped (Waris, Lavelley and Wang, 2003). Some people first notice symptoms following a minor joint injury or unusually strenuous physical activity (Porter, 2004).

Although the cause of osteoarthritis of the knee is often unknown and there is no cure, early diagnosis and treatment can help minimize symptoms and help patients maintain active lives [De-Angelo and Gordon, 2004]. Goals of treatment include decreasing joint pain, stabilizing and increasing joint mobility and reducing physical limitations (Kelley, 2005). The guideline for the medical management of osteoarthritis of the knee by Hochberg
et al, (2006) is the combination of Non Steroidal Anti-inflammatory Drugs (NSAIDs) and Physiotherapy.

Non Steroidal Anti-inflammatory Drugs include diclofenac sodium or potassium, ibuprofen, aspirin, and naproxen (Grainger and Cicuttini 2004). Diclofenac sodium is the most widely prescribed NSAID to reduce joint pain, but the inhibition of prostaglandin biosynthesis is directly related to many common and occasional severe side effects of this therapy. These side effects include: gastrointestinal bleeding, dyspepsia, electrolyte imbalances, hypertension, congestive heart failure, renal insufficiency, liver damage, ulcerative colitis and bone marrow depletion (Kearney et al., 2006). Several systemic reviews have reported that though these drugs may be effective in the management of joint pain, their prolonged use could put the user at risk of cardiovascular problems (Graham, 2006; Grainger and Cicuttini 2004; Sowers, 2001).

Physiotherapy includes: quadriceps strengthening exercises, infrared radiation, ultrasound therapy, transcutaneous electrical nerve stimulation (TENS), cryotherapy. (Porter, 2004.) Several studies (Hartling et al., 2005; Smidt et al., 2005; Shekelle et al., 2005) have documented the safety of physiotherapy in the management of medical and surgical conditions. Numerous studies (Roddy et al., 2005; Jyrki et al., 2004; Cassal, 2003) have reported that strengthening the quadriceps could be beneficial in the management of osteoarthritis of the knee. The benefits include improved knee joint range of motion, improved knee function and reduced joint pain. So many studies have also reported that infrared radiation, reduces joint pain and stiffness in patients with osteoarthritis of the knee (McCarberg, 2005; Nadler and Weingard, 2004; De Angelo and Gordon, 2004).

There are several reported studies on the use of the combination of NSAID and physiotherapy in the management of OA of the knee (Roddy et al., 2000, Solomon et al, 2001). There are also many documented studies [Gotzsche, 2005, Roy et al., 2002; Walker-
Bone, 2000] on the use of NSAID alone in the management of joint pain in osteoarthritis of the knee, but there is presently a dearth of literature on the use of physiotherapy alone in the management of osteoarthritis of the knee.

1.2 Statement of Problem

The age distribution of patients that suffer from OA of the knees is such that co-morbid conditions are often present (Felson et al, 2000). As a result, physicians and surgeons are often faced with a dilemma as to which NSAID to prescribe for effective management of OA without exacerbating co-morbid conditions (Ferri, 2004). In view of this problem, the following questions arose:

Will quadriceps strengthening and infrared radiation alone, reduce knee pain intensity in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively?

Will quadriceps strengthening and infrared radiation alone, increase knee joint flexion range of motion in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively?

Will quadriceps strengthening and infrared radiation alone, significantly increase muscle strength in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively?

Will quadriceps strengthening and infrared radiation alone, reduce walk-time in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively?
1.3 Purpose of study

1.3.1 General Objectives:

The study was carried out to determine if quadriceps strengthening and infrared radiation alone will be effective in the management of osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

1.3.2 Specific objectives:

The study is aimed at determining:

1. If quadriceps strengthening and infrared radiation alone will reduce knee pain intensity in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

2. If quadriceps strengthening and infrared radiation alone will increase knee joint flexion range of motion in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

3. If quadriceps strengthening and infrared radiation alone will significantly increase muscle strength in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

4. If quadriceps strengthening and infrared radiation alone will reduce walk-time in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

1.4 Clinical Importance of Study

The outcome of this study may reveal the effectiveness of quadriceps strengthening and infra-red radiation alone in the management of osteoarthritis of the knee, with positive
implications for patients who present with co morbid conditions, and who may be at risk of the side effects of diclofenac sodium.

The outcome of this study may stimulate further research on the use of other physical modalities alone in the management of degenerative joint diseases.

1.5 Hypotheses

It is hypothesized that:

1. There will be no significant reduction of pain intensity in the knee using quadriceps strengthening and infrared radiation alone in the treatment of patients with osteoarthritis of the knee compared with oral diclofenac; sodium alone and the combination of the three therapies respectively.

2. There will be no significant increase in knee joint flexion range of motion using quadriceps strengthening and infrared radiation alone in the treatment of patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

3. There will be no significant increase in muscle strength using quadriceps strengthening and infrared radiation alone in the treatment of patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

4. There will be no significant reduction in 30.4 metres walk- time using quadriceps strengthening and infrared radiation alone in the treatment of patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.
1.6 Delimitations of the study

The study is delimited to:

- The use of Box Numerical Scale to assess the patient’s present knee pain intensity.
- The use of Oxford grading to assess muscle strength.
- The use of 30.4m walk-test to assess functional ability of the knee.
- The use of oral diclofenac sodium (by Novartis) as NSAID Therapy.
- The use of quadriceps strengthening exercise protocol designed by the Arthritis Research Campaign, [2005] combined with infra-red radiation.
CHAPTER TWO

Literature Review

2.1 Anatomy of the knee

The knee is a synovial joint between the femur and the tibia, with the patella articulating with the femur at the front. It is a hinge joint, allowing flexion, extension and rotation (Moore and Dalley, 2006).

2.1.1 Articular Cartilage

The ends of the three bones (the femur, the tibia and patella) are covered with the articular cartilage, which is supremely adapted to transmit load and movement from one skeletal, segment to another. The cartilage increases the area of the articular surfaces and helps to improve their adaptability and stability. Usually it changes its shape under load and distributes compressive forces widely to the subarticular bone. In addition, it is covered by a film of synovial fluid, making it more slippery than any man-made material, offering very little frictional resistance to movement and surface gliding (Solomon et al., 2001).

This specialized connective tissue has a gel-like matrix consisting of a proteoglycan ground substance in which are embedded an architecturally structured collagen network and a relatively sparse scattering of specialized cells, (the chondrocytes) which are responsible for producing all the structural components of the tissue. It has high water content (60-80%), most of which is exchangeable with the synovial fluid (Solomon et al., 2001).

The proteoglycans exist mainly in the form of aggregans, a large aggregating molecule with a protein core along which is arranged up to 100 chondrotin sulphate and keratin sulphate glycosaminoglycans (GAGS). Hundreds of aggregan molecules are linked in turn, to a long unbranched hyalurinate chain to form an even larger molecule. These negatively charged
higher molecules are responsible for the stiffness and springiness of articular cartilage (Solomon et al., 2001).

The fibrillar component of articular cartilage is mainly type II collagen. The collagen bundles are arranged in structural patterns, parallel to the articular surface in superficial zone and perpendicular to the surface in the deeper layers where they anchor the articular cartilage to the subchondral bone (Frenando, 2003). There is considerable interaction between the molecules of each component and between the molecules of the different components of cartilage. If these links are degraded or broken, the cartilage will tend to unravel. This happens to some degree with ageing, but much more so in pathological states leading to osteoarthritis (Grainger and Cicuttini, 2004).

Proteoglycan has a strong affinity for water, resulting in the collagen network being subjected to considerable tensile stresses. With loading, the cartilage deforms and water is slowly squeezed onto the surface where it helps to form a lubricating film. When loading ceases, the surface fluid seeps back into the cartilage up to the joint where the swelling pressure in the cartilage is balanced by the tensile force of the collagen network. As long as the network holds and the proteoglycans remain intact, cartilage retains its compressibility and elasticity (Porter, 2004). If the collagen is disrupted, the matrix becomes waterlogged and soft; this in turn is followed by loss of proteoglycans, cellular damage and fibrillation (splitting) of the articular cartilage (Porter, 2004).

2.1.2 Menisci

Helping to cushion the knee are two c-shaped pads of cartilage called the Menisci. They lie between the tibia and femur; and are dense fibro- cartilaginous structures that project from the margins of the joint, which are interposed between articular cartilage
surfaces. Their functions are to increase joint stability, bear load, absorb shock and help lubricate the joint (Mow, 1995).

2.1.3 Joint Capsule and Ligaments
The joint capsule attaches to adjacent bones and across the knee joint while ligament are strong elastic bands of tissue that connect one bone to another. Joint capsule forms fibrous tissue cuffs that enclose the joints. Both restrict joint motion (Mow, 1995).

2.1.4 Synovial Membrane
Synovial membrane (synovium) attaches directly around the margins of the articular cartilage and lines the non-articular regions of the joint capsule, bone surfaces, intra-articular ligaments and tendons. This membrane secretes synovial fluid, a yellow viscous fluid that serves to lubricate the joint (Solomon et al., 2001).

2.1.5 Muscles Acting on the Knee Joint
The major extensor of the knee joint is the quadriceps femoris, consisting of the vastus medialis, vastus lateralis, vastus intermedius and rectus femoris (Moore and Dalley, 2006). The primary flexors of knee joint are the hamstrings muscle group, comprising: semitendinosus, semimembranosus, and two heads of biceps femoris. Other knee joint flexors include gastrocnemius, sartorius, gracilis and popliteus (Moore and Dalley, 2006). Muscles, which medially rotate the tibia on the femur, are popliteus, semimembranosus, semitendinosus with sartorius and gracilis providing some assistance. In contrast, the Biceps femoris is a sole lateral rotator of the tibia (Moore and Dalley, 2006).
2.1.6 Blood Supply to the Knee Joint

The blood supply to the knee joint is via branches of the vessels that form the genicular anastamoses around the knee which are the lateral, superior and inferior; medial superior and inferior, and middle genicular artery. The middle genicular artery penetrates the fibrous capsule and supplies, the collateral ligaments, synovial capsule and periphery of the menisci (Moore and Dalley, 2006).

2.1.7 Nerve supply

This is via the obturator, femoral, tibial and common peroneal divisions of the sciatic nerve. Its supply is L2 L3 and L4 but mainly L3 and L4 (Moore and Dalley, 2006).

2.2 Joint Biomechanics

Important mechanical characteristics of synovial joints include: stability during motion, joint lubrication that allows the slow-friction gliding of cartilage surface and load distribution across joints (Mow, 1995).

2.2.1 Stability

Efficient, controlled movement requires dynamic (active) joint stability during motion caused by muscles acting across the joint. Loss of dynamic joint stability not only compromises function but also leads to joint degeneration in many instances (Mow, 1995). Static (passive) joint stability (maintenance of the ligament and contact of articular surfaces at rest or during passive motion) depends primarily on joint shape and the restraint of abnormal or excessive motion provided by ligaments and joint capsule. Passive stability can usually be assessed when an examiner stresses the joint or moves it while applying stress. During active motion, the shape and congruence of the joint surfaces, the ligaments and
joint capsule combine to help guide joint motion and prevent abnormal motion. In the knee joint, however, forces generated by muscle contraction are equally or more important. For this reason, evaluation of knee joint stability requires assessment of the structure and passive stability of the joint as well as the ability of the muscles that act across the joint to provide dynamic stability (Porter, 2004; Mow, 1995).

2.2.2 Lubrication

Smooth, low-friction motion of the knee joint requires efficient joint lubrication. Many details of the joint lubrication systems remain unknown, but at least two mechanisms have been identified: boundary layer lubrication and hydrodynamic lubrication (Swann, 1979). Boundary layer lubrication occurs as a result of a thin layer of lubricant binding to the opposing surfaces and decreasing friction and wear. Some investigators have proposed that a joint specific glycoprotein, lubricin is a critical component of a layer of fluid that forms between opposing articular surfaces, providing boundary layer lubrication. Hydrodynamic lubrication occurs when joint loading and motion generate a fluid layer that separates opposing cartilage surfaces. As the joint moves, the fluid separates and decreases friction between the joint surfaces. When joint loading and motion cease, the fluid is reabsorbed. During joint motion, lubrication occurs by both mechanisms that is boundary layer lubrication in regions of articular surface contact and hydrodynamic lubrication in regions where the surfaces are not in contact (Swan, 1979).

2.2.3 Load Distribution

Load distribution decreases friction and shear stresses across joints generated by joint movement but it contributes relatively little to the distribution of compressive stresses. The elastic behaviour of cartilage, menisci and subchondral bone help distribute
compressive loads but this mechanism would fail if the muscles did not absorb most of the compressive stresses applied to joints (Porter, 2004).

Most of the stresses generated across the joints by jumping from a table can be absorbed by muscle contraction during flexion of the knees and hips with landing. If the knees and hip remain extended with landing, the impact on the joint is much greater and might even fracture the cartilage or bone. Failure of joint and muscular mechanisms of load distribution can increase stresses on cartilage and subchondral and metaphyseal bone, thereby contributing to joint degeneration (Jones, 2004).

2.3 Classification

There are two main types of osteoarthritis of the knee: Primary OA, or Generalized OA (GOA) and Secondary OA (Porter, 2004).

2.3.1 Primary OA or Generalized OA (GOA)

Osteoarthritis of the knee with no clear cause is called primary OA. It is due to an intrinsic alteration of the articular tissues themselves and affects the knee joint in a classical pattern. It is common in postmenopausal women who typically exhibit Herberden’s and Bouchard’s nodes (Porter, 2003).

2.3.2 Secondary OA

When OA of the knee is associated with a known cause or disorder that increases the probability of joint degeneration, it is considered as secondary OA (Porter, 2003). Secondary OA of the knee appears to be more common in people with a previous injury or fracture to the knee joint. Repeated minor trauma may lead to micro fractures and subsequent osteoarthritis (Sowers, 2001). Joint infection puts the knee joint at risk of OA, as
does deformity. Haemophilia, acromegaly and hyperthyroidism all predispose joints to secondary OA, as does Charcot’s joints - the phenomenon of joint destruction follows as a result of loss of joint proprioception and sensation, leading to abnormal stress and joint positions (Sowers, 2001).

There is a correlation between high body mass index and osteoarthritis of the knees, (Sharma and Lou, 2000). Being overweight may result to premature muscle fatigue, which may in turn lead to abnormal kinematics and the subsequent development of osteoarthritis of the knees (Porter, 2003). Interestingly, there is an overlap between primary and secondary OA. People who develop secondary OA also appear to have a predisposition to primary OA and the possibility of people with OA in one knee developing bilateral OA is very high (Porter, 2003).

2.4 Aetiology of Osteoarthritis of the Knee

Osteoarthritis was once considered to be a disease of hyaline cartilage. This is now being called into question, and evidence has emerged to suggest that the disease process does not originate in the cartilage, but that it begins with changes in the subchondral bone. These changes include redistribution of blood supply with hypertension in the subchondral bone marrow, oedema and micro necrosis, which may result in secondary hyaline cartilage degeneration (Solomon et al., 2001). The accumulation of micro-fractures in the sub-chondral bone makes it more brittle, which in turn places greater stress upon the articular cartilage. Lower proteoglycan content is found in the cartilage of immobile joints along with a decrease in synovial fluid volume, these are changes that are associated with cartilage degeneration (Solomon et al., 2001).
2.5 Pathology of Osteoarthritis of the Knee

The cardinal features of OA are (1) Progressive cartilage destruction (figures 3b and 4); (2) Subarticular cyst formation, with (3) Sclerosis of the surrounding bone (figures 3b and 4); (4) Osteophyte formation (figure 6) and (5) Capsular fibrosis (Grainger and Cicuttini, 2004).

Initially, the cartilaginous and bony changes are confined to one part of the joint - the most heavily loaded part. There is softening and fraying of the normally smooth and glistening cartilage (Solomon et al., 2001). With progressive disintegration of cartilages, the underlying bone becomes exposed and some areas may be polished or burnished to ivory-like smoothness called eburnation. Sometimes small tufts of fibro cartilage may be seen growing out of the body surface. At a distance from the damaged area, the articular cartilage looks relatively normal, but at the edges of the joint, there is remodeling and growth of osteophyte covered by thin bluish cartilage (Guidolin, 2001).

Beneath the damaged cartilage, the bone is dense and sclerotic. Often within this area of subchondral sclerosis and immediately sub adjacent to the surface are one or more cysts containing thick gelatinous material (Parmet, 2003). The joint capsule usually shows thickening and fibrosis, sometimes of extraordinary degree. The synovial lining as a rule looks only mildly inflamed; sometimes, however, it is thick and red and covered with villi (Parmet, 2003). The osteophytes appear to arise from cartilage hyperplasia and ossification at the edge of the articular surface. The capsule and synovium are often thickened but cellular activity is slight, however, sometimes there is marked inflammation or fibrosis of the capsular tissues (Porter, 2003).
2.6 Prevalence of Osteoarthritis of the Knee

Osteoarthritis of the knee is a universal disorder. It affects both sexes and races. Some studies have shown that women are more affected than men (Jones, 2004).

2.7 Risk Factors

1. **Trauma:** Fractures involving the articular surface of the knee are obvious precursors of secondary osteoarthritis of the knee, so are lesser injuries, which result in joint instability. Mal-union close to the knee joint may also predispose the knee to osteoarthritis (Grainger and Cicuttini, 2004).

2. **Obesity:** The simple idea that obesity causes increased joint loading and therefore predisposes to OA may be correct, at least for osteoarthritis of the knee (Sharma and Lou, 2000). This association is closer in women than in men (Parmet, 2003).

3. **Age:** The ability of the cartilage to heal itself decreases as people age (Parmet, 2003).

4. **Family History:** Women with generalized OA are likely to see the same condition developing in their daughters (Solomon et al., 2001).

5. **Abnormal Joint Anatomy:** Osteoarthritis of the knee is probably more likely to develop in persons with disruption or incongruity of the articular surface, joint mal-alignment, joint instability, and inadequate muscle strength. In these persons, subjecting the joint to daily activities, especially if repetitive impact or torsion is involved, increases the risk of OA knee (Sharma and Hayes, 1999).

6. **Occupation:** There is good evidence of an association between osteoarthritis of knee and certain occupations that cause repetitive stress. Workers engaged in knee bending or standing activities like (farmers) and (teachers and policemen) respectively are prone to OA knee (Porter, 2003). More controversial is the relationship between OA of the knee and sporting activities. Convincing evidence of causative relationship comes from studies,
which have shown an increase in risk of OA of the knees in athletes and footballers (Sowers, 2001).

7. **Other illnesses:** Repeated episodes of gout or septic arthritis, metabolic disorder and some congenital conditions can also increase the risk of developing OA knee (Sowers, 2001).

8. **Quadriceps muscle weakness:** This may be a primary risk factor for the development of OA knee. It is usually related to disability/disuse and pain (Slemenda, Brandt and Heilman, 1997).

### 2.8 Clinical Features

1. **Pain:** Pain is the usual presenting symptom. The pain starts insidiously and increases slowly over months and years. It is aggravated by exertion and relieved by rest, although with time relief is less and less complete (Brandt, 2000).

2. **Heat/redness:** The knee can be warm to palpation, signifying active inflammation (Porter, 2003).

3. **Swelling and Deformity.** Swelling may be intermittent (suggesting an effusion) or continuous with capsular thickening or large osteophytes (figure 6). Varus or valgus deformity (figures 5a and 6) may result from capsular contracture or joint instability which may have preceded and contributed to the onset of OA (Creamer, 2001).

4. **Stiffness:** In the late stage, the patient may have pain in bed at night. Stiffness is common. Characteristically, it occurs after periods of inactivity but with time it becomes constant and progressive. There is decrease in the speed and freedom of active movement (Porter, 2003).

5. **Muscle Spasm:** Spasm is a protective mechanism. Movement causes pain so the body attempts to stop movement, but spasm often occurs out of proportion to the underlying
pathological cause. Prolonged spasm causes pain due to metabolite accumulation, and fatigue itself may limit joint movement. It may also interfere with sleep. Adaptive shortening of muscles may also occur for example, hamstrings if the knee is held in flexion for prolonged period (Porter, 2003).

6. **Muscle atrophy:** Either through disuse or because of pain inhibition, the quadriceps muscles become weak (Porter, 2003).

7. **Joint enlargement:** Chronic oedema of synovial membrane and capsule makes the joint appear large. Osteophytes and chronic effusion also contribute. Muscle atrophy may also make the joint look bigger (Creamer, 2001).

8. **Crepitus:** Crepitus can range from mild crackling (which may also indicate synovitis), and loud cracking sounds in advanced disease. The flaked cartilage and eburnated bone ends grate against each other with a characteristic sound on movement (Porter, 2003).

9. **Joint Instability:** Loss of proprioception, loss of ligamentous control, and loss of negative pressure within the joints as a result of effusion all contribute to joint instability in OA knees (Porter, 2003).

10 **Loss of function,** though not the most dramatic is often the distressing symptoms. An altered gait, difficulty in climbing stairs, restriction of walking or progressive inability to perform everyday task or enjoy recreation may eventually drive the patient to seek help.

11. **Deformities** including (genu valgus and varus) and ultimately contractures may occur (Frenando, 2003).

**2.9 Diagnostic Evaluation**

The diagnosis of osteoarthritis of the knee is usually based on the history and physical findings. Characteristic changes on plain radiographs (figure 6) confirm the diagnosis but clinical presentation of the disease does not always correlate with
radiographic signs. Some patients with radiographic evidence of advanced joint
degeneration have minimal symptoms, whereas others with minimal radiographic changes
experience severe symptoms (Porter, 2003). The antero-posterior (AP) and lateral views that
evaluate the patella are most commonly ordered. When obtaining the AP view, the
technician should place the patient in a standing (or lying) position with knees bent at a 45-
degree angle. This positioning enables the joint space to be accurately viewed and any
altered bone and shape, narrowing formation, sclerosis to be evaluated (Porter, 2003).

Other imaging studies including bone scans, computer tomography (CT) and
magnetic resonance imaging (MRI) may help in evaluating OA in early stages or detecting
subtle changes in the joint tissues, but they are rarely necessary for establishing the
diagnosis (Lozada and Altman, 2001).

2.10 Treatment

2.10.1 Pharmacologic Intervention

Many studies have reported that pharmacologic therapies are the mainstay of the
non-surgical treatment of OA. The drugs most often used include: Acetaminophen, Non-
Steroidal Anti-inflammatory Drugs (NSAIDS) and Chondroprotective oral supplements
(Grainger and Cicuttini, 2004; Lonner, 2003; Raynauld and Buckland-Wright, 2003;
Brandt, 2000). Acetaminophen is usually a first line of therapy for OA of the knees.
Although it is considered one the safest analgesics, studies have documented that it could
be associated with clinically important adverse effects to the kidney and liver (Grainger and
Cicuttini, 2004). NSAIDS are utilized for their anti-inflammatory as well as their analgesic
properties. Studies have revealed that no one NSAID is superior to the other (Bradley et al.,
1991). Oral NSAIDS work by inhibiting Cox-1 and Cox 2 acid metabolism, which blocks
the production of inflammatory agents such as prostaglandin and leukotrienes. Although
effective, they have adverse effects such as inhibiting beneficial character of gastric
mucosal lining production, reducing renal blood flow, and causing abnormalities in sodium balance (Brater, 2002).

More serious effects of NSAIDS include dyspepsia, gastro-intestinal ulceration, hepatic toxicity, hypertension, cardiac failure and impairment of platelet aggregation that may lead prolonged bleeding time (Gotzsche, 2000). Cox-2 inhibitors, a new class of medications were developed to manage the pain and inflammation of arthritis with the intention of preventing the negative side effects of NSAIDS. Two products, celebrex and Vioxx were approved by the U.S. Food and Drug Administration (FDA) in 1999 and became the most used of the anti-inflammatory medications. Unfortunately Vioxx was found to have previously unrecognized and very significant unanticipated cardiovascular side effects, including increased risk of developing stroke or heart attack and was withdrawn from the market in September 2004. Celebrex though available is still under review (Graedon, 2006).

Corticosteroids and hyaluronic acid are the most frequently used intra-articular therapies for osteoarthritis of the knee. Despite the lack of strong, convincing and reproducible evidence that intra-articular therapies significantly alter the progression of osteoarthritis, they have been used in patients who have failed to get relief from the use of oral NSAIDS (Raynauld and Buckland-Wright, 2003). Earlier studies have reported that corticosteroid injections may suppress cartilage proteoglycan synthesis, worsen cartilage lesion or even cause degenerative lesions in normal cartilage (Uthman et al., 2003; Leopold et al., 2002). Meanwhile, some reports, using animal models (rabbits and guinea pigs) of osteoarthritis, showed that low dose intra-articular corticosteroids (sufficient to suppress catabolism) normalized cartilage proteoglycan synthesis and significantly reduced the incidence and severity of cartilage erosions and osteophytes formation (Pelletier et al., 1993). In humans, repeated corticosteroid injections in knee of patients with chronic OA
presented no evidence of destruction or acceleration deterioration. In a recent study, a single intra-articular injection of triamcinolone acetonide into the knees of patients with OA knees provided very short-term pain relief (Uthman et al., 2003). Increased benefits were associated with both clinical evidence of joint effusion and successful aspiration of synovial fluid at the time of injection (Brandt, 2000).

Many studies suggested that intra-articular injection of hyaluronic acid might improve the clinical condition and have a long-term beneficial effect in OA knees (Brandt, 2000; Raynauld, 2003; Guidolin, 2001). Hyaluronic acid is a polysaccharide consisting of a long chain of disaccharides (β-D- glycuronyl – β– D – η – acethylglucosamire). Intra-articular injection of hyaluronic acid aims at supplying replacement hyaluronic acid into the joint space of an OA patient to return elasticity and viscosity of the synovial fluid to normal. Though proven to be very effective in management of OA knees, they have severe side effects (Uthman et al., 2003; Guidolin, 2001; Brandt, 2000). Common adverse events reported for hyaluronic acid therapy were gastro intestinal complaints, injection site pain, knee swelling/effusion, localized reactions (rash, ecchymosis), pruritis and headache (Uthman et al., 2003; Leopold et al., 2002; Brandt, 2000; Kotz and Kolarz, 1999).

The uses of topical gels are common and some studies have shown their effectiveness (Walker-Bone, Javaid, Arden and Cooper, 2000; Moore, Tramer and Carroll, 1998), in the management of OA knees. However, they still have limited evidence for effectiveness and no guide as to which agent is any better than any other (Walker-Bone et al., 2000). Clinical trials had provided some justification for the use of glucosamine sulphate (a chondroprotective agent) in the management of OA knees but only for their analgesic or anti-inflammatory effects. Due to sparse data on structural efficacy and safety, further studies are warranted (Walker-Bone et al., 2000).
2.10.2 Surgical Intervention

Indications for surgical intervention are debilitating pain, major limits of daily activities and distance walked, impaired ability to sleep or work and joint deformity (Hassen et al., 2001). Surgical procedures to decrease or eliminate pain and improve function in OA knees include techniques that attempt to:

1. Preserve or restore articular cartilage surface (Autologous chondrocyte implantation, Arthroscopic Washout and debridement of the joint) (Fond et al., 2002).

2. Re-align joints (corrective osteotomy) (Billings, 2000; Scott 2000; Naudie and Bourne 1999).

3. Fuse Joint (Arthrodesis) (Hassen et al., 2001).


Although several studies (Shaw and Dixon, 2004; Scuderi, 2001 Billings, 2000; Scott, 2000) have reported that these procedures could produce excellent results, they have also been reported to expose patients to the risk of surgical complications, (Gidwani and Fairbank, 2004). Death, from total knee replacement is 0.5% within the first 90 days of the procedure, risk of infections or aseptic loosening is about 0.05% to 1.5% ,deep vein thrombosis (DVT) is about 0.7% (Limbeek, 2004; Jacobs and Anderson, 2000 ) and excessive wear of the polyethylene implant, (Khaw et al., 2001). Another risk factor is the effect of anesthesia on some patients (Gidwani and Fairbank, 2004).
2.10.3 Non-Pharmacological Intervention

The principles of non-pharmacologic treatment of OA knees include education about the condition, modification of life style, weight loss, physiotherapy, aerobic exercise, quadriceps muscle strengthening and stretching, supportive aids and appliances, patella strapping, heat therapy, cold therapy, use of TENS, ultra sound therapy, electromagnetic-pulse therapy, LASER therapy, occupational therapy and acupuncture (Grainger and Cicuttini, 2004). Education focuses on encouraging appropriate types of activities and outlining activities that should be avoided. They teach attitude changes and coping skills (Waris et al., 2003).

Kendall’s study of (2004) showed that proper diet and exercise help in weight reduction and a 5kg decrease in body weight reduces 10-15kg load on the knee. Several studies have shown that achieving and maintaining desirable weight is much a matter of exercise and activity as it is a matter of controlling calories (Deyle et al., 2005; Shekelle and Morton, 2005, Messier, Loeser and Mitchell, 2000). Acupuncture is also used as an adjunct therapy in osteoarthritis of the knee. Berman, Lao and Landenberg, (2004), carried out a randomized controlled trial on the effectiveness of acupuncture as adjunct therapy in OA of the knees. The study reported significant increase in function and decrease in pain in the subjects used. Though several other results (Shekelle et al., 2005; Barnes, Powell-Griner, McFann and Nahin, 2002) have indicated the effectiveness of this therapy, scientific inquiry is still trying to shed more light on the mechanisms and potential benefits especially, in treating painful conditions such as arthritis (Jones, 2004).

Leech therapy which is the use of leech saliva to reduce inflammation, had also been tried in the management of osteoarthritis of the knee but its effectiveness is still under review (Michalesen, Klotz, Ludtke, Moebus, Spahn and Dobos, 2003). So many patients with OA of the knees and wrists had used copper bracelets, magnetic cups for drinking
water in the management of pain but there is no evidence that these therapies offered any relief (Parmet, 2003). Autologous Chondrocyte Implantation Joint Repair is a new cell culture technique. Though results from some studies are very encouraging, it is still under consideration and observation (Kelly, 2005).

2.10.4 Physiotherapy

Several systematic studies have reported that exercises can reduce pain and disability in patients with OA knees (Sisto and Malanga, 2006; Shekelle et al., 2005; Hartling; McAllister and Bone, 2005). A randomized comparative study, by Bennel et al. (2006) reported the efficacy of quadriceps strengthening exercise and massage to the knee joint and self management in the management of osteoarthritis of the knee. The study revealed that quadriceps strengthening gave a better result than self-management.

A study by Roddy et al., (2005) revealed that aerobic and resisted quadriceps exercises, combined with education and drugs gave better results than education and drugs alone. A (2003) Cochrane review of 17 studies on exercise and OA of the knee found that exercise had a positive effect on pain and self reported physical function (Franzen et al., 2003). These results echoed the findings of a (2000) review of 17 studies, which concluded that exercises have beneficial long and short-term effects in patients with osteoarthritis of the knee (American College of Rheumatology Subcommittee, 2000).

A (2005) Australian review of the effectiveness of exercise therapy for patients with disorders of the musculoskeletal, nervous, respiratory and cardiovascular systems reported that exercise therapy consisting of strengthening, stretching and functional exercise is effective for patients with OA of the knees, compared to no treatment (Smidt, De-vet and Bouter, 2005). More specifically, a (2005) review by Smidt et al., compared the efficacy of
aerobic, walking and home based quadriceps strengthening exercises found that both reduced pain and disability from OA of the knees to similar degrees.

Sisto and Malanga, (2006) outlined the type of comprehensive, progressive exercise program that physiotherapists might prescribe for patients with OA of the knees. The programs emphasized quadriceps strengthening, stretching, conditioning as well as education. All articles and reviews also emphasized that physiotherapist should access the patient disease progress by measuring mobility of the joint, strength of supporting muscles and limitation of activities, and then prescribing and monitoring an individually tailored exercise program (Sisto and Malanga, 2006; Roddy et al., 2005). Though these studies have shown the effectiveness and benefits of exercise therapy in management of OA knee, the data revealed that 37% of people with arthritis got no exercise, 30% of people with arthritis got recommended levels of moderate or vigorous exercise while 20% of people with arthritis regularly performed quadriceps strengthening exercises.

A study by Stiskal in (2001) revealed that in osteoarthritic joints, range of motion exercises can help prevent motion loss that commonly occurs with disease progression or disuse or both. The study also revealed that if not put through a full functional range of motion regularly, the knee joint is especially susceptible to loss of flexion caused by bony ankylosis and soft tissue contractures. Both flexion loss and extension loss can adversely affect a patient's function. In particular, loss of flexion can make it difficult for patients to negotiate elevations, such as stairs or curb (Porter, 2003). Loss of extension can place the quadriceps muscles at a disadvantage during ambulation; the functionally shortened quadriceps cannot rest completely during the extension phase of gait (Stiskal, 2001).

The use of TENS, offers relief to some patients particularly those with moderate to severe arthritis of large joints such as hip and knees (Creamer, 2000). Other physical methods like short-wave diathermy and ultrasound therapy have limited values (Hartling et
Various studies have shown that the use of taping impact absorbing shoes, splints and braces for the knee joint, decrease pain on walking and possibly slows joint degeneration (Hinman et al., 2003; Kirkley and Litchfield, 1999).

Heat therapy is the most common popular therapy for osteoarthritis of the knee. The therapeutic effect being increased tissue metabolism, deep tissue temperature, increased blood flow, muscle relaxation and relief of pain (Nadler and Weingard, 2004). The usual sources of heat therapy include, infrared radiation, warm compresses, warm baths/showers, short wave diathermy, ultrasound treatment, (Nadler and Weingard, 2004).

Two studies by De Angelo and Gordon, (2004) and McCarberg, (2005) examined self management methods for OA and rheumatoid arthritis (RA), in order to determine which physical methods patients consider most effective for treating pain and functional disability. The results of the study revealed that heat applications are the most effective methods for self management of (OA) and (RA). Another study compared the efficacy of eight hour continuous low-level heat wraps (CLLHWS), ibuprofen and acetaminophen in the treatment of acute, low back pain in 332 ambulatory patients (Lloyd, Scott, Akehurst, Lurie-Luke, and Jessen, 2004). The results showed that CLLHWs provided significantly superior pain relief on the first day of treatment and better-sustained pain relief on follow-up days three and four.

Michlovitz, Hun, and Erasala, Hengehold and Weingard (2004), carried out the study on the effectiveness of continuous low level heat wrap therapy in the management of wrist pain. The study showed that heat wrap therapy significantly reduced pain. Also the National Aeronautics and Space Administration (2007) revealed in their clinical study that infra-red radiation is effective in the management of pain.
Figure 1: Normal Synovial Joints (adapted from Ciba, 1995).
Figure 2: Structure of a Normal Articular Cartilage (adapted from Ciba, 1995).
Figure 3a: Structure of a Normal Articular Surface (adapted from Ciba, 1995).

Figure 3b: Shows early degenerative changes.
Figure 4a: Showing advanced degenerative changes

Figure 4b: Showing end-stage degenerative changes (adapted from Ciba, 1995).
Figure 5a: Showing knee with osteoarthritis, exhibiting varus deformity, medial subluxation, loss of articular cartilage and osteophyte formation.

Figure 5b: Showing severe erosion of articular cartilage.

(adapted from Ciba, 1995)
Figure 6: X-ray of knee showing diminished joint space, varus deformity, osteophytes.
(Adapted from Ciba, 1995).
CHAPTER THREE
MATERIALS, METHODS AND DATA ANALYSIS

3.1 Introduction
This chapter dealt with the patients that participated in this study, materials used as well as the procedures adopted in conducting the study, and its data analysis.

3.2 Research Design
This was a quasi experimental research.

3.3 Target Population
The research population comprised patients, diagnosed with osteoarthritis of the knee, by an orthopaedic surgeon at Loveworld Specialist Hospital, an Orthopaedic and Rehabilitation Centre located in Nnewi.

3.4 Sampling Techniques
The patients were randomized.

3.5 Sample Size
An estimated sample size for this study was determined based on the 20% prevalence as reported by (Brandt, 2000).

\[
\text{Sample Size } (n) = \frac{Z^2 p(1-p)}{d^2} \quad (\text{Daniel, 1999})
\]

\[
p = \text{prevalence} = 20\% = 0.20
\]
\[
Z = \text{Z statistics for 95\% level of confidence} = 1.96
\]
\[
d = \text{precision} = 0.05
\]

It was recommended by various authors (Naing et al, 2006; Daniel, 1999; Lwanga and Lemeshow, 1991) that a precision of 5\% is appropriate for prevalence rates between 10\% and 90\%.
\[ n = \frac{1.96^2 \times 0.20}{0.05^2} (1 - 0.20) \]
\[ n = \frac{3.8416 \times 0.20 (0.80)}{0.0025} = 0.614656 \]
Calculated estimated sample size (n) = 246

3.6 Inclusion Criteria

1. Only patients referred to the researcher by the attending orthopaedic surgeon were involved in the study.

2. Only subjects of either sex aged over 45 years (Brandt, 2000) suffering from osteoarthritis of the knees for more than six months were recruited for the study.

3. Only subjects who live in Nnewi and its environs (Ichi, Amichi, Orifite, Utuh and Ozubulu) were recruited for the study. This was for proximity and easy access to the patients for drug administration.

4. Only patients who were able to give verbal information were recruited for the study.

5. Only patients who could walk without the assistance of a walking aid were studied.

3.6.1 Exclusion Criteria

i. Inflammatory arthropathy

ii. Recent injury in the area affected by OA of the knee

iii. History of peptic ulceration

iv. Uncontrolled hypertension

v. Congestive heart failure

vi. Pregnancy and lactation
vii. Any form of strenuous physical activity within the last three months

viii. Patients currently participating in another clinical evaluation.

Pregnant and lactating patients, patients with history of peptic ulceration, uncontrolled hypertension, congestive heart failure were excluded because NSAID therapy is contraindicated in these patients.

3.7 Materials

The following materials were used for data collection:

- Combined weighing scale and standiometer (SECA model): This was used to measure the weights and heights of the subjects. It had a range of 0-120kg and 0-200cm respectively.
- Infra-red Lamp (Infraphil, Philips model, 150watts): This was used for infra-red radiation.
- Oral diclofenac sodium (by Novartis): This was used for NSAID Therapy.
- Universal Goniometer: This was used to measure knee joint range of motion.
- Stop watch (Nokia model, 8850): This was used to record time during walk-time test.
- Water Marker: This was used to mark out anatomical land marks.
- Masking tape: This was used to mark out the starting and ending points of the 30.4m distance, used for the walk-time test.
- Inelastic Measuring tape (Bouncing Rabbit, made in China): This was used to measure out the 30.4m walk distance.
- Sand bags of different weights (0.5kg, 1kg, 1.5kg 2kg.): These were used to increase resistance during quadriceps strengthening exercises.
- Box Numerical Pain Scale: This was used to assess present pain intensity of the subjects.
3.8 Subjects Description

The subjects were randomized into four groups

- Oral Diclofenac Sodium Group
- Quadriceps Strengthening and Infra-red Group
- Combined Group (Quadriceps Strengthening, Infra-red radiation, Diclofenac Sodium)
- Placebo Group

3.9 Procedure for Data Collection

Ethical approval was sought and obtained from the Ethical Committee of the Nnamdi Azikiwe University Teaching Hospital Nnewi, before commencing the study. The procedure for this study was explained to each subject in a language most convenient to him/her and written informed consent obtained. Information such as the subjects’ sex, age, occupation, duration of knee pain, family and social history, x-ray of the knee/s, muscle strength for the quadriceps, joint flexion range of motion for the affected knee/knees as well pain intensity score was recorded.

3.10 Measurements

All measurements were carried out and recorded by the researcher.

Height

The patient’s height was obtained using the stadiometer. Each subject was asked to stand, backing the stadiometer, barefooted and eyes looking straight ahead. The measurement was read off and recorded to the nearest 1.0 centimeter (Fahey et al., 1999).
Weight
This was obtained using the weighing scale. The subject was asked to stand barefooted on
the weighing scale, looking straight ahead. The measurement was read and recorded to the
nearest 1.0 kilogram (Fahey et al., 1999).

Quadriceps Muscle Strength
The quadriceps muscle strength of the affected limb was obtained using the Oxford grading
(Porter, 2003). The patient was asked to sit on a well-supported chair. The patient was then
asked to extend his knee first against gravity and then against the resistance of the
researcher’s hand. The value obtained was recorded as initial muscle strength. The
procedure was carried out again at the end of the seventh week treatment session and
recorded as muscle strength week 7.

Pain Intensity Score
The pain intensity perceived by the subjects was obtained via the Box Numerical Pain Scale
(BNPS) of 1-10 (McDowell and Newell, 1996). The procedure was explained and the
subject requested to choose the numerical box that corresponded to the pain he/she:
whereby 0 is no pain and 10 is the worst imaginable pain. The value chosen by the subject
was then recorded as initial pain intensity score (PIS). The procedure was carried out again
at the end of the seventh week treatment session and recorded as PIS week 7.

30.4m (100ft) walk time
A straight-line distance of 30.4m (Roddy et al.,) was measured in front of the hospital
building using the tape measure. The starting point for the patient is marked “0m” while the
end point is marked 30.4m. Those points were marked out using a masking tape. The patient
was then asked to walk the distance in a straight line; while the researcher used the
stopwatch to record the time it took the patient to cover the 30.4m distance. The time was
recorded as initial walk time. The procedure was carried out again at the end of the seventh week treatment session and recorded as Walk-time week 7.
Plate 1: Researcher recording 30.4m walk-time
Joint flexion Range of Motion

The patient was asked to lie prone on a plinth. A water marker was used to mark the anatomical landmarks (greater trochanter of the femur, lateral condyle of the femur, and lateral malleolus of the tibia). The Universal Goniometer was then placed at the lateral aspect of the knee with the pivot lying at the mid joint crease. The stationary arm of the Goniometer was made to point towards the greater trochanter and fixed against the thigh, while the mobile arm was made to point towards the lateral malleolus and allowed to move. The patient was then asked to gently flex his knee as far as possible. The mobile arm of the Goniometer was then moved to point again to the lateral malleolus and the range of motion read off on the protractor. Values were recorded as initial joint range of motion (R.O.M). The procedure was repeated at the end of the seventh week treatment session and recorded as joint R.O.M week 7.
Plate 2. Researcher measuring joint range of motion.
3.11 Treatment

The study lasted for eighteen months, but each patient was treated for three sessions per week for seven consecutive weeks.

3.11.1 Drug Administration

The Non-steroidal Anti-inflammatory drug (NSAID) used in this study was oral diclofenac sodium (Norvatis) while the placebo drug used was oral vitamin B complex (Emzor) containing 1mg each of Vitamin B1 and B2 and 15mg of Nicotinamide. These drugs were prescribed by the attending orthopaedic surgeon and administered by the nurses recruited for the study. The drugs were also dispensed at the pharmacy unit of the hospital.

The patients in diclofenac sodium and combination therapy groups had 50mg of oral diclofenac sodium and oral vitamin B complex twice daily (morning and evening) while patients in the placebo and quadriceps strengthening and infrared radiation group had only vitamin B complex twice daily (morning and evening).

3.11.2 Exercise Therapy

The quadriceps strengthening (isometric and isotonic) designed by the Arthritis Research campaign (2005) was used for this study. The patients wore shorts that exposed their thighs and light t-shirts for the therapy. Only patients in the quadriceps strengthening and infrared radiation, and combination therapy groups received this therapy.

Quadriceps Strengthening

(a) Quadriceps strengthening (isometric): The subject performed this exercise in lying. With the other knee slightly flexed and supported with pillows, the patient was told to hold the knee of the limb to be exercised in full extension and the foot lifted off the exercise plinth. He/She was then told to hold the limb in that straight position for a slow count of 5
to 10 and gently lowered on the plinth. The procedure was repeated 5 times. The same was
done for the other limb for subjects with bilateral OA.

(b) Quadriceps strengthening (isotonic). This was done in sitting. This exercise was
designed to strengthen the quadriceps by graded resisted isotonic exercise (requires joint
motion). The patient was asked to sit up-right on the plinth with his/her back resting on the
wall. He/she was asked to keep the knee of the limb to be exercised in full extension, and
then held it in that same position for a slow count of 5 to 10. He/she was then asked to
slowly lower the limb. The procedure was also repeated for the other limb for patients with
bilateral OA knees. Weights were added at intervals for more resistance.
Plate 3: Patient performing left (isometric) quadriceps strengthening exercise in lying.
Plate 4: Patient performing right quadriceps strengthening exercise (isotonic) in sitting
(With sand bag to increase resistance)
3.11.3 Infra-red Radiation

The patient was asked to lie on the plinth in side lying while the infrared lamp was placed 90cm away from the patient (Shriber, 1981) and sham treatment (the infra red lamp was not switched on) used for the placebo and diclofenac sodium groups. Each patient in the four groups received the therapy thrice every week for 15 minutes at each session.

During the study period, all additional therapies (topical NSAIDs, intra-articular corticosteroid injections and other analgesics) were not allowed. However all other treatments for concomitant disorders that did not interfere with the study were continued and also documented.
Plate 5: Patient receiving infrared radiation.
3.12 ASSESSMENT

Clinical assessments were done at the beginning of the study and at the end of week 7 based on 30.4m walk-time in (seconds), patient’s knee pain intensity rating (1-10) on the Box Numerical Pain scale, quadriceps muscle strength (oxford grading), and knee joint flexion range of motion in (degrees).

3.13 Data Analysis

The SPSS (13.0) statistical software was used for the data entry and analysis. Microsoft Excel (XP Unlimited) worksheet was also used.

1. Descriptive statistics of mean, standard deviation, and percentiles were calculated for measurements taken.

2. Analysis of variance (ANOVA) was used to compare the baseline characteristics across the four groups.

3. Paired t-test was used to compare pre test/post test score changes for each parameter (knee joint pain, quadriceps muscle strength, joint flexion range of motion and walk-time) in each of the treatment group.

Alpha level for all statistics employed was set at $p < 0.05$
CHAPTER 4
RESULTS AND DISCUSSIONS

4.1 RESULTS:

4.1.1 Baseline Characteristic of the Patients

The baseline characteristics of the patients are shown in Table 1 while the physical characteristics of the patients in the four groups are compared in Table 2. One hundred and thirty patients with osteoarthritis of the knee participated in the study. They comprised 43 (33.08%) males and 87 (66.92%) females. The male to female ratio was 1:2. The participants were within the age range of 45 and 68, with a mean age of 52.35 ± 5.81 years. The mean weight, height and Body Mass Index (BMI) of the participants were 86±8.19Kg, 1.73 ±0.03m, 28.05±2.17Kg/m² respectively. The mean length of time since onset of condition is 2.79 ±1.33years.

There were more patients (38) in the quadriceps strengthening and infrared radiation group than in the other three groups. The placebo group had the least number (26) of patients. The mean age (54.23±5.68years) of the patients in the placebo group was more than the mean age of other groups. The quadriceps strengthening and infrared radiation group had the highest mean BMI (30.05±1.60kg/m²). The ratio of patients with either left or right to bilateral OA of the knees were 1:1.2; 1:1.6;1:2.1 and 1:2.3 for the quadriceps strengthening and infrared radiation, diclofenac sodium, combined and placebo groups respectively.
Table 1  
Baseline characteristics of patients evaluated at initial assessment.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Treatment Groups.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quadriceps strengthening Infra-red</td>
</tr>
<tr>
<td>Number</td>
<td>n(38)</td>
</tr>
<tr>
<td>Mean duration of condition (in years)</td>
<td>2.82 ± 1.16</td>
</tr>
<tr>
<td>Male/Female</td>
<td>12/26</td>
</tr>
<tr>
<td>Mean Age (years)</td>
<td>52.89 ± 5.74</td>
</tr>
<tr>
<td>Mean Height (m)</td>
<td>1.72 ± 0.03</td>
</tr>
<tr>
<td>Mean Weight (kg)</td>
<td>89.52 ± 5.78</td>
</tr>
<tr>
<td>Mean BMI (kg/m²)</td>
<td>30.05 ± 1.60</td>
</tr>
<tr>
<td>Location of OA</td>
<td></td>
</tr>
<tr>
<td>Right/Left</td>
<td>10/11</td>
</tr>
<tr>
<td>Both Knee</td>
<td>17</td>
</tr>
</tbody>
</table>
Table 2
Comparison of the physical characteristics of patients.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Treatment Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quadriiceps strengthening</td>
</tr>
<tr>
<td></td>
<td>Infra-red</td>
</tr>
<tr>
<td>Mean duration of condition (in years)</td>
<td>2.82 ± 1.16</td>
</tr>
<tr>
<td>Mean Age (years)</td>
<td>52.89 ± 5.74</td>
</tr>
<tr>
<td>Mean Height (m)</td>
<td>1.72 ± 0.03</td>
</tr>
<tr>
<td>Mean Weight (kg)</td>
<td>89.52 ± 5.78</td>
</tr>
<tr>
<td>Mean BMI (kg/m²)</td>
<td>30.05 ± 1.60</td>
</tr>
</tbody>
</table>

Values are presented as the Mean ± Standard Deviation.
* means p<0.05 is significant.
**Table 3- Analysis of objective 1:** To determine, if quadriceps strengthening and infrared radiation alone will reduce knee pain intensity in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

<table>
<thead>
<tr>
<th>Treatment Groups</th>
<th>Initial PIS</th>
<th>Wk 7 PIS</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quadriceps strengthening and Infra-red</td>
<td>7.74 ± 1.46</td>
<td>4.84 ± 2.64</td>
<td>6.73</td>
<td>0.045 *</td>
</tr>
<tr>
<td></td>
<td>n=38</td>
<td>n=38</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diclofenac sodium</td>
<td>7.03 ± 1.43</td>
<td>5.59 ± 2.34</td>
<td>3.749</td>
<td>0.001 *</td>
</tr>
<tr>
<td></td>
<td>n = 32</td>
<td>n = 32</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combined</td>
<td>7.24 ± 1.46</td>
<td>3.12 ± 2.09</td>
<td>9.309</td>
<td>0.000 *</td>
</tr>
<tr>
<td></td>
<td>n = 34</td>
<td>n = 34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>7.08 ± 1.09</td>
<td>6.92 ± 1.47</td>
<td>0.57</td>
<td>0.574</td>
</tr>
<tr>
<td></td>
<td>n = 26</td>
<td>n = 26</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PIS mean pain intensity score
Values are presented as the Mean ± Standard Deviation.
* means p<0.05 is significant.

**Summary of Table 3:**

The pre- and post- Pain Scores of each of the four groups, at initial visit and at the end of study are presented in Table 3. The result revealed that there was significant reduction in the knee pain intensity of the patients after 7 weeks of treatment in the quadriceps strengthening and infrared; combined and diclofenac groups (p<0.05). However, there was no significant reduction in pain, in the placebo group (p>0.05).
**Table 4 – Analysis of objective 2:** To determine, if quadriceps strengthening and infrared radiation alone will increase knee joint flexion range of motion in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Joint ROM at initial visit</th>
<th>Joint ROM at week 7</th>
<th>t- value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right Knee</td>
<td>Left Knee</td>
<td>Right Knee</td>
<td>Left Knee</td>
</tr>
<tr>
<td><strong>Quadriiceps strengthening and Infra-red</strong></td>
<td>89.89 ± 11.13 (n = 27)</td>
<td>91.94 ± 9.76 (n = 28)</td>
<td>104.33 ± 7.69 (n = 27)</td>
<td>103.71 ± 6.06 (n = 28)</td>
</tr>
<tr>
<td><strong>Diclofenac sodium</strong></td>
<td>95.09 ± 12.86 (n = 23)</td>
<td>91.67 ± 11.81 (n = 21)</td>
<td>97.65 ± 12.68 (n = 23)</td>
<td>95.86 ± 8.69 (n = 21)</td>
</tr>
<tr>
<td><strong>Combined</strong></td>
<td>83.61 ± 16.47 (n = 23)</td>
<td>84.27 ± 22.15 (n = 22)</td>
<td>109.74 ± 8.76 (n = 23)</td>
<td>107.45 ± 18.10 (n = 22)</td>
</tr>
<tr>
<td><strong>Placebo</strong></td>
<td>85.14 ± 14.47 (n = 14)</td>
<td>94.50 ± 12.18 (n = 20)</td>
<td>86.50 ± 13.48 (n = 14)</td>
<td>95.90 ± 11.13 (n = 20)</td>
</tr>
</tbody>
</table>

Values are presented as the mean ± Standard deviation.

* means p<0.05 is significant
Summary of Table 4:

The pre- and post- values of joint flexion range of motion at initial visit and end of study are presented in Table 4. The result revealed that there was significant increase in joint flexion ROM after 7 weeks of treatment, for right and left knees in the patients in quadriceps strengthening and Infrared group (p<0.05), patients in the combined group (p<0.05) and patients in the diclofenac group (p<0.05). However, there was no significant reduction in pain in the placebo group (p>0.05).
Table 5 – Analysis of objective 3: To determine, if quadriceps strengthening and infrared radiation alone will significantly increase muscle strength in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Muscle strength at Initial Visit</th>
<th>Muscle strength at Week 7</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quadriceps strengthening and infrared.</td>
<td>3.13 ± 0.34</td>
<td>3.95 ± 0.23</td>
<td>-12.30</td>
<td>0.000 *</td>
</tr>
<tr>
<td>Diclofenac sodium</td>
<td>3.41 ± 0.50 (n = 32)</td>
<td>3.59 ± 0.50 (n = 32)</td>
<td>-1.982</td>
<td>0.056</td>
</tr>
<tr>
<td>Combined</td>
<td>3.12 ± 0.33 (n = 34)</td>
<td>4.00 ± 0.00 (n = 34)</td>
<td>-15.632</td>
<td>0.000 *</td>
</tr>
<tr>
<td>Placebo</td>
<td>3.15 ± 0.37</td>
<td>3.19 ± 0.40</td>
<td>-1.000</td>
<td>0.33</td>
</tr>
</tbody>
</table>

Values are represented as the mean ± Standard deviation.
* means p<0.05 is significant.

Summary of Table 5:

The pre- and post- values of quadriceps muscle strength at initial visit and end of study are presented in Table 5. The result showed that there were significant changes in the muscle strength of the patients in the quadriceps strengthening and infrared, and combined groups after 7 weeks of treatment (p<0.05) and (p<0.05) respectively while there were no significant changes in the muscle strength of patients in the diclofenac and placebo groups (p>0.05) and (p>0.05) respectively.
Table 6 - Analysis of objective 4: To determine, if quadriceps strengthening and infrared radiation alone will reduce walk-time in patients with osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Mean walk time (in secs) at initial visit</th>
<th>Mean walk time (in secs) at week 7</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quadriceps strengthening and infrared</td>
<td>41.92 ± 6.22 n = 38</td>
<td>37.00 ± 5.64 n = 38</td>
<td>5.47</td>
<td>0.000 *</td>
</tr>
<tr>
<td>Diclofenac sodium</td>
<td>42.02 ± 7.52 n = 32</td>
<td>37.76 ± 5.46 n = 32</td>
<td>2.700</td>
<td>0.011 *</td>
</tr>
<tr>
<td>Combined</td>
<td>40.63 ± 6.27 n = 34</td>
<td>32.73 ± 3.1 n = 34</td>
<td>7.537</td>
<td>0.000 *</td>
</tr>
<tr>
<td>Placebo</td>
<td>40.45 ± 6.76 n = 26</td>
<td>40.47 ± 7.30 n = 26</td>
<td>-0.014</td>
<td>0.984</td>
</tr>
</tbody>
</table>

Values are presented as the mean ± Standard deviation
* means p<0.05 is significant

Summary of Table 6.

The pre- and post- values of 30.4 meter walk- time at initial visit and end of study are presented in Table 6. The reduction in walk- time was significant in the quadriceps strengthening and Infrared group (p<0.05), the combined group (p<0.05) and the Diclofenac group (p<0.05). There was no significant reduction of walk- time in the placebo group (p>0.05).
4.2 HYPOTHESIS TESTING

**Hypothesis 1**

*Statement:* There will be no significant reduction of pain intensity in the knee using quadriceps strengthening and infrared radiation alone in the treatment of patients with osteoarthritis of the knee compared to oral diclofenac sodium alone and the combination of the three therapies respectively.

*Alpha level:* 0.05

*Test statistic: Paired t-test*

\[ t-value: 6.73 \text{ for quadriceps strengthening and infrared radiation alone} \]

\[ p-value: 0.045 \]

\[ t-value: 3.749 \text{ for oral diclofenac sodium} \]

\[ p-value: 0.001 \]

\[ t-value: 9.309 \text{ for combination therapy} \]

\[ p-value: 0.000 \]

*Judgment:* Since \( p < 0.05 \), the hypothesis was rejected.

**Hypothesis 2**

*Statement:* There will be no significant increase in knee joint flexion range of motion using quadriceps strengthening and infrared radiation alone in the treatment of patients with osteoarthritis of the knee compared to oral diclofenac sodium alone and the combination of the three therapies respectively.

*Alpha level:* 0.05

*Test statistic: Paired t-test*

\[ t-value: -7.16 \text{(right knees), -7.06 (left knees) for quadriceps strengthening and infrared radiation alone} \]
p-value: 0.037 (right knees), 0.024 (left knees)

t-value: -2.59 (right knees), -3.00 (left knees) for oral diclofenac sodium

p-value: 0.026 (right knees), 0.007 (left knees)

t-value: -11.548 (right knees), -5.539 (left knees) for combination therapy

p-value: 0.000 (right knees), 0.000 (left knees)

Judgment: Since P<0.05 for right and left knees, the hypothesis was rejected.

Hypothesis 3

Statement: There will be no significant increase in muscle strength using quadriceps strengthening and infrared radiation alone in the treatment of patients with osteoarthritis of the knee compared to oral diclofenac sodium alone and the combination of the three therapies respectively.

Alpha level: 0.05

Test statistic: Paired t-test

t-value: -12.30 for quadriceps strengthening and infrared radiation alone

p-value: 0.000

t-value: -1.982 for oral diclofenac sodium

p-value: 0.056

t-value: -15.632 for combination therapy

p-value: 0.000

Judgment: Since P<0.05, the hypothesis was rejected for the quadriceps strengthening and infrared radiation alone and combination therapy but accepted for the oral diclofenac sodium.
Hypothesis 4

Statement: There will be no significant reduction in 30.4 metres walk-time using quadriceps strengthening and infrared radiation alone in the treatment of patients with osteoarthritis of the knee compared to oral diclofenac sodium alone and the combination of the three therapies respectively.

Alpha level: 0.05

Test statistic: Paired t-test

t-value: 5.47 for quadriceps strengthening and infrared radiation alone

p-value: 0.00 for oral diclofenac sodium

p-value: 0.011

t-value: 7.537 for combination therapy

p-value: 0.000

Judgment: Since P<0.05, the hypothesis was rejected.
4.3 Discussion

The patients involved in this study were not matched for age, height, or gender. The inclusion criteria that the patients had to meet made it difficult to match them. The age range of all the patients involved was rather narrow. Hence the effect of age, sex, and Body Mass Index was not considered in the study. No attempt was made to observe significant differences between patients affected by osteoarthritis of the right knee, those with osteoarthritis of the left knee and those with bilateralism.

The result of the study on objective 1, revealed that all the modalities used (quadriceps strengthening and infrared radiation alone, diclofenac sodium alone and the combination of all three) significantly reduced pain. The pain relieving effects of diclofenac sodium alone had long been documented (Nadler et al., 2004, Grainger and Cicuttini, 2004, Brand, 2000, Gotzsche, 2000) The pain relieving effect of infrared radiation had also been reported (Nadler and Weingard, 2004; Gur et al., 2004). The pain score of the patients in the quadriceps strengthening and infrared group and the combined group were reduced, probably because their quadriceps muscles were strengthened. This supports the findings of Roddy, (2005) and Lankhorst, (1985), whose studies revealed that quadriceps weakness is common in patients with OA of knee and correlates with pain. The combined effects of infrared radiation and quadriceps strengthening including: increase in tissue metabolism, deep tissue temperature, increase blood flow, muscle relaxation and improved stability in the knee could also be the reason why the quadriceps strengthening and infrared radiation group, showed significant reduction in pain score. In essence, the sum effect of the three therapies could then be a reason for the reduction in pain score in the combined group. This echoes the findings of Hochberg et.al, (2006) who in their study, recommended that the medical management of OA the knee should include a combination of NSAID, quadriceps exercises and other physical modalities.
Although the three therapies were shown to significantly reduce pain intensity in patients with osteoarthritis of the knee, the results revealed that the combination of the three therapies was superior \((p=0.000)\) to quadriceps strengthening and infrared radiation alone \((p=0.045)\) and also oral diclofenac sodium alone \((p=0.001)\). However, patients in the diclofenac group showed superior \((p=0.001)\) improvement to patients in the quadriceps strengthening and infrared group \((p=0.045)\).

Analysis of objective 2 revealed that quadriceps strengthening and Infrared radiation alone, diclofenac alone, and the combination of all three therapies significantly increased joint range of motion. This could probably be due to the fact that pain being a possible factor in joint motion limitation was significantly reduced, leading to increased range of motion in the affected knee or knees (Berarducci, 2006; Brandt, 2005; Bennel et al., 2005; Creamer and Lethbridge-Cejku, 2000). Infra red radiation is known to increase the extensibility of collagen tissues (Porter, 2004). This could be the reason why patients in the quadriceps strengthening and infrared group and combined group had increased range of motion in their knee joints. This supports a (2001) study by Justus which revealed that \(^{45}\text{c}\) heat may decrease joint stiffness by 20\%. Another reason why patients in the quadriceps strengthening and infrared group and combined group had increased range of motion in their knee joints may be because their quadriceps muscles were strengthened. This agrees with a study by Stiskal in (2001) that exercises improve functional capacities of patients.

However, the results also revealed that the quadriceps strengthening and infrared group and the combined groups showed superior improvement \((p=0.000)\) to the diclofenac sodium group \((p=0.007)\).

Furthermore, the result of the study on objective 3 showed that patients in the combined group, and quadriceps strengthening and infrared group, had increased quadriceps strength in the affected knee. The stability and the functional capacity of the knee joint are largely
dependent on the quadriceps muscle strength (Sharma and Hayes, 1999, Slemenda et al., 1997). Thus, the affected quadriceps muscles were put through a strengthening regimen and regained more strength in the two groups. This is in agreement with the findings of Roddy et al., (2005) and Bennel et al., (2005) that judicious quadriceps strengthening exercises to an osteoarthritic knee improve the quadriceps strength. To the best of the researcher’s knowledge, there are no previous studies on the effect of NSAIDs on quadriceps strength. Patients in the diclofenac sodium group had the least improvement in quadriceps muscle strength. This could probably be because the diclofenac group did not have any form of quadriceps strengthening exercises.

Analysis of objective 4 revealed that after seven weeks of treatment, there was reduction in the 30.4m walk-time in the quadriceps strengthening and infrared radiation group, combined and diclofenac groups. This could be due to the combined effect of reduction in pain, muscle strengthening and increased knee joint range of motion, all of which led to improved function and performance of the effected joint, in both the combined group and the quadriceps strengthening and infrared radiation group. This supports previous studies by Shekelle et al, (2005) and Barnes, (2002). This also agrees with a study by Stiskal in (2001) that exercises improve functional capacities of patients.

The reduction in walk-time in the diclofenac group could be because of reduced pain and increased range of motion in the knee joints of those patients and is in agreement of previous studies by Walker-Bone et al., 2000 and Moore et al., (1998). However the result also revealed that the combined group and quadriceps strengthening and infrared group showed superior reduction in walk-time to the diclofenac group (p=0.000, p=0.000 and p=0.011) respectively. This could be because greater quadriceps enhance dynamic stability (Hicks et al, 2001). Thus, including muscle-strengthening programme for the patients with OA of the knee leads to better functional outcome.
The study also revealed that there was no reduction in pain intensity, no reduction in 30.4m walk-time, no increase in quadriceps muscle strength, and knee joint flexion range of motion in the placebo group. This could be because this group did not receive any form of treatment (Bennet et al, 2005) The study also strongly agrees with a (2005) Australian review of the effectiveness of exercise therapy for patients with OA which concluded that exercise therapy consisting of strengthening, and functional exercise is effective for patients with OA of the knees, compared to no treatment (Smidt, De-vet and Bouter, 2005).

The findings from this study suggest that quadriceps strengthening and infrared radiation alone could be used in the management of osteoarthritis of the knee. This intervention holds beacon of hope to individuals with osteoarthritis of the knee who present with co morbid conditions and who may be at risk of the side effects of NSAID therapy.

Although, several studies (Grainger and Cicuttini, 2004; Creamer and Hochberg, 2000) have reported that diclofenac sodium relieves joint pain in patients with OA of the knee, it had not been ascertained, if it improves quadriceps muscle strength, in individuals with osteoarthritis of the knee. Clinically, the results of this study imply that the inability of diclofenac sodium to impact on quadriceps muscle strength may help physicians and orthopaedic surgeons, evaluate its sole prescription.
CHAPTER 5
SUMMARY, CONCLUSION AND RECOMMENDATION

5.1 Summary

Osteoarthritis of the knee is a chronic degenerative disorder of multi-factional aetiology, characterized by loss of articular cartilage and periarticular remodelling. Diclofenac sodium is the most widely prescribed NSAID in the management of osteoarthritis of the knee, but the inhibition of prostaglandin biosynthesis is directly related to many common and occasional severe side effects of this therapy (Kearney et al., 2006). Most often patients with osteoarthritis of the knee present with co-morbidities, so physicians and orthopaedic surgeon grapple with how best to manage this condition. Despite the fact that there is no known cure for this disease, comprehensive treatment plan can reduce knee pain, improve knee function and minimize disability (Porter, 2003). The study was carried out to determine if quadriceps strengthening and infrared radiation alone will be effective in the management of osteoarthritis of the knee compared with oral diclofenac sodium alone and the combination of the three therapies respectively.

Literature was reviewed in the following areas: anatomy of the knee joint, aetiology and patho-physiology of osteoarthritis of the knee, NSAIDs, quadriceps strengthening exercises, infrared therapy, some physical modalities, alternative medicine and some previous studies on the subject matter. Ethical approval was sought and obtained from the Ethical Committee of the Nnamdi Azikiwe University Teaching Hospital, Nnewi before commencement of the study. Participants were randomly selected. Only those who met the inclusion criteria were involved the study. A dual standiometer/weighing scale was used to assess the heights and weights of patients at initial visit. A universal Goniometer was used to measure the active joint flexion range of motion while the Box numerical Pain Scale was used to measure pain intensity at both
initial visit and at week 7. Their muscle strength was obtained using the Oxford muscle grading while the 30.4m walk-time was recorded, using a stop watch.

A total of 130 patients (87 females, 43 males) aged 45-70 years with a mean age of 52.35 ± 5.81 years, participated in the study. The mean weight, height and Body Mass Index (BMI) of the participants were 86± 8.19kg, 1.73 ±0.03m, 28.05±2.17kg/m² respectively. All the patients were referred by an orthopaedic surgeon and also recruited from Loveworld Specialist Hospital, an Orthopaedic and Rehabilitation Centre, Nnewi. All the data were analysed using the statistical package for social sciences (SPSS) version 13.0. Level of significance was set at p<0.05.

The quadriceps strengthening and infrared radiation group and combined group showed significant improvement after 7 weeks of treatment in all the outcome measures (p<0.05). The diclofenac group showed significant improvement after 7 weeks of treatment in all outcome measures (p<0.05) except in the quadriceps muscle strength (p>0.05). The placebo group did not show any significant improvement (p>0.05) in all the outcome measures after 7 weeks of treatment.

The combination therapy was superior to diclofenac sodium alone in all parameters used for comparison: pain (p=0.000, p=0.001) respectively; joint range of motion (p=0.000, p=0.026) respectively; muscle strength (p=0.000, p=0.056) respectively; and walk-time (p=0.000, p=0.000) respectively. The combination therapy was not superior to quadriceps strengthening and infrared radiation in all outcome measures (p=0.000, p=0.000) respectively except in outcome of pain (p=0.000, p=0.045) respectively. However quadriceps strengthening and infrared radiation alone was superior to diclofenac sodium alone in all outcome measures except reduction in pain intensity thus: joint range of motion (p=0.000, p=0.026) respectively; muscle strength (p=0.000, p=0.056) respectively; walk-time (p=0.000, p=0.011) respectively and pain intensity (p=0.045, p=0.001) respectively.
5.2 Conclusion

1. Quadriceps strengthening and infrared radiation alone could be used in the management of patients with knee osteoarthritis.

2. Each of quadriceps strengthening and infrared radiation alone, oral diclofenac sodium alone and a combination of all three therapies significantly reduced pain, increased joint flexion range of motion and reduced walk-time in patients with osteoarthritis of the knee.

3. Diclofenac sodium did not increase quadriceps muscle strength in patients with knee osteoarthritis so, physicians and orthopaedic surgeons should evaluate its sole prescription in the management of osteoarthritis of the knee.

5.3 Recommendation

1. Quadriceps strengthening and infrared radiation alone could be used in the management of patients with osteoarthritis of the knee.

2. The combination of quadriceps strengthening exercises, infrared radiation and oral diclofenac sodium should only be prescribed for patients who are not at risk of the severe side effects of diclofenac sodium.

3. The effect of sex, age, weight, height, Body Mass Index on osteoarthritis of the knee should be investigated.

4. Other physiotherapeutic modalities should be investigated for their effects on osteoarthritis of the knee.

Limitation.

Some of the patients who participated in this study were hypertensive and the anti-hypertensive drugs they were taking may have affected their pain rating.
REFERENCES


